

Submission

By



to the

NZ Food Safety Authority

on

Data Protection for Agricultural Compounds

September 2009

Agcarm
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**DATA PROTECTION FOR AGRICULTURAL COMPOUNDS
SUBMISSION BY AGCARM Inc**

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1. Key Points In Submission

- **Data protection for agricultural compounds 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.**
- **Farmers and growers, particularly of minor crops and minor species, are missing out on technologies available overseas due to New Zealand's weak data protection regime.**
- **Increased data protection will have minimal, if any, price impact on the highly competitive market for plant science and animal health markets.**
- **There is no evidence that an absence of data protection has benefits in terms of increased competition, lower prices, and better service.**
- **Agcarm seeks the following periods of data protection commencing from the date of regulatory decision:**

	Currently	Should be
For innovative substances/new organisms	5 years	10 years
For new uses and new formulations of existing substances and compounds	zero	10 years
For reassessments of existing substances	zero	10 years*

* with compensatory sharing of data

Replies to Questions

Agcarm's specific comments on the questions raised in the discussion document follow. The following numbers refer to sections in the NZ Food Safety Authority discussion paper 'Data Protection for Agricultural Compounds':

4.1.2 Questions

Do you think that the current period of data protection for innovative new compounds (5 years) balances the competing interests in this area?

No, it does not.

If not, what would be an appropriate period and why?

Ten years would be an appropriate period.

Five years data protection for innovative new compounds (close to expiry or out of patent protection) is insufficient to create an environment of innovation for companies which invest in development of active ingredients and associated products.

Agcarm therefore disagrees with the Covec report which concluded "There do not appear to be any significant issues arising from the five year data protection period provided for the registration of new, innovative agricultural compounds and veterinary medicines.¹"

Five years protection creates an environment which heavily favours generic producers who copy existing products already registered in New Zealand.

New Zealand is too small to be a world leader in research and development in active ingredients. It must therefore rely on international research and development companies to bring their proprietary active ingredients and products to New Zealand.

Availability of the best technologies is vital for New Zealand agriculture to continue to boost productivity, maintain environmental best practice, and to stay ahead or in step with agricultural production in other countries.

Unfortunately for New Zealand, insufficient (ie, 5 years) data protection is a strong disincentive to bring some technologies to New Zealand.

Being denied access to these products is of concern to New Zealand farmers and growers. It is also of concern to Agcarm members who - to obtain market entry for their active ingredients - have to collectively invest millions of dollars, only to see their registrations quickly copied by generic companies at no cost to these piggybacking companies.

Why 10 years? First, it is the international norm and a balance between insufficient data protection (five years) and infinite data protection (unlimited protection). Second, it is closely aligned with New Zealand's major trading partners; Australia,

¹ Irvine, R. And Denne, T. 2009. Data Protection for Agricultural Compounds and Veterinary Medicines. Copyright Covec Ltd. p45

the United States, and the European Union.

4.2.4 Questions

Do you think that data protection should be provided for registration or approval of new uses of existing products, or reformulations of products using existing chemistry?

Yes.

Please give your reasons.

New Zealand offers no data protection for information supporting the registration of new uses and reformulations of existing substances.

Consequently there is little incentive in New Zealand to develop new uses and reformulations.

Examples of new uses and reformulations are the extension of use of a pesticide that is registered for apples to include kiwifruit; the extension of a vaccine used in cattle to sheep; or the development of a new formulation to improve efficacy, lower transport costs, and improve safety when handling.

These extensions require trials, usually conducted in New Zealand, to generate appropriate information for the regulatory authorities. It is this additional information - regardless of the country in which it is generated - for which protection is sought.

Such protection would provide an incentive to develop new applications, especially in respect of minor crops and minor animal species. This incentive would apply equally to New Zealand and multi-national organisations.

Extending data protection for new uses and reformulations will provide real benefits to New Zealand agriculture.

If yes, how long should this period be?

Ten years.

Do you think that extending data protection for the original product when minor uses are added would be useful in New Zealand?

Yes, as it would encourage minor uses to be added to labels.

The case for extending data protection to encourage minor uses was convincingly put in the Covec report.²

It should be noted that there are two scenarios:

- a) **Protection For New Use Only:** The first scenario is when a new use is added to a product that **does not** contain an innovative active ingredient that is data protected. In this case, the data protection applies only to the new use.

² Irvine, R. And Denne, T. 2009. Data Protection for Agricultural Compounds and Veterinary Medicines. Copyright Covec Ltd. Section 3.4

It does not apply to the other already-permitted uses that are not data protected, meaning generics suppliers can continue to supply the product for these uses. This is an important point to consider as there is minimal impact on competition in the market for already-permitted uses. (For example, a product has 10 uses which have no data protection. A new use is added, but only that single use has data protection.)

- b) **Protection For Whole Product.** The second scenario is when a new minor use is added to an innovative product that **does** contain an innovative active ingredient that is data protected. In this situation, if enough minor uses are added, the whole innovative product is given additional protection. This approach is used in the United States to successfully add minor uses. (For example, a new product has eight years data protection. If five minor uses are added during the eight-year period, data protection is extended for a further year, giving a total of nine years. This process can be repeated for up to 15 new uses to obtain three extra years of protection, giving a total of 11 years.)

Scenario (b) has been most successful where the number of new uses required to trigger greater data protection is kept to a minimum (eg, three minor uses = one additional year in the United States).

Both of these scenarios are appropriate, depending on the situation. Agcarm recommends that both options should be added to the data protection regime.

Are there any other options or tools that could be used to encourage the development and registration of new uses for existing products and product reformulations?

Sharing the cost of data generation with other stakeholders could encourage the addition of new uses to existing products. In the United States the government provides much of the cost in situations where the potential market is too small to justify the cost of registration.

Grower industry groups which would benefit from a new use could share the cost of providing the data with a registrant and the government. At present this is rarely happening in New Zealand, because industry groups are often small and not sufficiently organised to participate in cost sharing. In Australia, the smaller industry groups are coordinated by government-supported rural development corporations to help them participate in cost sharing.

A possible solution is establishing a fund which grower industry groups with minor uses/crops could access to help pay for data trials.

4.3.3 Questions

Should data protection be required for data required to support reassessments?

Yes.

Please give your reasons.

ERMA and ACVM can, and do, formally reassess the continued use of existing products available in New Zealand. Examples of recent reassessments by ERMA include endosulfan, hydrogen cyanamide, and 1080. The reassessment process

may result in a product receiving continued approval to be sold, approval to be sold with additional controls, or having its approval cancelled.

During a reassessment, regulators may require additional data. But this proprietary information may not be supplied into the New Zealand system without sufficient protection, putting the continued supply of important agrichemicals (eg, 2,4,D) into doubt. A lack of data also 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 chemical being removed from the market.

Without adequate data protection a data owner may decide to withdraw from that market in preference to other markets where data protection occurs and there is a greater chance of obtaining a return on investment.

If yes, what form should this take:

The two options below are not mutually exclusive. Both can be used.

A – A specified period of protection (eg, 1 year, 5 years)

Yes.

B – Compulsory compensation (cost sharing)?

Yes.

If (A), how long should this period be?

10 years. A period of at least 10 years is necessary to be consistent with the U.S., the EU, and Australia (Note: in Australia, 10 years protection from regulatory decision has been agreed by the government, but the empowering legislation has yet to be passed).

If (b), how do you see this working?

The only fair way is for the company (or companies) which own the data to obtain compensation for the cost of the data from all companies which sell the product being reassessed.

Compensation occurs after the regulatory decision. The terms of cost sharing can be voluntarily negotiated, or if that fails then mediation, and if necessary arbitration, occurs. In Australia these processes are set out in law. In the U.S. there is common law legal precedent. The EU uses a different approach that forces registrants to form cost-sharing taskforces prior to submitting the required data.

For post-regulatory decision compensation, registrants would have a deadline of, say, three to six months to agree on cost-sharing and provide evidence of an agreement to the regulator. Registrants who are unable to reach agreement within the required time would have their approvals/registrations cancelled. This would add a powerful incentive to negotiate a cost-sharing deal as soon as possible.

2. Additional Points.

2.1 Generics And Data

The Covec report talks about one of the benefits of minimal data protection being greater competition. It is important to note that other companies can obtain the same approval/registration if they are prepared to provide the same data. Data protection only prevents the regulator from using data it already holds to approve another product without agreement from the data owner.

Generics companies whose business model is to copy existing products and their labels generally choose not to generate their own data because of the cost of doing so, preferring instead to piggyback on another company's development work and investment.

Some may argue that companies with data protection are given a right to be exclusive suppliers of their product. In reality, this exclusivity does not happen. Experience in countries with effective data protection shows that companies with data-protected products will supply these to generic companies under suitable supply arrangements.

Real examples can be supplied confidentially if required.

2.2 Competition Argument Flawed

The Covec report states that a lack of data protection facilitates competition and that "increased competition can in turn result in reduced prices, improved service standards and better quality products"³. This is incorrect.

How do you get better quality products from registrants who are just copying the original product? Indeed, it is a truism that generic products are often of an inferior nature due to trying to provide cheaper products than the original proprietor's product.

Agcarm also disagrees that increased competition leads to improved service. In fact the opposite occurs. As more copy products arrive, there is less profit to be made to support service. The companies which provide innovative products that can be sold at a reasonable profit can still provide service for low profit product through cross subsidisation.

We also disagree with the view that increased data protection results in higher prices. In a mature market like New Zealand, there are always many different active ingredients used for the same problem. This also provides price competition.

In situations where new uses are added to an existing product that has generic competition, it is not possible to increase the price of the product just because of the

³ Irvine, R. And Denne, T. 2009. Data Protection for Agricultural Compounds and Veterinary Medicines. Copyright Covec Ltd. p2

new use. The value of the new use comes from the potential to increase volume, not price.

2.3 International Norm

The Covec report states that the international norm for data protection is “around five years”. This is incorrect. The international norm for new actives and re-assessments is 10 years. For new uses, reformulations and reassessments, it’s 5-10 years. This is supported by the appendix in the Covec report that describes data protection in other countries.

2.4 Patents v Data Protection

There is often confusion about the link between patents and data protection.

Patent and data protection are two distinct intellectual property rights. Patent protection is the reward you receive for disclosing your invention; data protection is the reward you receive for the cost and risk associated with generating the required health, efficacy, and environmental safety studies.

Some assume that a new active ingredient brought into New Zealand is automatically covered by a 20-year patent. This is incorrect.

It is important to clarify this misunderstanding as it is easy to reach an incorrect view that a 20-year patent negates the need for data protection.

Innovator companies must patent their new active ingredients very early in the active’s development. This ensures their invention and significant early investment is protected. However it can take a further 10 years to fully develop and gain approval to sell a product based on the new active. This time delay significantly erodes the benefits of the 20-year patent term. Hence, the effective patent period is typically only 10 years.

Markets for products develop over many years and at varying times around the world. It can take many years before innovator companies see a market opportunity to bring a new active to New Zealand, which represents less than one percent of the global market in agrichemicals and animal health products.

Decisions about introducing an active ingredient to New Zealand are often made after a new active has come off patent or at the end of the 20-year patent period. New Zealand’s minimal data protection is therefore a key influencer on the decision to introduce the active ingredient.

Doubling the data protection to 10 years for new actives would encourage the registration of active ingredients new to New Zealand. This would benefit New Zealand agriculture in three ways:

- Bringing new technology to NZ farmers.
- Increasing the pool of active ingredients that can be used to minimise the development of pest resistance to pesticides and antibiotics.

- Increasing the pool of products for subsequent approval/registration by generics companies (after the patent and 10-year data protection period has expired).

2.5 When Clock Starts Ticking

It can take many months or, in some cases, years for an application to market a agricultural compound to be approved.

The proposed 10-years of data protection should therefore continue to commence from the date a regulator gives the go ahead to allow marketing of pesticides and veterinary medicines. It should not commence from the date the application is lodged.

2.6 Existing Generic Products

No products would be withdrawn from the New Zealand market as a result of greater data protection.

Any change in data protection would not be retrospective, so it will have no impact on the availability of existing products. This is of particular relevance in high-volume markets of off-patent products which have many suppliers (eg weedkillers glyphosate and 2,4-D).

2.7 Striking A Balance

Opponents to data protection may say that innovator (research and development) companies have a vested interest in supporting greater data protection. They would argue that the status quo is workable for the industry.

It is true that innovator companies receive higher returns for longer if they can optimise intellectual property protection. This applies to all innovators in business, including makers of proprietary software, movies, music, pharmaceuticals, animal health products, and agrichemicals. These higher returns are reinvested in further innovation and service to the user.

However, R&D companies see the importance of a balance between infinite or unlimited protection, and no protection. It is important to note that Agcarm members are seeking to strike that balance - between the rights of R&D companies to receive an acceptable return from their investment in innovative products, while working in a competitive market in which generic copies of their products offer more choices.

That is why Agcarm is not asking for unlimited or infinite data protection, as occurs in Japan.

Greater data protection will only have relevance to future registrations of new actives, new uses, and reformulations of products that are off patent, and products which are being reassessed.

2.8 Which Products Require Protection?

The proposed protection periods should cover all agricultural and veterinary compounds:

- Agricultural and horticultural products;
- Animal health products used on the farm and for pet care;
- Home garden products;
- Household pest control products;
- Public health pest control products (products used on road and railway verges, etc);
- Industrial pest control products;
- Turf products (for golf courses, sports fields, parks, etc).

2.9 Public Access

Data protection prevents a regulator from using data from one company to approve/register a product for another company without permission of the data owner. Importantly, it does not prevent release of a summary of that data for public consultation purposes. Nor does it override freedom of information laws.

In fact, overseas legislation specifically allows access to regulatory data (protected data or not) under carefully specified circumstances (no note taking, no photocopying, the signing of a statement that the information will not be used by a competitor, etc).

Also, in overseas jurisdictions, including Australia, 'public release summaries' are provided. These summaries are usually developed jointly by the applicant and the regulator.

2.10 Canada

Canada has recently revised its on Data Protection and Access to Information for pesticides. These revisions⁴ are the most recent and comprehensive explanation of a system which protects data but allows transparency. We attach a copy.

⁴ Health Canada Pest Management Regulatory Agency, 2007. Protection of Proprietary Interests in Pesticide Data in Canada. DIR 2007-03.

3. Appendix: About Agcarm

Agcarm is an industry association which represents crop protection, animal health, and rural supplies firms. Agcarm members distribute and sell the majority of animal remedies and crop protection products in New Zealand. For further information and a full list of members, see www.agcarm.co.nz.

We represent more than 30 manufacturers and distributors of crop protection and animal health products.

These products protect public health, improve animal welfare and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food and fibre products;
- Help supply healthy, nutritional and affordable food;
- Keep New Zealand's agriculture, horticulture and forestry sectors internationally competitive.
- Our members are committed to safety, innovation and product stewardship.

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