Data Protection for Agricultural Compounds

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Submissions

MAF welcomes submissions from all interested parties on any aspect of the data protection proposals contained in this document.

The following points may be of assistance in preparing comments:

- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or please make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the document.
- Your name and title (if applicable).
- Your organisation's name (if applicable).
- Your address.
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 15 December 2011

Your comments should be sent to:

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Introduction

In 2008 the New Zealand Food Safety Authority (NZFSA), the Environmental Risk Management Authority (ERMA) and the Ministry of Economic Development (MED) commissioned a study of the effects of New Zealand's current rules in respect of data protection for agricultural compounds, to inform policy decisions on possible changes to the rules, and to assess the net benefits to New Zealand of any such changes.

The study report (the Covec Study)[1] was released in 2009, along with a discussion paper[2] asking for stakeholder comment on the study findings.

Taking into account the information provided by the Covec Study, submissions received on the discussion paper, and assessment of the costs and benefits of policy options, officials have reached the following conclusions:

- There is no compelling case for a change to either
    - the length of the data protection period for innovative products/substances; or
    - the current rules in respect of data provided for reassessments (no data protection).
- For approval of new uses or reformulations of existing products, while the status quo (no data protection) remains an option, the introduction of a period of data protection could be considered.

The options in respect of new uses and reformulations of existing agricultural compounds are:

(a) No change i.e. no data protection; or

(b) Provide a period of data protection.

Further, if protection were to be introduced under option (b), the appropriate period of protection needs to be determined. Options of 1, 2 or 3 years are proposed.

MAF welcomes submissions from all interested parties on any aspect of the data protection proposals contained in this document. The closing date for comments is **15 December 2011**. All comments received will be considered before recommendations, if any, are made to the Minister for Food Safety.

[1] http://www.nzfsa.govt.nz/consultation/covec-data-protection-report.pdf
[2] http://www.nzfsa.govt.nz/consultation/data-protection-for-agricultural-compounds/discussion-document/page.htm

Background

Before any hazardous substance, agricultural compound, or veterinary medicine is used in New Zealand, approval must be granted by the appropriate regulatory authority (ERMA New Zealand and/or MAF). The approval process requires applicants to supply supporting test and research data.

The Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) provides a five-year period of protection for data provided in support of applications for registration or approval of "innovative agricultural compounds" – products that are, or contain, new active ingredients, that is, ingredients that have never been registered in New Zealand before. During this period there can be no evaluation of another product based on this data, and no disclosure of the data to third parties.

There are some exceptions to the five-year protection period. Data may be disclosed where an original applicant consents to it being used or disclosed; where it is necessary to address public health, environmental or efficacy concerns; to other government departments or statutory bodies, an advisor for the purposes of obtaining advice about the agricultural compound to which the information relates; or to the World Health Organization, the Office International des Epizooties, the Food and Agriculture Organization, or a regulatory agency of a World Trade Organization country, provided that those persons, agencies, or organisations will take reasonable steps to ensure the information is kept confidential.

Protection for data supplied in support of applications for approvals under the Hazardous Substances and New Organisms Act (HSNO Act) is provided by cross-referencing the relevant provisions in the ACVM Act. Where these provisions apply, ERMA cannot release information to another party, or use it in the consideration of other applications.

New Zealand's current data protection provisions were put in place to implement our obligations under Article 39.3 of the GATT:TRIPs[3] agreement to "protect the registration data of manufacturers of proprietary products that utilise new chemical entities from unfair commercial use".

Stakeholders have argued that changes to the provisions are needed because:

- the current protection period of five years for innovative agricultural compounds is inadequate and inhibits the flow of novel products onto the New Zealand market;
- the lack of data protection for new uses and reformulations of existing products inhibits the flow of products onto the New Zealand market; and
- the lack of data protection for reassessment of agricultural compounds means that information may not be made available to the regulator. This has the potential to adversely affect New Zealand agriculture should a product not survive the reassessment process due to unavailability of required data.

[3] General Agreement on Tariffs and Trade: Agreement on Trade-related Aspects of Intellectual Property Rights

Covec Study conclusions

The conclusions of the Covec Study were:

- The current regime does not appear to be having a major effect overall on the number of products available in New Zealand.
- However, in the case of registrations of new uses for existing products, there is some evidence of a negative impact from the current rules, and there seems to be little downside in terms of effect on competition and/or prices from providing a period of data protection in such cases.
- The situation with respect to reassessments is less clear. The conclusion is that introducing data protection in such circumstances would lead to a reduction in competition, and creation of an effective marketing monopoly for original applicant for the period of protection. This could be addressed by compulsory cost-sharing arrangements.
- There do not appear to be any significant issues arising from the current length of the data protection period for innovative products, that is, five years.

Submissions received

Eleven submissions were received (see Appendix for list of submitters):

- nine agricultural compound manufacturers or distributors, including their representative industry body;
  - three animal health (veterinary medicines);
  - five crop protection (herbicides, insecticides, fungicides etc);
- one user representative body; and
- one research institute (CRI).

Of the manufacturers and distributors, four were independent New Zealand-owned businesses and four were subsidiaries or associates of international companies.

As would be expected, positions taken on data protection issues varied according to the interests of the submitter.

Summary of submissions

5.1 PERIOD OF DATA PROTECTION FOR INNOVATIVE PRODUCTS

Status quo: data submitted in support of registering or approving an innovative product or substance is protected for five years from the date of registration or approval.

Two submitters supported the status quo. Another expressed support for a modified status quo, involving five years data protection for products developed for the New Zealand market, and a period of two to three years data protection for products developed initially for an overseas market.

Six submitters supported a 10-year data protection period for innovative products. One supported a seven-year period. Another submitter supported an extension to the existing five years, but did not specify the length of the extended period.

5.2 PERIOD OF DATA PROTECTION FOR NEW USES/CLAIMS FOR EXISTING PRODUCTS

Status quo: data submitted in support of registering a new use or a reformulation of an existing approved product or substance is not protected.

One submitter supported the status quo.

Four submitters supported a 10-year data protection period for new uses (one of whom stipulated that it should only apply to locally-generated data). Another expressed support for more data protection for new uses, but did not mention a preferred period.

Three submitters supported a five-year data protection period for new uses – each of these submitters stipulated a different condition. One stated that the new use must involve the generation of New Zealand data; one stated that the five-year period should not apply to reformulations; and one stated that the five-year period should only apply to label extensions and novel reformulations.

One submitter supported tiered data protection periods, namely five years for a significant change that requires residue data; three years for a significant change that offers a dramatic economic advantage for New Zealand; one year for a minor advance that requires field trials; one year for a new crop/use, extended to three years if the new crop/use requires residue work.

One submitter expressed support for the United States model, whereby data protection is extended for one year per three minor uses, to a maximum of three years.

5.3 PERIOD OF PROTECTION FOR DATA SUPPLIED FOR REASSESSMENTS

Status quo: no protection for data supplied for reassessments.

Ten submitters commented on this issue.

Two submitters supported the status quo. Another opposed having any rule apply in this area, on the basis that it would be preferable to have the flexibility of a case by case approach.

Four submitters supported a 10-year period of protection for data supplied for reassessments. One submitter supported a three-year period. Two submitters supported having some data protection for reassessments, but did not mention a period.

Costs and benefits of increased data protection

The ACVM and HSNO Acts are intended and designed to manage risks associated with the use of agricultural compounds and hazardous substances.

It is not a primary purpose of the Acts to manage product markets. However, the Government does take account of the effects of regulation on competition, prices and product supply, and the need to balance competing interests of stakeholders.

The following table identifies the potential costs and benefits associated with increasing data protection, compared to the status quo, and where they would fall.

LONGER PERIOD OF PROTECTION		
Party	Costs	Benefits
Government	Potential reduction in competition in agricultural compounds markets in New Zealand, with consequent effects on economic growth and development.	Potential increase in competitiveness of agricultural sector through quicker access to latest products.
Industry (Manufacturers/Importers/Distributors of Agricultural Compounds)		
(a) Initial Registrant		Increased ability to recoup costs of registering new products in New Zealand.
(b) 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.	Quicker access to innovative products.

NEW USES/REFORMULATIONS

Party	Costs	Benefits
Government (MAF/ERMA)	Increased complexity of administration e.g. new registers to maintain. *Note: registrations are cost recovered so no or minimal financial impact for regulator*	Reduced costs of monitoring for compliance if off-label use is reduced.
Industry *(a) Initial Registrant*	Potential increase in registration costs, from increased complexity of administration.	Increased profitability of registering or developing new uses in New Zealand, through exclusive marketing advantage.
(b) Generics	• Reduced sales/loss of market share • Potential increased registration costs as above.	
Consumers/Users	• Reduced choice due to delayed registration & production of generic products. • Higher prices due to lack of competition.	• Greater range of products for minor and/or specific uses, with resultant productivity gains, if registrants are encouraged to bring products onto the New Zealand market, or develop new products specifically for the NZ market. • Potential benefits for international trade from ability to comply with purchasers' requirements to show that only approved products have been used.

REASSESSMENTS

Party	Costs	Benefits
Government	*Data protection:* Negative effect on relationship with generic agrichemical industry: • anticompetitive • potential for litigation. *Compensation/Cost sharing:* Costs of administering process	Fuller access to data on which to base decisions.
Industry *(a) Initial Registrant*	*Data protection:* *Compensation/cost sharing:* Cost of negotiating and implementing cost-sharing arrangements	• Increased sales due to removal of competition. • Ability to recoup cost of providing additional data required.
(b) Generics	*Data protection:* Loss of business *Compensation/cost sharing:* Cost of negotiating and implementing cost-sharing arrangements	
Consumers/Users	*Data protection:* Reduced choice with exit of generics from market; potential for increased prices *Compensation/cost sharing:* Potential for increased prices	Continued access to product, if it would not otherwise survive the reassessment process.

Conclusions

Taking into account the information provided by the Covec Study, submissions received, and assessment of the costs and benefits of policy options, the following conclusions have been reached:

- There is no compelling case for a change to either
    - the length of the data protection period for innovative products/substances; or
    - the current rules in respect of data provided for reassessments (no data protection).
- The one area where a change could be considered is in respect of new uses or reformulations of existing products.

7.1 LENGTH OF DATA PROTECTION PERIOD FOR INNOVATIVE PRODUCTS

No significant issues around the current five-year period of protection for innovative products were identified by the study or in submissions; there is no evidence that it is unduly inhibiting the flow of products onto the New Zealand market. Information from submitters indicates that the New Zealand market offers numerous treatment options, with healthy price competition, and that new products are continually being introduced.

Therefore no change to the existing protection period is proposed.

Officials note that data protection is not about protecting the level of investment made by registrants in researching and developing innovative products; that is the role of patents and other legal mechanisms (such as the Official Information Act) for protecting commercial-in-confidence information. Data protection is concerned with the costs associated with registration of products and/or substances. Preventing cross-referencing of proprietary data needed to support applications for marketing approval is a mechanism for addressing the "free rider" problem caused by the requirement to register.

7.2 REASSESSMENTS

On the available evidence, officials do not consider that the benefits of introducing protection in this area would outweigh the costs. Therefore no change is proposed to existing data protection provisions in respect of reassessments.

Reassessments usually arise due to new concerns or evidence that might affect the risk assessment of a product (or substance).

If the data required to demonstrate that the product meets contemporary standards for continued use already exists, there will be no (or minimal) costs involved in providing it, and no data protection is needed. The competitive situation between the holder of the data and competitors will not change. There will be no "free riding", since the relative status of all products will not change, and the data holder is selling in the market already having incurred the costs of producing the data.

If additional, new data is needed, this will involve costs. The regulatory options for addressing this issue were:

(a) Data protection for data supplied by the original applicant.

This would mean that 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.

Officials concede that, as noted in the Covec Study, some large multinational companies may choose not to supply existing data despite there being no financial or economic rationale for not doing so, and that lack of data protection may be a factor.

However, officials consider that the costs of providing data protection in the form of market exclusivity would outweigh the benefits.

(b) Compulsory cost sharing arrangements, whereby other firms in the market compensate the original registrant for the cost of providing the data required.

This would address most of the anti-competitive impacts that may arise from data protection, 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, and access to information (for example, market share) to ensure fair allocation of costs between firms.

Officials consider 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, and the cost of implementing compulsory cost sharing arrangements is not justified.

7.3 NEW USES/REFORMULATIONS

Officials have concluded that, while the status quo (no data protection) remains an option, the introduction of a period of data protection for approval of new uses or significant reformulations of existing products could be considered.

Evidence from a range of industry participants suggests that the current data protection rules are inhibiting the availability of some agricultural compounds, particularly for the horticultural sector. It is not possible to determine with certainty whether the net impact of the current rules is positive or negative across the entire sector, or for New Zealand as a whole.

However, the effects of introducing data protection in this area are assessed as follows.

- The level of competition in existing product markets (for uses that are already approved and registered) will remain unchanged.
- Unless the new use market is significantly bigger than existing uses, registrants are unlikely to be able to raise prices, as only those wanting the new use would be willing to pay a premium.
- Registrants would gain marketing advantage (market share) through exclusive label claim.
- The rights or ability of existing product marketers to sell their products in existing markets would not be affected; however they would have to generate their own data and apply for approval for the new use.

If data protection were introduced, the regulatory authority would not, for the period of protection, be able to cross-reference data submitted by the original applicant to approve other applications for the new use

For data protection purposes, "reformulation" would mean

- an agricultural compound containing two or more previously assessed active ingredients whose combination in a formulation has not been previously assessed by MAF; or

- an agricultural compound containing a previously assessed active ingredient or a combination of previously assessed active ingredients and manufactured in a such a way that its form or nature is significantly different from registered formulations with a similar active ingredient or combination of active ingredients.

Options

(a) No change i.e. no data protection for new uses and reformulations of existing agricultural compounds

(b) Provide a period of data protection for new uses and reformulations.

In respect of option (b), if protection were to be provided, the appropriate period needs to be determined. That is, what period of protection would provide a reasonable period for data owners to recover the costs of registering new products for the New Zealand market, while not inhibiting competition in the marketplace for too long?

Officials do not consider that it would be appropriate to provide the same length of protection as for innovative products (five years); registration costs to applicants are likely to be significantly less, given the existing product knowledge and database. Officials therefore consider that if protection were to be introduced, it should be for a period of 1, 2 or 3 years.

Other issues

Several issues were raised in submissions regarding the regulatory regime for agricultural compounds that do not directly relate to data protection, but which submitters believe have a bearing on the availability of products on the New Zealand market.

8.1 REGULATORY REQUIREMENTS FOR ADDING NEW/MINOR USES

Some submitters stated that simplifying and speeding up the process for adding new or minor uses to existing products, or approving reformulations of existing products would assist in bring new and/or improved products to market.

They assert that a simple process, with reduced registration requirements, for example with respect to efficacy and residue testing, would reduce the costs associated with registering products with new features or for new/minor uses and encourage more firms to work innovatively to further develop existing products.

Comment:

Current processes are entirely based on the time taken to assess an application. Only the additional data in respect of the new use is assessed; current knowledge of the product is taken into account and there is not a re-assessment of the whole product from scratch.

With respect to registration requirements, assessments are risk-based and it is difficult to see why additional uses should be assessed to a reduced requirement; there is no reason to assume that new uses pose lower risks than existing uses. Products that pose a greater degree of hazard, or where risks are widespread will require more data. Also, if the same standards are not required, there would be an issue of the registration not meeting the international standards that New Zealand has signed up to (for example, Good Laboratory Practice for residues).

Officials note that other options to help address minor use issues are being worked on, for example Codex crop grouping work, which will reduce the need to register products separately for each specific plant. New Zealand as a member of Codex will adopt the recommendations from this work.

8.2 OFF-LABEL USE

Some submitters argued that even if data protection is provided for new uses, the policy of allowing off-label use provided it does not breach default residue guidelines renders such protection less effective. “Look alike” products could still legally be used even though the new use could not be stated on their label.

Comment:

Maximum Residue Limits (MRLs), including default limits, are set in the context of food safety; the effect on data protection is not a food safety issue. It could be considered to come within the ambit of the “international trade” purpose of the ACVM Act, if the use of agricultural compounds in line with the default guidelines can be shown to create a risk to trade in primary produce.

However, if the commercial incentives are to use only approved products, that is, purchasers will not, or are less likely to, buy products if the intended use is not approved, then there is unlikely to be a trade risk arising from the default limit policy. If an approved product is available, producers who are concerned to comply with purchasers’ requirements will use that product in preference to a product that is not approved. Data protection for new uses would still bestow a market advantage over products that are not approved for the new use.

If it is not an international trade issue, then changing the default limit policy for commercial data protection reasons is not within the ambit of the ACVM Act.

8.3 RESEARCH AND DEVELOPMENT FUNDING

Some submitters stated that government should provide more funding for local research and development activity to generate the data to support innovative new products and new uses that would benefit the agricultural sector. If this was provided the issue of data protection would be less important as the research would not have to be undertaken by private companies who would then have to protect their investment.

Comment:

This suggestion is outside the scope of this review of the data protection regime.

8.4 COST SHARING

Some submitters argued that establishing mechanisms to enable the sharing of costs of data generation between stakeholders could encourage the addition of new uses to existing products. For example, a government contribution where the potential market is too small to justify the costs of registration from a commercial perspective, or setting up a contestable fund to provide for the costs of registration.

Comment:

The Working Group notes that funding for development work should come from the sector or group(s) that the extension would benefit, in a commercial relationship with the manufacturer. If the benefit to users is insufficient for them to make the investment, a government financial contribution would amount to a subsidy for that group.

Appendix – List of submitters

Ancare Ltd
Bomac Ltd
Dow Agrosciences Ltd
Elliott Technologies Ltd
Federated Farmers of New Zealand
New Zealand Association for Animal Health and Crop Protection (Agcarm)
New Zealand Institute for Plant & Food Research
Orion Crop Protection Ltd
Pfizer NZ Ltd
Syngenta Crop Protection Ltd
Zelam Ltd