

Final Report

Study of Data Protection for Agricultural Compounds and Veterinary Medicines

Prepared for

New Zealand Food Safety Authority

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Authorship

This document was written by Reuben Irvine and Tim Denne. For further information email phone (09) 916-1967 or reuben@covec.co.nz.

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Covec Limited Level 15 Qantas House 191 Queen Street
PO Box 3224 Shortland Street Auckland New Zealand
t: (09) 916-1970 f: (09) 916-1971 w: www.covec.co.nz

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Executive Summary

This report considers the impact of data protection rules on the availability of agricultural compounds and veterinary medicines in New Zealand. These rules constitute part of the regulatory regime governing the approval and registration of these products. Approval to use these products is granted by the Environmental Risk Management Authority (ERMA) and the New Zealand Food Safety Authority (NZFSA).

The regulatory approval process typically requires applicants to supply supporting information regarding product features, such as toxicology, safety, efficacy and the likelihood of residues remaining after use. The package of data supplied in support of an application may represent a significant investment by the applicant. Any ability to use, or rely on, this data is of considerable value to competitors.

In relation to 'non-innovative' products, as defined under the ACVM Act, the current rules allow for applicants' data to be cross-referenced by the aforementioned regulatory bodies, allowing competitors to register 'copy-cat' products. These are registrations products that do not contain 'new' chemistry, for instance:

- the registration of new uses for existing products, or
- the registration of reformulations of existing products.

Similarly, data provided to ERMA or NZFSA for reassessment of products currently in use are also not protected. Data provided in relation to the registration of 'innovative' products using new chemistry is protected for a period of five years.

Analytical framework

This report seeks to evaluate whether the present rules regarding data protection are consistent with maximising the net benefits to the agricultural compound and veterinary medicines industry in particular, and the agricultural sector and New Zealand more generally. To this extent, this report seeks to inform policy makers on whether there is a need for change to the regulatory environment relating to data protection so as to maximise these net benefits.

To ensure a rigorous analysis of the overall net impact it is necessary to consider all of the individual beneficial and adverse impacts of the current rules. This includes not only those effects that impact on the agricultural compound and veterinary medicines industry and the agricultural sector, but also any wider impacts within New Zealand. This is because activities within these industries can have important environmental, social, cultural and economic impacts outside of the sector itself.

Identifying and evaluating the individual impacts of the current rules requires contrasting the existing outcomes with the outcomes that would be expected under a different regulatory setting. For the purposes of this report, the counter-factual used to make this comparison is a scenario whereby suppliers would be provided with a greater degree of data protection in relation to applications for new uses and reformulations

and for reassessments. In the absence of specified alternative rules, this report considers a more general alternative scenario whereby data protection would be provided for period that is roughly in line with international norms, ie around five years.

As a result, this report seeks to evaluate whether the overall net benefits to New Zealand are likely to be increased if the data protection rules were altered to provide greater protection in relation to non-innovative, agricultural compounds and veterinary medicines that use existing chemistry.

However, a number of factors prevent a precise determination of the net overall impact of any such changes. For instance:

- much of the relevant information regarding the impact of these 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; and,
- as discussed above, the counter-factual scenario against which the status quo is compared is not fully specified.

In light of these factors, this report utilises anecdotal evidence and economic analysis to assess the likely beneficial and adverse impacts of these rules where possible.

Beneficial impacts of current rules

Because data provided for these types of regulatory approval is not protected from (indirect) use by competitors, these competitors can produce similar products and obtain regulatory approval and/or registration by having the relevant regulator cross-reference the data provided by the original applicant. This can allow competitors to obtain regulatory approval and bring copy-cat products to market at lower cost and within a shorter timeframe than the original applicant. This facilitates a higher degree of competition for these products than would occur if data protection were provided. Increased competition can in turn result in reduced prices, improved service standards and better quality products.

Of note is that these pro-competitive beneficial impacts are more likely to occur in relation to certain types of registrations or approvals. For instance, allowing rival suppliers to rely on data provided in support of a new use registration (ie an extended label claim) is not likely to have a significant impact on the price of that product. 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 for use. As a result such a product would already be competitively priced.

The pro-competitive impacts of the absence of data protection may be greater in relation to new reformulations and reassessed products. Regarding reformulations, a supplier selling a new product could potentially exploit any market power for any period of data protection if its new formulation were sufficiently superior to existing products. For instance, the supplier may be able to charge a price premium during this period. By enabling rival suppliers to reference the applicant's data, these suppliers can obtain

approval for and/or register copy-cat products and enter the market at a lower cost than if they were required to generate their own data. This can impose a competitive restraint on the price of the reformulated product.

Similarly, if data protection were in place for reassessments it may allow the original supplier to effectively exclude other rival suppliers from the market for the data protection period. This is because rivals would need to generate their own data to replicate that provided by the original supplier. If the costs of rivals generating their own data were sufficiently large, rival suppliers may pull out of the market and the competitive pressure on prices would be temporarily reduced.

The reduction in competitive pressure that may occur from such data protection can be mitigated by allowing more than one supplier to obtain regulatory approval.¹ Concerns regarding the loss of competitive pressure may also be somewhat alleviated to the extent that compounds that are up for reassessment are older compounds that already face competition from other, newer compounds.

Adverse impacts of current rules

Although the current rules facilitate vigorous competition and can lower prices for end-users, the absence of data protection can also deter suppliers from:

- developing and registering new products using existing chemistry,²
- registering existing products for new uses, or
- providing data for reassessments.

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 (eg 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.

¹ Some jurisdictions that provide data protection attempt to resolve this problem by allowing rival suppliers that wish to continue selling the product to compensate the original applicant for some proportion of the total data costs, eg Australia.

² Within this report 'new products using existing chemistry' refers to all those products for which do not use innovative active ingredients and, consequently do not tend to be eligible for either patent protection or data protection. Examples include reformulations.

To the extent that the current rules lead to fewer available products, end-users may be forced to use products that are:

1. less effective;
2. more expensive;
3. more environmentally damaging; and/or
4. more harmful and raise greater occupational health and safety issues.

Regarding reassessments, the absence of data protection may deter the provision of data by suppliers. Because data protection is not available for reassessments, suppliers may choose not to provide with any additional data requested by the regulators (ie ERMA or NZFSA). A refusal is especially likely if providing the requested data would impose significant costs on the supplier and/or if the supplier has other products which may be substitutable.

Several suppliers have indicated that even if they already possessed the data requested by a regulator, the data may not be provided. Such a refusal may appear irrational from an economic perspective because few additional costs would be imposed by providing this data and its provision would allow a product to remain on the market. However, such a refusal may reflect the relative unimportance of the New Zealand market to large multi-national brand-owners which tend to have a high degree of centralised management control and are highly protective of their intellectual property.

Evaluation of net impact of current rules

Evidence from a range of industry participants suggests that the current data protection rules are inhibiting the availability of some agricultural compounds and veterinary medicines. However, it is not possible to determine with certainty whether the net impact of these rules is positive or negative across the entire sector as a whole.

Because many suppliers would benefit from greater data protection, they have an incentive to claim that the current rules are the cause of a particular product or new use not being registered. Without in-depth, firm-specific information and analysis, it is not possible to verify the extent to which this is actually the case. It is even more difficult to evaluate the extent to which the development of new products using existing chemistry has been curtailed because of the current rules, although analysis suggests that this impact is likely to occur to some degree.

Because end-users have the potential to benefit from both increased competition and a greater range of products, they would be expected to support greater data protection only if it were likely to generate net benefits. Unfortunately, many of the large number of small-scale end-users are not sufficiently informed to be able to make an accurate assessment in many of the specific product markets affected. However, a number of groups representing end-users have considered these issues, particularly with respect to agricultural compounds. The view of several of these groups, eg Horticulture New Zealand, Pipfruit New Zealand, New Zealand Citrus Growers and the Foundation for

Arable Research, is that these rules are creating a barrier to both the registration of some new products using existing chemistry and new uses of existing products.

If greater data protection were provided, this would not tend to affect the pro-competitive benefits from the current rules in relation to products that are already available. Assuming that any increase in data protection would not apply retrospectively, a reduction in pro-competitive benefits would only apply to any future reformulations and new uses, but not to any products currently available. That is, the level of competition in relation to products that are already approved and registered is unlikely to be affected, with one exception.

This exception relates to reassessments. 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.

In relation to the data protection of five years provided for registrations of new, innovative products (ie containing previously unregistered active ingredients), the fact that the majority of such products are typically eligible for patent protection of 20 years means that this level of data protection does not have appear to have a significant impact on the registration of new products across the sector.

Overall, the evidence and analysis outlined in this report suggests that any increase in net benefits to New Zealand from increasing data protection are likely to be greatest in relation to new use registrations. There may also be benefits from providing data protection for reformulations, although this is less clear. Whether the net impact of an extension of data protection for reassessments would be positive is perhaps even more uncertain, although there may be policy approaches (eg cost sharing) that could address any anti-competitive impacts that may arise from such a change. 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. Background

Before any hazardous substance, agricultural compound or veterinary medicine is used in New Zealand, approval must be granted by the appropriate regulatory agency; the Environmental Risk Management Authority (ERMA) and/or the New Zealand Food Safety Authority (NZFSA).

The approval process requires applicants to supply supporting information regarding product features, such as chemistry and manufacture, toxicology, safety, efficacy and the likelihood of residues remaining after use. The package of data supplied in support of an application may represent a significant investment by the applicant. This data also has the potential to be of considerable value to competitors.

If the product or substance in question is not an innovative agricultural compound (and, consequently, would be unlikely to have patent protection), this data is not 'protected' from (indirect) use by competitors.³ Consequently, other parties can produce similar products and obtain regulatory approval and/or registration by having the relevant regulator cross-reference the data provided by the original applicant without these competing parties having to incur the costs of producing this data. This can allow competitors to obtain regulatory approval and bring 'copycat' products to market in less time and at a lower cost.

The rules relating to the protection, or release, of proprietary data submitted to a regulator are provided in the following New Zealand legislation:

- The release of confidential information is covered by the Official Information Act 1982 and Privacy Act 1993;
- Provisions to allow for the protection of data are contained in the Agricultural Compounds & Veterinary Medicines Act 1997 (ACVM Act), in particular:
 - **Sections 72, 73 and 74** – These sections are contained within Part 6: Protection of certain confidential information about innovative agricultural compounds. They provide protection for a defined period for confidential information that supports an application for an innovative agricultural compound.
- The Medicines Act 1981 also provides for data protection:
 - **Sections 23A, B and C** – These sections are contained within Part 2: Dealings with medicines and medical devices, and were inserted by the Medicines Amendment Act 1994. They provide protection for a defined period for confidential information that supports an application for an innovative medicine.

³ When making 'copy-cat' applications, competitors do not obtain direct access to data and information provided by original applicants. However, if data is not subject to protection, regulators are required to cross-reference any relevant data provided by the original applicant in assessing competitors' applications.

- The Hazardous Substances & New Organisms Act 1996, (HSNO Act) allows for data protection by way of Part 5.
 - **Section 55 (4A) and (4B)** provide that, if an application is made to ERMA for approval of a substance for which registration is also being applied for under the ACVM Act as an innovative agricultural compound,⁴ then the provisions of Part 6 of the ACVM Act apply to any confidential information supplied to ERMA, and to ERMA's handling of that information.

In respect of registration under the ACVM Act, Section 20 of the Act states that:

"The Director-General must, when evaluating the risks and benefits under Section 21, have regard to all relevant scientific and technical information held by the Director General other than information protected in accordance with Section 73..."

The effect of this provision is that NZFSA must use the test reports, etc that are provided to it by one party if the information is relevant to another party's application, unless data protection applies (ie unless the application relates to the approval and registration of innovative compounds that use 'new' chemistry).

The situation is different for ERMA approvals. This is because there is no similar compulsion in the HSNO Act for ERMA to necessarily use existing information. The cross-referencing between the HSNO Act and the ACVM Act only involves Part 6 of the ACVM Act, not section 20. However, despite not being forced to do so, ERMA would typically choose to cross-reference any relevant, non-protected information.

In either case, in the absence of specific data protection, the consent of the applicant who provided the original data is not required for the relevant authority to cross-reference the data.

1.1. What is the issue?

Some stakeholders (such as suppliers and users) claim that the data protection rules in New Zealand are inadequate. The most common argument is that suppliers are deterred from bringing new products using existing chemistry onto the New Zealand market or extending label claims for existing products. In particular, industry participants claim that innovation based on existing chemistry is inhibited, and protection is needed for data supplied in support of applications for new uses (ie new label claims) for existing products to prevent competitors 'free-riding' on others' investments.

The absence of data protection for reassessments of existing products has also been raised as an issue by both industry and ERMA. As with new products using existing chemistry, an absence of data protection may inhibit the provision of data by suppliers because they may be unable to recover the costs of generating the data requested by ERMA. From ERMA's perspective, if data is not provided they may have insufficient

⁴ 'Innovative agricultural compound applications' are defined in Section 72 of the Agricultural Compound & Veterinary Medicines Act.

information to make the 'correct' approval decision about whether a compound should continue to be approved for use, and what, if any, controls should be placed on its use.

The data protection provisions of the ACVM Act only relate to the application for the registration of what is defined under the Act as 'innovative' agricultural compounds and veterinary medicines.⁵ Once the original period of data protection for a new, innovative compound has expired, the data supplied can be cross-referenced to support any number of applications for similar products by competitors.

1.1.1. Registration of 'non-innovative' new products

Under the regulatory regime, (the ACVM and HSNO Acts), when assessing applications for registration of new products using existing chemistry or approval of hazardous substances, the relevant regulator is required to have regard to all the information it holds. For instance, if the NZFSA is assessing third-party applications for a new or amended approval for a 'copy-cat' or generic product that contains the same active ingredient as the initial registrant's product, it must consider the information provided by the original registrant.

In many cases regulatory approval is required from both agencies, ie the NZFSA, as stipulated in the ACVM Act, and ERMA, as stipulated in the HSNO Act. However, in some cases regulatory approval from only one of these bodies is required. For instance, if the prospective product for which ERMA approval is sought is not used in relation to animals or crops, NZFSA registration may not be necessary. Examples of this may include some turf products. In other cases, ERMA approval may not be required. For instance, a supplier maybe seeking to register an existing product for a new use. If ERMA has already approved the use of the product without any conditions further approval from ERMA may be unnecessary.⁶

New uses of existing products

Under the ACVM Act, products are registered for use for specific purposes; this is noted on product labels. Research and testing, such as residue trials, and resultant data supplied in an application are specific to those uses. Any use of the product for another purpose (ie on another crop or animal) is 'off-label' use. Off-label use of products requires that the crops or animals on which a product is used are subject to more stringent default residue regulations.

Under the HSNO Act, approval for use may be given to a hazardous substance such as an agricultural chemical on the basis that certain controls, or restrictions around use, are imposed. For example, based on available information a risk assessment by ERMA may mean that the approval for use of an agricultural chemical is only given if its use is restricted in some manner. To obtain approval to use a substance more extensively an

⁵ Innovative compounds, or products, are those that contain chemistry (an active ingredient) for which registration has not been previously applied for in New Zealand.

⁶ Note that ERMA may choose to reassess at a later time if there is a significant change in use that leads to a change in risks.

applicant may need to provide additional data to justify the removal of ERMA-imposed controls.

Reformulations

From time-to-time some existing products are reformulated, so that the same active chemical ingredient is combined with other substances that it has not been combined with previously, such as a different adjuvant. Similarly, a product may be reformulated into a different state, eg from a spray to a granulised product. If so, new data may need to be submitted in accordance with the ACVM Act to indicate that any new formulations meet the necessary regulatory standards.

It may also be the case that, under the HSNO Act, ERMA approval is needed for reformulations that do not fit within current ERMA approval conditions. This may necessitate the provision of new data by the supplier.

1.1.2. Reassessments

There is a trend, both domestically and globally, towards more government-initiated reassessment of older chemicals. Consequently, there are likely to be more instances of data being required for such reviews. Reassessment is one of the main tools available for changing, or revoking, substance approvals under both the HSNO and ACVM Acts.

Without data protection, the additional data requested for an agricultural compound that is a hazardous substance may not be supplied to the regulator. This may mean that the reassessment is not based on the best information available. This has the potential to hinder the regulator carrying out its regulatory function, as it is required to weigh up the benefits of continued approval against the risks and costs. This process could be more difficult if the relevant data is not provided.

1.2. Analytical framework

This report seeks to evaluate whether the present rules regarding data protection are consistent with maximising the net benefits to New Zealand of the agricultural compound and veterinary medicines industry in particular, and the agricultural sector and wider community more generally.⁷ To this extent, this report seeks to inform policy makers on what changes, if any, should be made to the regulatory environment for data protection to maximise these net benefits.

To ensure a rigorous analysis of the overall net impact it is necessary to consider all of the individual beneficial and adverse effects of the current rules. This includes not only those effects that impact on the agricultural compound and veterinary medicines industry and the broader agricultural sector, but also wider impacts on the overall New Zealand community. This is because activities within these industries can have important environmental, social, cultural and economic impacts outside of the sector itself.

⁷ As outlined in NZFSA Request for Tender, Section 2. Service Description.

Identifying and evaluating the individual impacts of the current rules implicitly requires contrasting the existing outcomes with the outcomes that would be expected under a different regulatory setting. For the purposes of this report, the counter-factual used to make this comparison is a scenario whereby suppliers would be provided with a greater degree of data protection in relation to new use and reformulation applications and in relation to reassessments. In the absence of specified alternative rules, this report considers a more general alternative scenario whereby data protection would be provided for period that is roughly in line with international norms, ie around five or so years.

Thus, this report seeks to evaluate whether the overall net benefits to the wider community are likely to be increased if the data protection rules were altered to provide greater protection.

Because the counter-factual for comparison is not fully specified it is not possible to provide definitive conclusions regarding the overall net impact of the current rules. Additionally, the precise evaluations of the effects of the current rules are hampered by the fact that detailed, commercially sensitive, firm-specific information has not been provided by suppliers.

Although the absence this information hinders definitive conclusions regarding the magnitude of overall net benefits, preliminary conclusions of a general nature have been put forward where this is supported by economic analysis and anecdotal evidence.

1.2.1. Beneficial impacts

The beneficial impacts of the current regime are in comparison to a counter-factual of greater data protection and can be broadly characterised as pro-competitive effects. That is, the current rules facilitate greater market entry for 'new' generic products that use existing, non-innovative chemistry.

Determining the magnitude of these pro-competitive effects poses significant difficulty. First, all products whose registration was facilitated by the absence of data protection would need to be identified, as opposed to products that would have been introduced regardless of the current rules. This would involve a case-by-case analysis of all registration and reassessment information held by NZFSA and ERMA since the introduction of the ACVM Act to determine how many 'copy-cat' products relied on data provided by other applicants. The date at which such copy-cat registrations occurred would also need to be determined, as the counter-factual scenario used for analysis would be one in which data protection were provided for a temporary period, eg five years.

Having identified the total number of products that have benefitted from the absence of data protection, ie those products whose registration would have otherwise been delayed if data protection were provided, the actual effect on competition and prices that each of these products generated would need to be determined.

These effects will vary across each product market depending on the specific competitive environment within each such market. For instance, in a market where a new product using existing chemistry, say a reformulation, is vastly superior to other existing products, the absence of any close substitutes could allow the supplier of the new product to exploit the demand and raise prices. In this case, the current rules can facilitate the entry into the market of similar rival products much sooner than would otherwise be the case under the counter-factual scenario. This allows buyers to benefit from lower prices earlier than if this competitive entry was stalled by the presence of more extensive data protection rules. Conversely, if the new product does not have significant advantages over existing similar products within an already relatively competitive market, the benefits of the current rules, if any, are relatively small.

Because carrying out a full market analysis of each individual product market is outside the scope of this report, the pro-competitive benefits of the current rules are assessed at a general level. Section 3.3 provides more detail on these beneficial impacts.

1.2.2. Adverse impacts

The adverse impacts of the current regime stem primarily from the lower number of products, or product uses, made available. Because the current rules facilitate competitive entry by rivals sooner than would occur if there were data protection, the expected return to suppliers from introducing new products using existing chemistry is diminished. This is because such new products are likely to lose market share and/or face more intensive price competition from rivals' copy-cat products.

However, evaluating whether the absence of data protection is the crucial factor in determining the viability of introducing a non-innovative new product or new use requires an analysis of both a supplier's expected revenue as well as the firm-specific costs relating to product development and regulatory approval. Because this information is commercially sensitive and not publicly available, suppliers have only provided anecdotal evidence of a general nature. Although anecdotal evidence is useful, it cannot be verified. This is an important consideration because suppliers face an incentive to suggest that the current rules are the cause of adverse impacts (ie fewer registrations) even in situations where that is not the case.

This incentive arises because many suppliers would benefit from greater data protection. The profitability of new products using existing chemistry would be increased because these suppliers would be able to obtain greater market shares than if they faced immediate competition from copy-cat products. Consequently, without access to suppliers' cost information and revenue projections, it is not possible to determine the precise extent to which data protection rules are impacting on suppliers' registration decisions. For instance, it may be the case that the total level of market demand for a particular product or product use is insufficient to justify the registration of a product or use regardless of whether data protection were provided.

As well as deterring the introduction of both new products available in other jurisdictions and the registration of new uses for existing products, the current rules

may also lead to a lower level of domestic development of new products using existing chemistry. Because an absence of data protection lowers the expected return from new products using existing chemistry, it reduces the expected return from carrying out such product development. Although this is likely to reduce the level of product development activity, it is not possible to determine precisely how much less development activity is being undertaken. In any case, it is not possible to predict how many fewer products using existing chemistry have been created because of a lower level of development activity.

Consequently, these information constraints mean it is not possible to determine the precise extent to which the current rules are reducing the availability of products. However, the analysis in this report coupled with the anecdotal evidence obtained from both suppliers and buyers suggests that this reduced availability is occurring to some degree. This in turn generates adverse effects because buyers are forced to use products that are:

- less effective;
- more expensive;
- more environmentally damaging; and/or
- more harmful and raise greater occupational health and safety issues.

Adverse impacts may also arise in relation to the absence of data protection for reassessments. In this situation, refusal by suppliers to provide data requested by regulators may result in regulators making decisions based on incomplete information. Without sufficient data, regulators may be forced to remove approval for the continued use of a particular product or group of products. This has the potential to lead to a safe, appropriate product being removed from the market.

Whether such an outcome would occur depends entirely on the facts in each reassessment. For instance, during at least one previous ERMA-initiated reassessment data requested by ERMA was not provided by a supplier. However, in this case ERMA was able to source sufficient public data to provide it with enough information to maintain approval. Whether such alternative sources of information would be sufficient for any future reassessments is unknown.

A further complicating factor in this analysis is that, even if it is possible to identify particular products that are unavailable because of the current rules, it is difficult to quantify the adverse impact that this creates. A simple comparison of the price between the available product and the desired alternative (based on its price in overseas markets) is unlikely to be sufficient. For instance, a desired unavailable alternative product may be more expensive than the currently available product but it may be more effective or have sought-after environmental or safety advantages. Conversely, the desired alternative product may be cheaper than currently available products.

1.2.3. Overall net impacts

Given the uncertainty outlined above, it is not possible to determine the precise magnitude of either the beneficial or adverse impacts that arise from the current rules. Consequently, a definitive conclusion regarding the net impact of these rules is not possible.

However, within specific approval or registration 'types' (eg new uses, reassessments, etc), the analysis and anecdotal evidence can be used to form preliminary conclusions about the likely net impacts.

2. Sector Overview

Agricultural compounds⁸ and veterinary medicines are used by a range of different groups. They are perhaps most important as inputs into New Zealand's agricultural sector, which is the main purchaser of these products. Agricultural compounds 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 and transport infrastructure (railways and roadsides). Similarly, veterinary medicines are heavily used for the treatment of companion animals.

This section provides an overview of the two industries, including the different players and the nature and importance of these products to the major users.

Data from the NZFSA indicates that approximately 3,000 different products are registered for sale in New Zealand under the ACVM Act, which became effective in 2001. A majority of these are likely to have been previously registered under the Pesticides Act and Animal Remedies Act. The breakdown of these products into agricultural compounds and veterinary medicines is roughly 35:65.

The NZFSA classifies these products into around 40 to 50 different product types,⁹ although there may actually be somewhere in the vicinity of 200 to 300 different product markets, perhaps more. For example, there are 506 products recorded in the herbicide category, although many of these will not be registered for the same use. There are around 300 different companies that have registered compounds with the NZFSA as required by the ACVM Act.

The number of products in any given market varies considerably. For example, a supplier could face little competition in a particular market if their product has patent protection and there are few, if any, other products that are close substitutes. In other cases, eg markets for glyphosate products, there may be 20 or more different competing glyphosate products.

These 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.

2.1. Agricultural compound industry

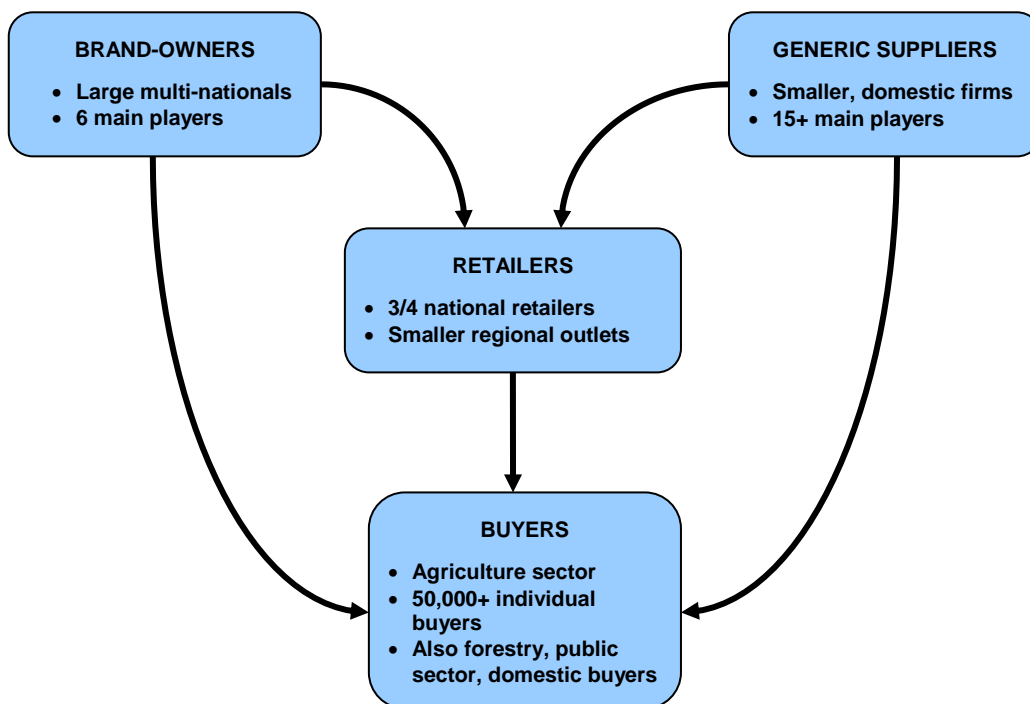
Within the agricultural sector agricultural compounds are generally used to protect targeted plant species from pests and in so doing promote growth and reduce spoilage. Typically they are used to eradicate unwanted plants (weeds), insects, bacteria or fungi.

⁸ Within this report the term agricultural compound is used to refer only to plant protection products, and is not used to refer to veterinary medicines or any products used on animals.

⁹ See <http://www.nzfsa.govt.nz/acvm/register-lists/acvm-register/index.htm>

These products are produced and sold by a host of different suppliers, ranging from large multi-national companies, with global sales in the order of billions of dollars, to small, local companies with sales less than \$1 million. These suppliers may sell directly to buyers and/or via retail channels.

Figure 1: Agricultural compound industry structure



Many of the products that are available in the market change over time. Older chemicals may be withdrawn by suppliers because they have been superseded by newer products or regulatory approval may be withdrawn. As patents expire, rival suppliers are able to develop products that compete with once-patented products. Suppliers, particularly larger, brand-owning multi-national agricultural compound companies, are also constantly undertaking research and development activity in an effort to generate new, ‘better’ products.

2.1.1. Size of the agricultural compound industry

There is no complete data on the total sales of agricultural compounds in New Zealand although some industry data is available. This information, along with previous estimates,¹⁰ suggests that the total value of sales in this sector is likely to be in the vicinity of \$240 million for the year ending March 2008.¹¹ This constitutes an estimated 10% increase on sales from a year earlier, see Table 1.

¹⁰ NZIER “Cost of Compliance” Report to the Ministry of Agriculture and Forestry, 2001. This study suggested that total pesticide sales were \$190 million.

¹¹ ScottEconomics Ltd “Quarterly Sales Audit of Plant Protection Products” March 2008. Figures were scaled up to account for 10 – 15% of the industry which is not included in survey.

As a proportion of total world sales, which are in excess of NZ\$50 billion,¹² the New Zealand industry is relatively small, approximately 0.5%.

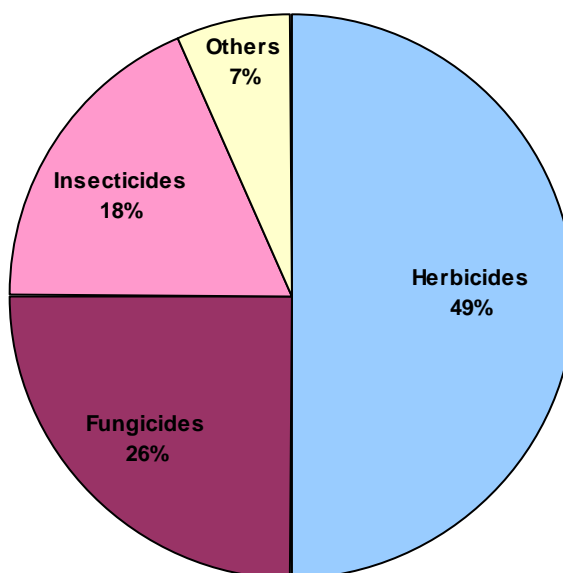
Approximately half of agricultural compound product sales are herbicides, a quarter fungicides, 20% insecticides and there is a small number of other products (eg plant growth regulators), see Figure 2. The sales of agricultural compound products are highly cyclical, with sales peaking around summer and falling in winter.

Table 1: Estimated annual sales of agricultural compound products

Product	Year ended Mar-08 (\$)	Year ended Mar-07 (\$)	Increase from Mar-07
Fungicides	62,288,873	57,346,264	8%
Insecticides	44,675,427	37,567,976	16%
Herbicides	121,183,946	112,619,844	7%
Others	16,000,148	14,603,859	9%
Total	244,148,393	222,137,943	9%

Source: Scott Economics, 2008. Available data scaled up to estimate figures for entire sector.

Figure 2: Agricultural compound product sales by product type, Mar 2008



Based on discussion with industry participants, it has been suggested that of the estimated 200 to 300 different agricultural compound product markets, a large proportion have annual sales of less than \$50,000. Fewer products have higher annual sales, only around 30 to 40 products are estimated to have sales that exceed \$1 million, see Table 2.

¹² Agrow World Crop Protection News, "Top six all ahead in 2007", 13 March 2008.

Table 2: Estimated agricultural compound products markets by annual sales volume

Annual Sales	Number of products (est)
Under \$50,000	80 – 120
Between \$50,000 - \$100,000	60 – 80
Between \$100,000 - \$1m	50 – 60
Above \$1m	30 – 40
Total	200 – 300

Source: Discussions with industry participants

Such an industry structure would be consistent with that of the Australian market, where figures have previously indicated that the majority of agricultural compounds sold for less than A\$100,000 turnover per year.¹³

2.1.2. Market trends

Several trends in the agricultural compound industry, as reported by industry participants, are worth noting. The first is that, over time there has been, and continues to be, pressure to reduce the use and/or toxicity of chemicals from the public and from export markets. This pressure is reflected both at a political level domestically and by the demands of overseas buyers of agricultural products, eg foreign supermarket chains. This preference has also led to the greater use of biological methods of pest control, typically as part of integrated pest management programmes.

In response to this pressure to reduce the potentially harmful effects of chemical use, there is a trend within the industry for the development of new “softer” chemicals and compounds that are less toxic to humans and the environment. Together with more integrated pest management programmes, industry participants have suggested that the result appears to be an increased reliance on a limited range of specialist chemicals that are less harmful to the wider environment.

With regards to the industry structure itself, the expiry of patent protection for several chemicals, for instance glyphosate, has led to the increased proliferation of generic products, increasing choice and reducing the price of broad-spectrum applications. This has contributed to significant changes in recent years as the proliferation of suppliers has resulted in a range of different approaches to sales, marketing and distribution.¹⁴

2.2. Agricultural compound suppliers

The suppliers of agricultural compound products in New Zealand can be placed broadly into two categories. The first is the large, multi-national agricultural compound companies (or their franchise operations). Although these companies provide a wide range of products, they are typically the only suppliers that engage in large-scale research and development with a view to inventing new chemistry and developing new

¹³ 70% of agricultural compounds sold in Australia sell for less than A\$100,000. See Figure 2.2, Centre for International Economics “Impacts of Proposed Data Protection for Agvet Chemicals” prepared for Agriculture, Fisheries and Forestry – Australia, October 2001.

¹⁴ Responsible Resource Recovery Ltd for the Ministry for the Environment “Study of the New Zealand Stewardship Scheme for Agricultural Containers, 2006

products using this new chemistry that will obtain patent protection. These companies are known as ‘brand owners’.

The remaining suppliers are smaller, domestic companies that utilise chemicals (active ingredients) that have already been registered. Although some of these companies carry out their own innovative product development, this occurs on a much smaller scale and typically relies on the use of off-patent active ingredients originally developed by brand owners.

The different players in the industry have differing approaches to sales and distribution, for example some may sell products directly to end users, some may use established retail channels, whereas others may use a combination of these approaches.

2.2.1. Brand owners

The core, large-scale internationally recognised agricultural compound companies all operate in New Zealand, either directly or via secured relationships (such as New Zealand-based parties holding the rights to their chemicals and/or products). Together, they account for around 70% to 80% of the domestic agricultural compound market by sales. They are:

- BASF;
- Bayer CropScience;
- Dow AgroSciences;
- DuPont;
- Nufarm; and
- Syngenta.

The costs associated with R & D and the risks associated with such development means that these companies operate on a global scale and tend to develop chemicals for crops that are grown on a high-volume, worldwide basis. Although some product development and innovation using existing chemistry may occur within New Zealand, most R & D activity and product manufacture occurs offshore. In terms of product manufacture, or formulation,¹⁵ the only large scale domestic formulators are Dow Agrosciences and Nufarm although formulation is also carried out by a small number of other suppliers, including AGPRO, Zelam and Rainbow & Brown. Some of the products formulated by these suppliers include generic products that are formulated for other brand owners.

These six companies typically have a wide product and service range far beyond agriculture or agricultural compounds. In most cases, they have agriculture-specific sales teams that interact directly with farmers and growers and also have relationships with the retail sector (primarily specialist farm retail/service suppliers).

¹⁵ Formulation refers to the combination of individual chemicals into an agricultural compound product. Most, if not all, individual chemicals (active ingredients) are imported into New Zealand. In the case of Dow Agrosciences, Nufarm and a small number of others, these chemicals are mixed up into a final product, packaged and then sold. In contrast, other companies import final products that are already formulated.

2.2.2. Generic suppliers

In addition to the main brand owners, "generic" suppliers import and formulate products for sale in New Zealand. Generic suppliers typically have a physical presence in New Zealand and operate nationwide. These companies either sell direct to farmers and growers or through retail chains.

The generic sector has grown in recent years through price competition and direct relationships with end-users. Generic suppliers may represent up to 30% of the total agrichemical market by sales.¹⁶ For some of the more common agricultural compounds there may be up to 15 different generic suppliers, in addition to the "big six" brand owners. An example of this is glyphosate, which was originally patented in the 1970s by Monsanto and used in its branded product 'Roundup'. Within New Zealand, glyphosate is now sold by over 20 companies and is registered as an ingredient in 85 different products.

Some of the main generic companies in this section of the market include:

- Orion Crop Protection Ltd;
- Ravensdown;
- AGPRO;
- Agronica.

Because they do not focus on research and development regarding new chemistry, the general approach of these firms is to target high-volumes of sales of low-margin generic products, eg glyphosate. Consequently, although these companies may account for the bulk of products on the market, they do not account for the majority of total sales by value.

However, some of these smaller firms also undertake significant product development, at least within a domestic context, and in relation to existing chemistry. Because brand owners typically focus most of their product development on crops that are grown on a large scale on a worldwide basis, this provides niches for some smaller, domestic companies to enter the market and service minor specialist crops within New Zealand, such as onions, asparagus and olives. As niche suppliers, some of these firms may use generic chemistry and innovate and or adapt existing agricultural compound products to local conditions or for New Zealand-specific crop varieties.

2.2.3. Industry representation

Most of the agrichemical brand owners are represented by the industry association, Agcarm. Agcarm has existed since 1948 as the non-profit trade association of companies that manufacture, distribute and sell animal health and crop protection products. Agcarm is a member of Crop Life International (a global federation representing the plant science industry) and the International Federation for Animal Health. Agcarm also represents some generic manufacturers.

¹⁶ Responsible Resource Recovery Ltd, 2006.

The other main industry association is the Animal Remedies and Plant Protection Association (ARPPA). Membership typically consists of non-Agcarm member suppliers. Although membership predominantly consists of companies that supply generic products, some member companies operate on a larger scale and are focused on carrying out product development to generate proprietary products which may be eligible for patent protection.

2.2.4. Retailers

There are currently between 15 and 20 different distributors of product although further changes in the sector could alter this. The main operators are:

- PGG Wrightson (incorporates Fruited, W&K);
- RD1 (owned by Fonterra);
- Farmlands; and
- Other regional brands, eg Combined Rural Traders, Skelton Ivory, Allied Farmers, Ashburton Trading Supplies.

The rural services sector has gone through significant change in recent years with a number of amalgamations, concentration of service and rationalisation of outlets. Recently, some retailers have moved to stock their own generic brands in direct competition with brand products from the research-based firms. Some generic brand owners sell directly to farmers through call centres and/or websites.

2.3. Agricultural compound buyers

The main consumers of agricultural compounds are farmers and growers, some of whom rely heavily on agricultural compounds as an input into their farming operations.

The agricultural sector is an important component of the New Zealand economy and generates around \$17 billion of output per year.¹⁷ Agricultural compounds are used throughout the sector, although their use is a more important input for some farm types/crops than others. See Table 3 for a description of the different crops that these products are used for.

Based on annual rates of use of chemicals per hectare as estimated by Holland & Rahman, we have estimated that somewhere in the vicinity of 2,500 tonnes of active ingredients are used in the agricultural sector each year.¹⁸

Our estimates suggest that over 40% of this amount is likely to be used for pastoral farming and around one third is used on horticultural crops (fruit and vegetables). Arable crops and wine grapes together account for just under one quarter of total usage, see Figure 3.

¹⁷ Statistics New Zealand, 2007.

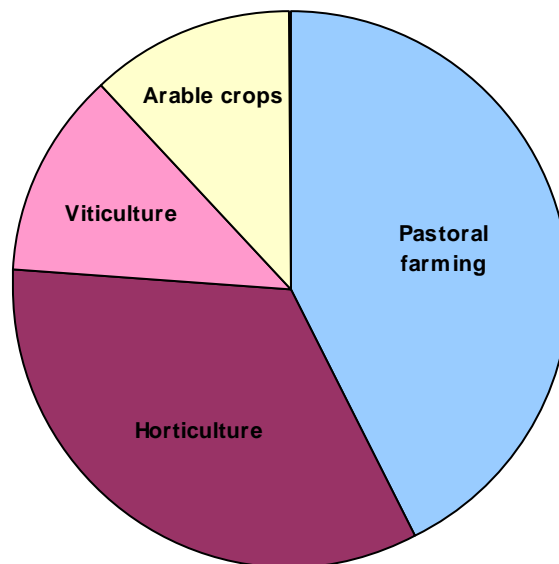
¹⁸ This does not include chemicals used for forestry and turf management.

Table 3: Pesticide use by category

Farming type	Crop
Horticulture	Apples Kiwifruit Avocado Citrus fruit Berryfruit (blackcurrant, boysenberry, blueberry)
Vegetables	Onions Asparagus Sweet corn Field tomatoes Field peas Potatoes Lettuce Brassicas (cabbage, cauliflower and broccoli)
Arable farming	Cereals (wheat and barley) Maize (grain and green feed) Herbage seed crops (grasses, legumes)
Pastoral	Beef and sheep Dairy
Viticulture	Wine grapes
Forestry	Exotic plantations

Source: Holland & Rahman, 1999.

Figure 3: Agricultural usage of active ingredients, by tonnes (industry estimate)



Although agricultural compounds are of much less importance to the performance of pastoral farming output, and are used in much lower proportions, the scale of this farming activity means that pastoral farming accounts for the largest share of agricultural chemical use. As shown in Table 4 below, pastoral farming covers over 100 times as much land as the next largest usage, arable cropping.

Table 4: Land use by farming type

Land use	Hectares	
Pastoral:		
Beef and sheep	10,000,000	
Dairy	<u>2,000,000</u>	12,000,000
Horticulture (including vegetables)		91,000
Arable crops		117,000
Viticulture		30,000
Total		12,238,000

Source: Statistics New Zealand

Throughout New Zealand there are about 24,000 sheep and beef farms, 14,000 dairy farms, 2,000 deer farms, 1,500 arable farms and about 10,000 orchards.¹⁹

In terms of purchasing behaviour, farmers typically store one year's stock of agricultural compounds on-farm. A Taranaki Regional Council survey of farmers found 82% of farms stated they only held one year's supply, 9% held approximately two years' supply and 9% held approximately three years' supply.²⁰ Although some farmers may apply chemicals themselves, others contract out application to specialised third parties.

Although the majority of new product development using existing chemistry is carried out by product suppliers, this is not always the case. In fact some of the development for new products, or more commonly the adaptation of existing chemistry for new uses, is undertaken by organisations operating on behalf of agricultural buyers. These groups, including the Foundation for Arable Research and Horticulture New Zealand, are funded by and operate on behalf of agricultural users. Characteristically, these organisations seek to develop new uses for existing products on relatively minor, niche crops for which the original products are not registered for use in New Zealand. Although these organisations may develop new uses, they are not involved in the direct supply of any products to end users.

2.3.1. Pastoral farming

Pastoral farming largely consists of dairy, beef and sheep, although small numbers of other animals are also farmed, such as deer, goats and ostriches. The value of output from pastoral farming in 2005 was \$9.6 billion.²¹

Agricultural compounds are typically used by pastoral farmers to control weeds on grazing paddocks. An example would be they use of a 2,4D product to control thistle.

Agricultural compounds comprise a small proportion of total farm expenditure;²² however, the sheer scale of pastoral farming in New Zealand means that this form of farming accounts for a substantial share of agricultural compound purchases.

¹⁹ Statistics New Zealand.

²⁰ Taranaki Regional Council "Investigation into Taranaki's Rural Waste Stream" 2005.

²¹ Statistics New Zealand

²² Source: Federated Farmers.

2.3.2. Arable crops

The major arable crops are wheat, barley and maize, as illustrated in Table 5. The value of output from arable crop farms in 2005 was \$430 million.²³

Table 5: Land use and production by arable crop, year to June 2007

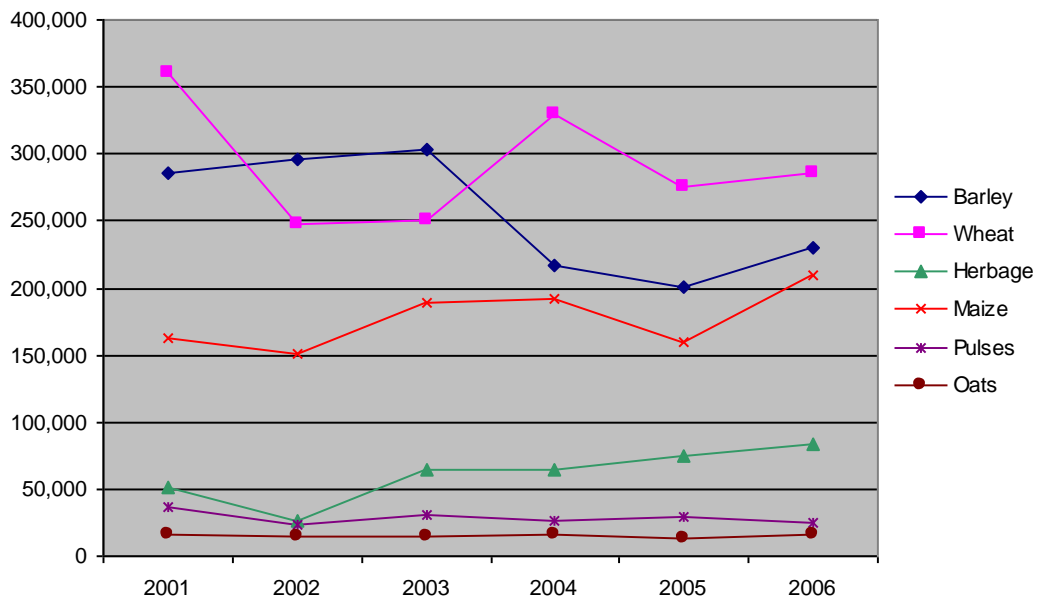
Crop	Hectares	Tonnes
Wheat	40,500	344,400
Barley	51,500	335,600
Maize	17,000	185,600
Oats	5,800	27,500
Other cereals	2,300	13,700
Total	117,100	906,800

Source: Statistics New Zealand

For arable crops, the use of agricultural compounds is often of vital importance. Expenditure on these chemicals can constitute one of the largest annual expenses for growers (fertiliser, interest and labour are the other main expenses). The use of agricultural compounds can have a substantial impact on farm productivity. Some arable crops are highly developed and may be very susceptible to particular pests, eg mildew. Consequently, these crops may be characterised as relatively high risk, high return crops. This means that farmers will often choose not to specialise in arable crops but may also carry out other forms of farming so as to diversify and reduce risk.

The variability in this sector, particularly in the output of the three major crops (wheat, barley and maize) is illustrated in Figure 4.

Figure 4: Arable crop production, tonnes (2001 - 2006)



²³ Statistics New Zealand.

2.3.3. Horticulture

The horticultural sector consists of the production of a large range of fruit and vegetables with over 50 different crop types. The total value of output from the horticultural sector in 2005 was \$2.1 billion. Of this, fruit contributed \$1.4 billion and vegetables \$740 million. In terms of export earnings, the highest value crop is kiwifruit, with exports of \$765 million in 2007. The second biggest export crop was apples, at \$343 million, with onions next at \$121 million and exports of potatoes worth \$81 million.²⁴ The remaining 45 horticultural crops had exports totalling around \$680 million.

The largest fruit crops in terms of growing area are kiwifruit and apples, the largest vegetable crop is potatoes.

Table 6: Land use by fruit crop, year to June 2005

Crop	Hectares
Kiwifruit	12,026
Apples	10,983
Berryfruit	2,132
Avocados	3,400
Olives	2,485
Other	6,827
Total	37,853

Source: Statistics New Zealand

Although the majority of horticultural crops are grown outdoors, there are also a small number of crops that are grown indoors in glasshouses, ie mushrooms, capsicums, cucumbers and a small amount of tomatoes. The total area used for indoor crops in 2005 was 299 hectares.

Table 7: Land use by vegetable crop, year to June 2005

Crop	Hectares
Potatoes	11,033
Peas	8,747
Squash	7,152
Sweetcorn	7,115
Onions	5,229
Other	13,549
Total	52,825

Source: Statistics New Zealand

As with arable crops, the use of agricultural compounds is of high importance to growers. However, because of the small scale on which most horticultural crops are grown in New Zealand and the costs involved with registering agricultural compounds for use on each additional crop, the number of products available is relatively limited in comparison to other jurisdictions, such as the USA or the UK. Consequently, there is likely to be a higher prevalence of the 'off label' use of products in this industry according to industry participants.

²⁴ Statistics New Zealand. Note that because domestic sales figures comprise of both domestic production and imports, it is not possible to determine the net value of domestic production for most horticultural crops.

2.3.4. Other buyers

Other notable primary sector users of agricultural compounds include the viticulture industry, forestry, flower growers and the beekeeping industry. In terms of size, wine grapes account for around 30,000 hectares of land, making it the third biggest crop by growing area. In terms of export receipts, wine totalled \$696 million in 2007.

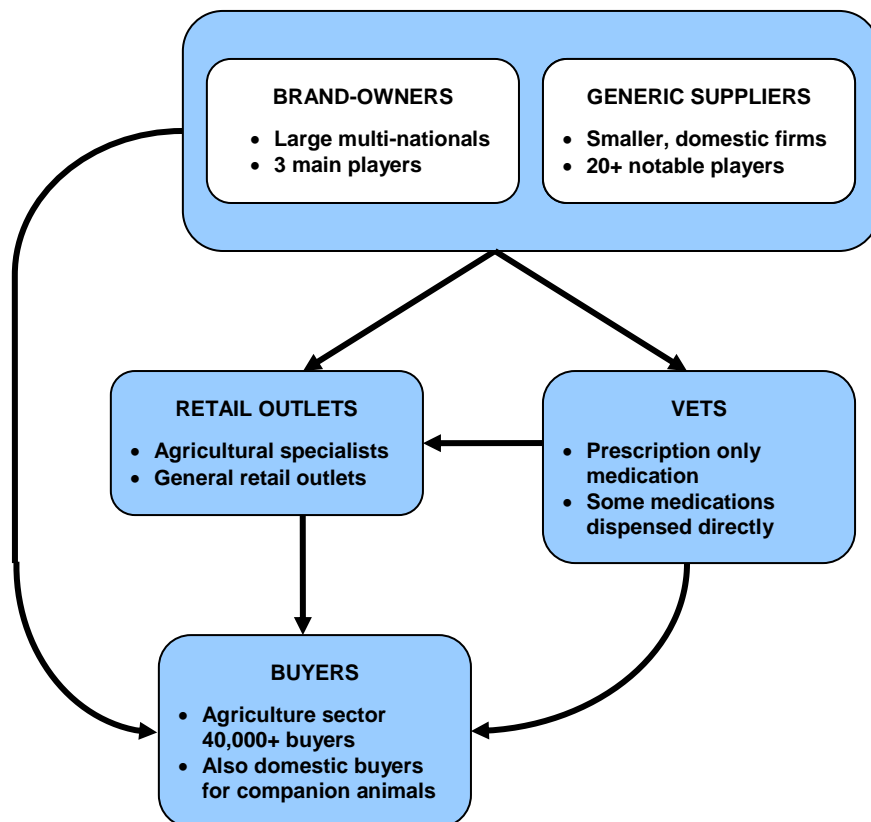
Another two significant users of agricultural compounds are:

- public sector land owners or pest controllers, such as the Department of Conservation, Biosecurity New Zealand, local authorities and those responsible for transport infrastructure (roadsides and railways); and
- domestic users who use these products for gardening purposes.

2.4. Veterinary medicine industry

Within the agricultural sector veterinary medicines are generally used to promote animal health for the purpose of meat, milk and wool production. Similarly to agricultural compounds, veterinary medicines are produced and sold by a range of different suppliers, ranging from large multi-national companies to small, local operations. The main agricultural product categories include de-wormers (ie anthelmintics or drenches), lice treatments, mastitis treatments (antibiotics) and metabolic disease treatments. Other products include reproductive and hormone treatments, anaesthetics and anti-inflammatory treatments.

Figure 5: Veterinary medicine industry structure



The channel by which veterinary medicines are sold to end users depends on the type of product. Some products are only available if prescriptions are provided by veterinarians, whereas other products are available without prescription and can be purchased either directly from suppliers or via retail outlets.

The majority of products can be purchased ‘over the counter’, ie drenches and lice treatments. Only around 25% of product sales relate to ‘vet only’ medicines, eg antibiotics.

2.4.1. Size of the veterinary medicine industry

There is little publicly available data on the total sales of veterinary medicines in New Zealand although some estimates are available. Industry sources and previously reported estimates,²⁵ suggest that the total value of sales in this sector is likely to be in the vicinity of \$200 million to \$250 million for the year ending March 2008.²⁶ This is roughly the same size as the market for agricultural compounds.

Based on discussions with the industry, the largest market segment is de-wormers (ie anthelmintics or drenches) which may account for around half of all veterinary medicines sold, see Table 8 below. The next largest segment is lice treatment products (ectoparasiticides) which is estimated to account for around one quarter of total sales. The next largest category is companion animal products. This category consists of a wide range of different products. Because these products are marketed differently and sold specifically to treat companion animals they are treated as a separate category even though there is some degree of overlap, eg de-wormers and lice treatments are also common treatments for companion animals. Treatments for mastitis (antibiotics) constitute another significant market segment.

Table 8: Main veterinary medicine categories, relative sales

Product	Share of sales
De-wormers/drenches	50%
Lice treatment	25%
Companion animal treatments	12%
Mastitis products	10%
Other	3%
Total	100%

Source: Industry estimates

2.5. Veterinary medicine suppliers

As with agricultural compounds, the suppliers of veterinary medicines range from large multi-national companies that focus on producing products that use new chemistry to smaller locally-based companies that may focus more on generic products. Although

²⁵ NZIER “Cost of Compliance” Report to the Ministry of Agriculture and Forestry, 2001. This study suggested that total annual sales of relevant animal health products were \$170 million.

²⁶ ScottEconomics Ltd “Quarterly Sales Audit of Plant Protection Products” March 2008. Figures were scaled up to account for 10 – 15% of the industry which is not included in survey.

some of these smaller companies may focus mainly on selling generic products, some may also undertake development of new products using existing chemistry locally.

The three largest suppliers in the market are Merial (which owns Ancare), Intervet (which is part of Schering-Plough) and Pfizer which together account for over \$150 million worth of sales, more than half of the total market.

Other notable suppliers include Bomac, Stockguard and Elanco Animal Health. The next tier of three or four suppliers would account for around \$50 million to \$80 million worth of sales. The remaining 20% or so of the market would be accounted for by smaller operators, consisting of about 10 to 15 smaller firms along with a number of very small operators, eg individuals that import one line of specific products. In total there may be around 20 notable suppliers of generic products.

Much of the product manufacturing and research and development of veterinary medicines occurs offshore, particularly in the US and Europe, as well as in other countries such as India and Australia. However, for some livestock products, particularly vaccines and de-wormers, there is a significant amount of research and development (including clinical trials) carried out in NZ to support product registration. This is because New Zealand's farming system is significantly different to many of the major markets where global research and development work is conducted. For example, US cattle are intensively barn-raised in large feed lots and, consequently, they suffer from respiratory diseases that are uncommon in NZ where pasture-based farming is the norm. This means that many of the products on offer in other jurisdictions are not appropriate to meet the needs of the domestic market.

Because of the nature of the domestic livestock market there are a few companies that manufacture vaccines and anthelmintic products within New Zealand to meet local requirements. Some products are also manufactured in Australia, which has a more similar livestock market than many other jurisdictions.

Of note is that some products which were developed in response to demands within the New Zealand livestock market have since become global projects once the value to markets in other jurisdictions (eg Brazil and Australia) has been recognised.

With respect to companion animal products little clinical trial work is carried out in New Zealand as the veterinary medicine requirements for these animals tends to be fairly universal. Consequently, products for these animals (eg antibiotics, parasiticides, vaccines, etc) tend to be imported from overseas.

2.5.1. Industry representation

As with agricultural compounds, the main industry organisations are Agcarm and ARPPA. Vets are represented by the New Zealand Veterinary Association.

2.6. Veterinary medicine buyers

There are two main categories of buyers of veterinary medicines; agricultural buyers; and private individuals who purchase these medicines for companion animals (ie pets). Other buyers of veterinary medicines include zoos and game parks.

2.6.1. Agricultural buyers

Animal products make up a significant proportion of the total agricultural sector. The main commercial activities are beef, sheep, dairy, poultry and pig farming. The value of agricultural output from these animals was \$9.9 billion in 2005.²⁷ Table 9 below provides a breakdown of total annual numbers of livestock.

Table 9: Annual livestock numbers, 2007 (unless stated)

Animal type	Number
Poultry ^a	83,214,000
Sheep	38,460,000
Dairy cattle	5,261,000
Beef cattle	4,394,000
Deer	1,396,000
Pigs ^b	355,501
Goats ^b	131,033
Horses ^a	72,847
Total animals	133,284,381

Source: Statistics New Zealand, Poultry Industry Association NZ

^a2005 ^b2006

Industry sources have suggested that the ratio of use of veterinary medicines between cattle and sheep is approximately 70:30. This indicates that cattle use a greater amount of products per animal than sheep.

2.6.2. Companion animal owners

A growing area of the veterinary medicine market is in relation to companion animals. The total number of dogs in New Zealand has been estimated at 500,000.²⁸ Although figures on other companion animals, such as cats and birds, are not available, the total is likely to be in the vicinity of 1 million.

²⁷ Statistics New Zealand.

²⁸ Department of Internal Affairs, Dog Control Final Report, 2003.

3. Impacts of Data Protection Regime

The absence of data protection for some ERMA approvals and/or ACVM registrations has the potential to generate adverse impacts. Primarily, it may reduce the incentive for suppliers to innovate and register new products using existing chemistry or new uses for existing products. Conversely, the absence of data protection can generate beneficial impacts by enhancing the ability of generic suppliers to compete with newly registered products, which benefits end-users.

Determining whether the present rules regarding data protection are consistent with maximising the net benefits to New Zealand of the agricultural compound and veterinary medicines industry requires assessing the likely magnitude of these adverse and beneficial impacts. These individual impacts are implicitly contrasted with the outcomes that would be expected to arise if different (ie more generous) data protection rules were introduced.

The following sections discuss the impacts of the current rules in more detail. The extent to which these impacts are likely to occur in relation to the specific registration types, ie new uses, reformulations, reassessments and new products is also addressed.

3.1. How do adverse impacts arise?

An absence of data protection creates a disincentive for suppliers to register either new products using existing chemistry or new uses for existing product. This is because providing the data needed for approval and registration imposes costs on applicants. These costs are less likely to be recouped if this data can be readily used by the relevant regulator to allow competitors to bring similar products to market at a lower cost than that faced by the original applicant. Any barrier to applicants recouping these data costs works to reduce the incentive to obtain regulatory approval in New Zealand for products that are already used in other jurisdictions or for new uses of existing products. Because an absence of data protection reduces the expected return of bringing new products using existing chemistry to market, this absence of data protection also reduces the incentive to carry out research and development of new products using existing chemistry (eg reformulations) or new uses of existing products more generally.

The magnitude of these impacts depend on a range of factors, including the type of registration or approval sought, the existence of any intellectual property protection and the structure of the relevant product markets, the nature of the data required and the availability of useful public data.

Data requirements depend on the type of approval that is sought. Approval and registration of a new active ingredient ('new chemistry') requires the most data as these chemicals would not have been assessed previously by either ERMA or the NZFSA. ERMA reassessments and NZFSA registrations for new uses and reformulations generally require less data because some degree of relevant information would have already have been submitted to regulators.

The cost to applicants associated with different types of applications can vary substantially. For instance, the cost of obtaining registration for a product that uses previously registered active ingredients can vary from around \$10,000 to \$20,000 to more than \$500,000, see Table 10. These costs can include the expenses incurred in undertaking trials as well as internal company time and labour effort. Trials that require the slaughter of animals, for instance if the product is to be used on pastures, tend to be more expensive.²⁹

An important consideration relating to potential registration costs is that some proportion of these expenses will be incurred in the development of new products using existing chemistry regardless of the regulatory regime. For instance, a supplier would need to carry out its own trials to some extent to determine that a prospective new product would be sufficiently effective, safe, etc before it could be marketed as such to end users.

Table 10: Potential product development and ACVM registration costs for agricultural compounds.

Cost type	Estimated \$
Application fees – NZFSA	\$2,000 - \$5,000
Chemistry & manufacturing data	Up to \$150,000
Residue trials	\$20,000 - \$150,000
Efficacy trials	\$50,000 - \$100,000
Internal labour for application	\$5,000 - \$50,000
Total New Zealand Cost Range	\$10,000 - \$500,000

Source: Industry estimates. Note: Not all cost types may apply to each product

The cost to the applicant of obtaining approval from ERMA under the HSNO Act, whether for new products using existing chemistry or for reassessments, may also vary. Costs will depend on the extent of data that is requested, whether this data already exists or needs to be generated, and the extent to which a supplier decides to respond to any data request from ERMA.

For reassessments that have been initiated by ERMA under the HSNO Act, administrative charges are not imposed by ERMA. The only costs faced by applicants in this situation would be costs associated with providing any data that is sought by ERMA. This may include the costs of generating data if the data does not already exist. If the data already exists, then the costs to applicants of reassessments may be negligible.

What data would be requested by ERMA, and whether this would need to be generated from scratch, is determined entirely on a case-by-case basis. Consequently, until such time as ERMA carries out this analysis for each of the products on its proposed

²⁹ Of note that other jurisdictions (eg the European Union) have moved towards the compulsory sharing of data in relation to animal testing so as to avoid duplication and promote animal welfare.

hazardous substance reassessment list, it is not possible to predict in advance the scope of the data that may in future be requested by ERMA in relation to each individual product.

Additionally, as there is no compulsion on suppliers to respond to ERMA's data requests, any potential data provision costs would be entirely voluntary. However, should a supplier not provide the data requested, this could result in ERMA approval for the substance in question being withdrawn if the necessary data is not able to be acquired from other sources, eg publicly available studies.

However, such alternative data may not be available or may not be sufficiently relevant. The precise extent to which new data is required is determined on a case-by-case basis by regulators and varies considerably across applications.

Suppliers will only incur the costs of providing data for approvals and/or registrations if they consider that there is a sufficient likelihood that they will recover these costs from subsequent sales of the product. To the extent that generic suppliers are able to copy these products and cross-reference the data that has been supplied by the original registrant, generic suppliers would be able to enter the specific product market in question and compete without incurring the same data costs. This would reduce the returns to the original applicant of bringing the product to the market. It may even be possible that in some cases such competition could eliminate any net returns and instead could impose losses on the original registrant.

3.1.1. Impact depends on specific product market

Whether or not the absence of data protection is likely to prevent a potential registrant from deriving a sufficient return from a product depends not only on the costs of that registration but also on the expected sales of the product.

If the target market for a new or reassessed product or new use is too small, even the existence of data protection rules may not provide a potential registrant with the scope to derive a sufficient return to make registration worthwhile. In other cases, the target market may be sufficiently large so that, even without data protection, the applicant could reasonably expect to make a sufficient return to cover the costs of development and registration. Registering a new product using existing chemistry or new use before other rival suppliers can also give a supplier a one or two year 'headstart' in the market, which could better allow the initial applicant to recover costs and derive an adequate return. Consequently, in many cases the presence or absence of data protection rules will not affect whether a new product or new use for an existing product would be introduced to the market.

However, in other more finely balanced cases, an absence of data protection and the corresponding threat of generic competition is likely to be the crucial factor that decides whether a supplier can reasonably expect to make a return on developing a new product or use.

Thus, the impact of data protection rules depends on the scale and structure of the specific product market in question. This varies considerably from product to product. In some cases there may be no close competitors. This could occur if a supplier has a patent for particular feature of the product (other than the active chemical ingredient) that results in that product being far superior to rival products, for example micro-encapsulation. In other cases, it could even be possible that products that have patent protection for their active ingredients may face effective competition. This can occur if generic suppliers are able to alter their products sufficiently to avoid breaching patent restrictions, but their generic products are nevertheless sufficiently similar so that they are able to cross-reference the original applicants' data. Although one brand owner has suggested that has occurred on at least occasion, this outcome is rare.

Because of the range of relevant factors, accurately determining the impact of data protection rules would require assessing the structure and scale of each different potential product market. Determining what constitutes a separate market typically requires carrying out in-depth market definition analysis. This involves assessing the substitutability of alternative products (ie product characteristics), the area of the market (ie geographic characteristics), the nature of market transactions and the barriers to competitive entry.³⁰

3.2. Adverse impacts

A negative impact of the current rules is that buyers may not have access to certain products that would otherwise be available if data protection existed. For instance, there may be fewer new use registrations and reduced development of new products using existing chemistry, such as reformulations. Existing products that are to be reassessed could also potentially be removed from the market. Consequently, the result of the current rules may be to force end-users to use products that are:

1. less effective;³¹
2. more expensive;
3. more environmentally damaging; and/or
4. more harmful and raise greater occupational health and safety issues.

The use of less effective and/or more expensive products could be reducing New Zealand's agricultural output below that which it otherwise could be. The effects of such limits on the products available may be particularly pronounced because of the ongoing removal of some chemicals from use.

If a product is withdrawn from use within another jurisdiction it often can no longer be used on crops or agricultural products that are exported to that country from New Zealand. Given the importance of exports to the agricultural sector, this effectively prevents the product from being used in New Zealand as well. Any such reduction in

³⁰ Appendix Two provides a discussion of the factors that need to be assessed in carrying out a market definition.

³¹ Note that the resulting reduced range of available products has the potential to contribute to increased pesticide resistance.

available products has the potential to exacerbate any adverse impacts that arise from an absence of data protection, such as a reduced range of new products.

Suppliers also seek to develop new products using existing chemistry that have fewer environmental impacts or are better in terms of occupational health and safety. Such products provide benefits to both end-users and the wider community even if they are no more effective than existing products and may be achieved by the development of reformulations in particular. To the extent that there is a disincentive to develop and introduce such reformulated products, reduced product development of this nature constitutes an adverse impact of the current data protection rules to New Zealand as whole.

3.2.1. Data protection and sunk costs

The absence of data protection has also been raised as an issue in terms of the refusal by some brand owners to release data for registrations and/or reassessments. Such refusals have occurred in some instances despite the fact that the data in question has already been generated.

Brand owners often incur many of the costs of producing the data required for new registrations in jurisdictions other than New Zealand. This is because most of their products are targeted for use in larger, more lucrative markets elsewhere, eg US, EU. This means there may be little additional cost to applying for registration or approval in New Zealand. However, some brand owners have claimed that an absence of data protection is the reason that data has not or would not be provided locally.

To the extent that New Zealand's data protection rules are, in fact, the reason for these firms to refuse to provide data, this approach appears to economically irrational. Because data generation costs are sunk costs (ie they have already been incurred and will not be altered whether or not data is provided in New Zealand), any additional domestic revenue gained from new registrations or maintaining ERMA approval would contribute to increasing returns to these firms.

However, if there is a high degree of centralisation to these firms' operational decisions and policies, decisions relating to the provision of data may be made by those who have little understanding of New Zealand's regulatory environment. Because some of these firms' New Zealand operations constitute only a very small fraction of their overall global business, they may not consider it worthwhile to address these issues in any detail. Consequently, they may apply a blanket policy that precludes providing data where there is no protection in small markets like New Zealand.

Effectively, given the relative unimportance of the New Zealand market to these firms, they may not consider it an efficient use of their management resources to analyse whether or not to provide data for regulatory purposes, especially for relatively small product markets for relatively minor crops. As a result, these companies may simply impose broad-ranging internal policies that ban the provision of data if it is not

protected. This is despite the fact that such a policy may not appear to be economically rational.

3.3. Beneficial impacts

Despite an absence of data protection, a number of new use and reformulation registrations are made each year under the ACVM Act. By allowing others to ‘piggy-back’ on registration data provided by initial applicants, other suppliers are able to enter and compete in these markets more easily. This provides end-users with the benefits of increased competition, which may include lower prices, more product and/or after-sale service innovation and increased choice.

If data protection were to be introduced, some of these competitive benefits could potentially be lost’ although only in relation to future registrations and only for the period within which protection were granted.

The scale of future competitive benefits that are expected from the current data protection rules would vary across product markets. In some cases, the benefits of maintaining the current rules would be negligible, particularly for new use registrations. The competitive environment for a product registered for a new use is unlikely to be altered whether or not data protection is available. This is because the ability of the applicant to raise prices of the product in the new use market would be limited because this product would already face competition in the existing product (ie crop or animal) markets in which it is sold. Section 3.4 regarding registrations for new uses provides a further discussion of this situation.

Regarding the extent of the competitive benefits of the current rules, figures from the ACVM unit of the NZFSA indicate that in the five years from 2003 there have been over 1,400 product registrations for products that do not have new active ingredients.³² Because these products use existing chemistry and do not contain ‘innovative’ active ingredients these products are not subject to data protection. Consequently, some proportion of these registrations will be copy-cat registrations of other new products using existing chemistry that were originally registered by another supplier. These copy-cat registrations would place competitive pressure on the products registered by original applicants.

However, without further analysis from NZFSA it is not possible to determine what proportion of these registrations are copy-cat products whose registration would have been affected (ie delayed) if data protection were provided, and what proportion were ‘genuinely’ new products using existing chemistry (eg an ‘original’ reformulations).

Further analysis would also be necessary to determine to what extent data already provided was able to be cross-referenced in the process of registering copy-cat products and how much new data was required for each registration. The extent to which any given application can utilise existing data depends on a number of factors, including

³² NZFSA registration data.

how similar the new product is, how it is formulated, how it is used, etc. Additionally, a number of these registrations are likely to be almost identical products that are registered by the same initial applicant as minor variations within the same product line. Consequently, the actual figure of registrations which would not have occurred within the previous five years if data protection had been in place is likely to be significantly lower than 1,400. However, without further analysis it is not possible to determine the actual number.

3.4. Impacts on new uses

One area where the current rules may be having a negative impact is in relation to the registration of existing products for new uses, ie the use of products on crops or animals for which they are not currently registered.

A number of suppliers and users have expressed concern over the disincentive the data protection rules under the ACVM Act provide to register existing products for new uses, ie to extend label claims. This is particularly the case in the horticultural and arable crop industries where the relatively small size of many crop markets means that any increase in sales revenue from such registrations would be relatively small. This is because the absence of data protection means that suppliers are less likely to recoup the costs of developing and registering an existing product for a new use in these smaller markets if competitors can register their products for the same new uses and free-ride on the data provided by the initial applicant.

Some growers' organisations have expressed a strong preference for increased choice in the supply of available products, particularly as they are aware of existing products that are not registered for use on their crops. There are also examples of products that are not registered for use in certain crops in New Zealand but are registered for use on these crops in other jurisdictions.

Another potential issue surrounds 'off-label' use. To the extent that the current rules deter new use registrations, suppliers consider that they contribute to a higher level of off-label use. Growers are legally entitled to use existing products on crops for which these products are not registered provided that use does not breach the relevant residue regulations, ie Maximum Residue Limits.³³

Despite the fact that growers may be entitled to use products for off-label uses, suppliers are not legally entitled to endorse such use. This means that growers are prevented from receiving accurate information and appropriate after-sale service regarding the use of these products. This could facilitate the inappropriate use of some products to the detriment of the end-users and the wider community.

³³ There are some exceptions to this, for instance if the use of a chemical is restricted to the approved label claim either by the registration conditions set out under the ACVM Act or the approval conditions issued under the HSNO Act.

In relation to veterinary medicines, suppliers have also suggested that the disincentive to register existing products for new label claims is possibly the biggest adverse impact of the data protection rules.

Regarding the potential price impacts that data protection for new use registrations might have, it is worth noting that these products are already available for sale for use in other use markets at established prices. These prices are unlikely to be exploitative because the initial applicants of these products already face competition from generic products because the original period of data protection available when the product was first registered would have expired. Thus, prices are likely to be set by the normal competitive forces, based on supply and demand. This means that if greater data protection were introduced in relation to new uses it would be unlikely to allow suppliers to raise prices for any products that are already on the market. However, data protection would provide applicants with a better chance of obtaining a high market share in the new use markets as these products could be marketed directly for these new uses. This would better allow them to recoup development and registration costs without having to raise prices.

Below are some illustrative examples of the potential adverse impacts of the current data protection rules relating to new uses.

3.4.1. Examples: Pipfruit New Zealand and Horticulture New Zealand

Because of the relatively small scale of some of the pipfruit crops in New Zealand, especially compared with pastoral farming, the scope for suppliers to recoup the costs of registering products especially for these crops is often small.

Even in relation to some of the more commonly grown fruit, eg apples, the size of the relevant agricultural compound market may be insufficient to entice suppliers to register products. For example, Pipfruit New Zealand has attempted to get the two domestic suppliers of Imidacloprid, an insecticide sometimes sold under the brand name Confidor, to have the product registered for use as a ground drench on apple trees. The main advantage of this product has is that it is more effective than the alternative products. However, Pipfruit New Zealand was unsuccessful in getting the suppliers to provide the data required to extend the label claim to include apples. One of the reasons put forward by the suppliers for not providing data was the absence of data protection. In contrast, Imidacloprid is registered in Australia for this use on this crop.

Horticulture New Zealand has identified a range of compounds that are registered for crops other than tomatoes and capsicum, but which would be of use for these crops. These products display one or more advantages over existing options, ie they are more effective at pest control and/or cheaper and/or safer, etc.³⁴

³⁴ Note that products sought after by growers may actually be more expensive than existing alternatives. If these sought-after products are more effective and would lead to significantly greater profitability, however, growers are likely to consider any additional expense justified. This means that

Although there could be various factors as to why suppliers of these compounds have not extended the label claims to include tomatoes and capsicum, it is likely that an absence of data protection is a contributing factor.

Table 11 below provides examples of compounds that are not registered for use on tomatoes and/or capsicums, but which would be useful for controlling pests on these crops.

Table 11: Compounds not registered for use on tomatoes, capsicum

Compound	Crop	Pest
Lufenuron	Capsicum	Thrips
Pyriproxyfen	Tomato, Capsicum	White fly, Psyllid, Thrips
Spinosad	Capsicum	Thrips
Spiromesifen	Tomato	White fly, Psyllid
Sulphur	Tomato	Psyllid
Thiacloprid	Tomato, Capsicum	White fly, Psyllid, Thrips
Thiamethoxam	Tomato, Capsicum	White fly, Psyllid, Thrips

Source: Horticulture New Zealand

3.4.2. Example: Fruit growers

The industry group for citrus fruit growers previously undertook trialling and testing of a product ANA with a view to the registration of this product being extended to citrus fruit. However, after carrying out significant work and producing a substantial amount of data, costing around \$30,000, the supplier has been extremely reluctant to proceed with registration of the product for use on these crops. The argument put forward by the supplier is that there is an absence of data protection.

3.4.3. Example: Product B and Western Flower Thrip

Western Flower Thrip is an insect pest that affects glasshouse crops. A product sold by Syngenta that is currently on the market could potentially be used to deal with this pest, but it is not registered for this use. If this product were to be registered for use on this pest, Syngenta 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. Of concern to Syngenta is that 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 Syngenta's ability to recover registration costs.

3.5. Impacts on reformulations

Reformulations can involve existing products being reformulated so as to be sold in a different format, eg from a wettable powder to a concentrated liquid. This may involve

a direct comparison between the price of the sought-after products and existing products is insufficient for providing a quantification of the expected benefits of the sought-after products.

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.

The development costs for reformulations can be significant. This means that an absence of data protection may deter suppliers from seeking regulatory approval for reformulations or even from undertaking this form of product development at all. Regulatory approval is typically required from both NZFSA and ERMA, although ERMA does not require a full assessment in a number of cases.

In some cases, it may be possible for a reformulation to be eligible for a new patent, particularly if the substance with which the active ingredient is mixed with is particularly innovative. This can provide a supplier with intellectual property protection so as to allow them to recoup registration costs. However, even where there is patent protection, it may be possible, although uncommon, for products to be designed by competitors to be sufficiently different so as to not breach patent protection but also be sufficient similar so as to enable the cross referencing (a substantial amount) of registration data. An absence of data protection could then open up the original registrant to generic competition, making it more difficult to recoup registration costs.

Barriers to the increased registration of reformulated products can have negative implications, not just in terms of the productivity and efficiency of the agricultural sector, but also because reformulations can lead to reduced environmental harm and/or reduced occupational health and safety risks. In some cases products are developed to better achieve these objectives even if there is no change to efficacy.

In other cases, reformulations may occur as the result of industry-wide changes. For example, EU regulations that prohibit the use of a certain adjuvant, for instance, may lead to changes for all suppliers throughout an entire product market. To the extent that all of the suppliers in the market in question reformulate their products, the absence or otherwise of data protection rules may have little, if any, impact.

Below is an example of the potential adverse impacts of the current data protection rules relating to reformulations.

3.5.1. Example: Products for arable crops, Foundation for Arable Research

The Foundation for Arable Research has suggested that there are plant protection products, including reformulations of existing products, that are registered in other jurisdictions for certain crops, but are not registered for use here. For instance, several fungicides that can treat Powdery Mildew are available in other countries, such as the UK, but are not available in New Zealand. In the absence of these product growers are forced to use existing products that may be inferior for a number of reasons, eg not as effective, more expensive, less safe, etc.

This may be less of a problem for the major arable crops that are grown here, because less effective generic products may be sufficiently substitutable. However, it may be a

greater problem in relation to vegetable seed crops which are grown on a much smaller scale and for which there are fewer options.

3.6. Impacts on reassessments

Both the NZFSA and ERMA may carry out reassessments of specific products or chemicals from time to time, as stipulated in the ACVM and HSNO Acts respectively. Reassessments are carried out on a case-by-case basis.

In particular, ERMA has a priority list of substances that it wishes to reassess over the next five years. In so doing it is likely to seek data from the brand owners that originally obtained approval for products containing these substances. As these reassessments will be carried out on a case-by-case basis it is not possible to determine the scale and scope of any data requests in advance of ERMA fully assessing the data it currently holds.

When carrying out a reassessment either ERMA or NZFSA may seek data held by brand owners which has not previously been provided. It is also possible that any such additional data sought by the regulators does not already exist. In this case brand owners would effectively be asked to generate new data.

In either case, there is no compulsion on brand owners to comply with a request for more data. To the extent that this data already exists there may be little additional cost to brand owners in providing it. For instance, no administrative charges are levied by ERMA in relation to ERMA-initiated reassessments. Consequently, there may be little reason for suppliers to withhold data (see Section 3.2.1) although data has been withheld previously in at least one instance.

In contrast, if data requested in the course of a reassessment does not exist, generating this data may impose costs on the brand owner. Recovering this cost could create a problem for a brand owner under the current rules however, because any such data that is used by the regulator can also be used to provide regulatory approval for other competing suppliers. This means that these other suppliers would not incur any additional data generation costs and, consequently, they may be able to undercut any attempt by the brand owner to raise prices so as to recover its data costs. This could create an incentive for brand owners not to generate and provide data for reassessments. This in turn could ultimately lead to the withdrawal of regulatory approval and/or registration for a particular product.

To the extent that a brand owner has, or is developing, an alternative product that is substitutable for the product being reassessed, the absence of data protection for reassessments may provide brand owners with an even greater incentive to withhold, or not generate, data. This is because the withdrawal of regulatory approval for the current product would provide the brand owner with an advantageous position in the market because of its substitute product. However, if any such substitute product were in some manner inferior to the original product (eg more expensive), users may be worse off by the removal of the original product from the market.

In the event that private data is not provided, the relevant regulator may attempt to carry out the reassessment with incomplete data. This could severely limit regulators' ability to carry out full and complete assessments and could negatively impact on their ability to make effective and efficient regulatory decisions. This can result in adverse impacts, for example, a supplier's refusal to provide data could lead to the withdrawal of approval and/or registration for a safe and effective product for which there is high demand.

As well as these negative potential impacts of an absence of data protection for reassessments, a beneficial impact of the current rules is those brand owners who have products approved continue to face vigorous competition. This would continue to assist buyers in obtaining competitive prices for reassessed products.

3.6.1. Example: Mancozeb

Mancozeb is a fungicide that was reassessed under the previous regulatory regime, ie prior to the HSNO Act. The previous regime explicitly allowed for suppliers that wished to maintain approval to group together to share data costs in exchange for obtaining exclusive approval to sell the product for a specified time period, ie the data provided was effectively protected.

As a result of this arrangement three companies agreed to share the costs of providing data. One industry observer suggested that there was an increase in price after these three companies were provided exclusive approval, but that this increase in price was relatively minor. Whether any increase in price was in excess of that required to recover any data costs is unknown.

In contrast, the current regulatory framework prevents this type of arrangement from being instituted. The application of the Commerce Act, which prohibits anti-competitive behaviour, could also provide a barrier to this type of activity.

3.7. New active ingredients

In most cases, a new product that contains previously unregistered active ingredients will be sufficiently innovative so as to be eligible for patent protection. Patent protection is typically sufficiently long (20 years) to allow a brand owner with the opportunity to develop a product and recover development and registration costs.

In rare cases it may take a supplier the majority of this patent protection period to bring a product to market. In this situation, the absence of more extensive data protection (existing rules allow five years) may provide a disincentive to register a new innovative product. However, this was not raised as a major issue by industry participants.

3.8. Provisional registration

A provisional registration is required under the ACVM Act before an applicant may undertake studies on animals or plants using a product that:

- does not have a current registration or provisional registration; or

- has a current registration or provisional registration, but the intended study will not comply with the conditions of that registration.

Data provided in relation to a provisional registration is typically protected for a five year period. However, at least one applicant was unable to obtain data protection for a provisional registration application because the applicant was unable to determine whether a product has been provisionally registered previously. The applicant claims that in this situation the relevant information concerning the product's previous provisional registration was not publicly available. This caused a problem because if a product has obtained provisional registration previously and this registration has lapsed, a new application by a different applicant may not obtain data protection, as outlined in Section 72 of the ACVM Act in the definition of 'Innovative agricultural compound application', subsection (b).

Although this issue may not prevent a supplier from seeking provisional registration for a specific product, the uncertainty regarding whether data protection will be provided serves to increase the general disincentive to carry out such product development.

4. Preliminary conclusions

The current data protection rules generate both beneficial and adverse impacts. They create benefits by promoting vigorous competition in markets for new, off-patent agricultural compounds and veterinary medicines. They also impose costs in the form of reducing the range of such products available to end-users.

4.1. Extent of beneficial impacts

By allowing suppliers to reference data provided to regulatory agencies, the data protection rules facilitate the new entry, or continued activity, of rival suppliers who wish to compete with original applicants.

These pro-competitive beneficial impacts are more likely to occur in relation to certain types of registrations or approvals. For instance, allowing rival suppliers to rely on data provided in support of a new use registration (ie an extended label claim) is not likely to have a significant impact on the price of that product. 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 for use. As a result such a product would already be competitively priced.

The pro-competitive impacts of the absence of data protection may be greater in relation to new reformulations and reassessed products. Regarding reformulations, a supplier selling a new product could potentially exploit any market power for any period of data protection if its new formulation were sufficiently superior to existing products. For instance, the supplier may be able to charge a price premium during this period. By enabling rival suppliers to reference the applicant's data, these suppliers can obtain approval for and/or register copy-cat products and enter the market at a lower cost than if they were required to generate their own data. This can impose a competitive restraint on the price of the reformulated product.

Similarly, if data protection were in place for reassessments it may allow the original supplier to effectively exclude other rival suppliers from the market for the data protection period. This is because rivals would need to generate their own data to replicate that provided by the original supplier. If the costs of rivals generating their own data were sufficiently large, rival suppliers may pull out of the market and the competitive pressure on prices would be temporarily reduced.

The reduction in competitive pressure that may occur from such data protection can be mitigated by allowing more than one supplier to obtain regulatory approval.³⁵ Concerns regarding the loss of competitive pressure may also be somewhat alleviated to the

³⁵ Some jurisdictions that provide data protection attempt to resolve this problem by allowing rival suppliers that wish to continue selling the product to compensate the original applicant for some proportion of the total data costs, eg Australia.

extent that compounds that are up for reassessment are older compounds that already face competition from other, newer compounds.

The magnitude of any such pro-competitive benefits also varies across the many different product markets on account of the different competitive structure in each distinct market.

4.2. Extent of negative impacts

The main negative impact of the current rules is that there are fewer products available for end-users in the agricultural chemical and veterinary medicine sector than would be expected if there were greater data protection. Consequently, end-users may be forced to use products that are:

1. less effective;
2. more expensive;
3. more environmentally damaging; and/or
4. more harmful and raise greater occupational health and safety issues.

The current rules are likely to have resulted in fewer products being available because of the reduced ability of suppliers to recover development and regulatory costs and make sufficient returns from new products using existing chemistry or new uses. There is evidence that some products available overseas are not registered in New Zealand, at least in relation to some uses. The market segments that appear to be most affected are smaller-scale agricultural industries, including a range of horticultural crops and some arable crops (eg vegetable seed crops). Some animal health product markets may also be affected. Because new development more typically occurs in relation to drenches and mastitis treatments, these types of products are more likely to be affected by an absence of data protection, as opposed to lice treatments and metabolic disease treatments.

In addition to limitations on the availability of existing products, the current data protection rules reduce the incentive for suppliers to carry out development in relation to new products using existing chemistry. Although this effect cannot be quantified, it is entirely possible that fewer new products using existing chemistry are developed because the current rules reduce the expected return from such activity.

The current data protection rules could also lead to the withdrawal of currently available products because of the potential impact on regulator-initiated reassessments. Because data protection is not available for reassessments, suppliers may choose not to provide data requested by the relevant regulator. This is especially likely to occur if providing such data would impose significant costs on the applicant and/or if the applicant has other products which may be substitutable. Several suppliers have also indicated that even if they were to already have the data requested, they may not provide it. Such a refusal may appear irrational from an economic perspective because few additional costs would be imposed by providing requested data and doing so would allow a product to remain on the market. However, such a refusal may reflect the relative unimportance of the New Zealand market to large multi-national brand-owners and the highly protective approach they apply towards their intellectual property. The

centralised management structures of these firms may also mean that these decisions are made in global head offices that do not have a full appreciation of New Zealand's data protection rules.

If data requested for reassessments is not provided, the relevant regulator will be placed in a position of carrying out the reassessment with incomplete data. This could severely limit regulators' ability to carry out full and complete assessments and could negatively impact on their ability to make effective and efficient regulatory decisions. This could ultimately lead to the withdrawal of approval and/or registration for a safe and effective product for which there is high demand because the regulator may not have access to data that would otherwise indicate that the product would be safe to continue using.

4.3. Findings

Evidence from a range of industry participants suggests that the current data protection rules are inhibiting the availability of some agricultural compounds and veterinary medicines. However, it is not possible to determine with certainty whether the net impact of these rules is positive or negative across the entire sector as a whole.

Because many suppliers would benefit from greater data protection, they have an incentive to claim that the current rules are the cause of a particular product or new use not being registered. Without in-depth, firm-specific information and analysis, it is not possible to verify the extent to which this is actually the case. It is even more difficult to evaluate the extent to which the development of new products using existing chemistry has been curtailed because of the current rules, although analysis suggests that this impact is likely to occur to some degree.

Because end-users have the potential to benefit from both increased competition and a greater range of products, they would be expected to support greater data protection only if it were likely to generate net benefits. Unfortunately, many of the large number of small-scale end-users are not sufficiently informed to be able to make an accurate assessment in many of the specific product markets affected. However, a number of groups representing end-users have considered these issues, particularly with respect to agricultural compounds. The view of several of these groups, eg Horticulture New Zealand, Pipfruit New Zealand, New Zealand Citrus Growers and the Foundation for Arable Research, is that these rules are creating a barrier to both the registration of some new products using existing chemistry and the registration of new uses of existing products.

If greater data protection were provided, this would not tend to affect the pro-competitive benefits from the current rules in relation to products that are already available. Assuming that any increase in data protection would not apply retrospectively, a reduction in pro-competitive benefits would only apply to any future reformulations and new uses, but not to any products currently available. That is, the level of competition in relation to products that are already approved and registered is unlikely to be affected, with one exception.

This exception relates to reassessments. 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.

In relation to the data protection of five years provided for registrations of new, innovative products (ie containing previously unregistered active ingredients), the fact that the majority of such products are typically eligible for patent protection of 20 years means that this level of data protection does not have appear to have a significant impact on the registration of new products across the sector.

Overall, the evidence and analysis outlined in this report suggests that any increase in net benefits to New Zealand from increasing data protection are likely to be greatest in relation to new use registrations. There may also be benefits from providing data protection for reformulations, although this is less clear. Whether the net impact of an extension of data protection for reassessments would be positive is perhaps even more uncertain, although there may be policy approaches (eg cost sharing) that could address any anti-competitive impacts that may arise from such a change. 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.

Appendix One: Data Protection in other Jurisdictions

European Union

EU Member States are bound by Council Directive 98/414/EEC for policy on provision of data protection within their jurisdiction. Directive 98/414 provides the following policies on protecting all relevant data used to support new substances approved for use in the EU (annex 1).

- a) Active substance data will be protected for 10 years from the date of the first inclusion in Annex I.
- b) Product data will be protected for 10 years from the date of first authorisation in each Member State following inclusion of the Active substance in Annex 1. However, Member States may determine which data is eligible for protection (eg Belgium limits to data no more than 10 years old).
- c) Additional data provided to maintain an active substance Annex 1 listing, or varying the conditions for the substance will be protected for 5 years. (only required not voluntary data will be protected). Repeated studies to comply with GLP will not be protected where the original study is deemed to still be valid.
- d) Some member states interpret Directive 98/414 as not providing separate protection of data provided to support changes to the product or additional uses, but are given protection for any of the remaining time of the 10 year period. However, some MS (eg UK) view data provided for product changes and new uses as data in support of a "new product" and are given 10 years protection from the date of the new approval.
- e) MS may introduce a compensatory process (eg Germany) with a view to avoiding duplicative testing on vertebrate animal.

Proposed replacement of EU Directive 91/414/EEC

EU Directive 91/414/EEC concerns the marketing and use of plant protection products. The Commission has proposed a Regulation to replace the current Directive, which would, among other changes, simplify the rules applicable to data protection.

During consultation, Member States complained that the current system is too complicated and a major administrative burden. The research industry complained that the data protection period is too short and that it should be extended to all data; data sharing is accepted but only for data involving vertebrate animals. The generic industry complained that no fair competition is possible because of data protection, in particular at the 10 year review of an active substance.

The proposed Regulation would simplify the system. Data protection for 10 years after the first authorisation would be maintained, but there would be no protection for test or study data required for review or renewal of an active substance or product

authorisation. There is an obligation to share data studies involving vertebrate animals, with financial compensation for the data owner.

Australia

The provisions relating to the current protection of call-in data have not yet been passed into law. They are contained in the Agricultural and Veterinary Chemicals Legislation Amendment (Data Protection) Bill. This Bill makes amendments to relevant agricultural and veterinary chemicals legislation to implement the second tranche of data protection for agricultural and veterinary chemicals. The proposed amendments include:

- review of data protection amendments in 4 and 8 years;
- provisions to protect information required by and relied upon by the regulator in carrying out a reconsideration of an approval of an active constituent, registration of a chemical product and/or a label for a container of a chemical product; and
- amendments linked to data protection provisions that were introduced as part of the Australia-United States Free Trade Agreement (AUSFTA) legislation.

Table 12: Summary of data protection changes from 1 January 2005

Category	New scheme
Category 1: new active constituent and its associated product(s) not previously registered in Australia	8 years exclusive data protection, starting from the date of regulatory decision. Extension by 1 year for each 5 minor uses, up to 3 additional years (= 11 years maximum).
Category 2: new product, formulation or use of an active constituent	5 years exclusive data protection for agricultural chemicals, and 3 years exclusive data protection for veterinary chemicals from the date of regulatory decision. (For veterinary chemicals, excludes non-food-producing species).
Category 3: call-in data for APVMA review	(Proposed) 10 years CCR from date of regulatory decision. (For veterinary chemicals, excludes non-food-producing species).

USA

The system of data protection has been in place since 1978. Some of the key elements are:

- Registration of a new active and first product(s) receive one-off 10 years exclusivity from the date of first registration, plus 15 years compensatory protection from date of submission and running concurrently on "required" data.
- Approval for three additional minor uses within 7 years of the first label acceptance generates an additional year of exclusive use of the entire data package (making 11 years rather than 10 years). If there are an additional three minor use approvals within that 7 year period, another year of data protection may be added up to 3 additional years (if there are 9 or more minor crops added to the label).
- Registration of new use results in exclusive protection during any existing 10 year period of exclusive protection plus 15 years compensatory protection from

date of submission on "required" data and running concurrently with any remaining exclusive period.

- Where there is a call-in data there is 15 years compensatory protection from the date of submission of required data.
- All generic applicants have to cite existing data (cite-all), provide their own data, or cite some and provide some (selective citing) if DP applies. In the case of cite-all and selective the applicant provides EPA with a copy of a letter to the data owner offering to pay compensation. EPA will then proceed with the application regardless of the outcome of the compensation negotiations. If compensation cannot be negotiated the parties go to binding arbitration where the arbitrator can make an assessment on suitable compensation. Either party can file for arbitration 90 days after the offer to compensate is made.

Canada

Canada has implemented Regulatory Directive DIR2007-03 that provides for the protection of proprietary interests in pesticides data. This Directive has the following features:

- Data submitted to the Pest Management Regulatory Authority (PMRA) by the first registrant and that formed the basis for registering the technical grade of a new active ingredient (TGAI) and its associated end-use product and/or manufacturing concentrate.
- Data submitted to the PMRA after the first registration of a TGAI, an end-use product or a manufacturing concentrate and that formed the basis for additional/amended registration or the maintenance of a registration, i.e., data submitted for use expansions, new formulations, updating of existing data.
- Data requested by and used by the PMRA for re-evaluation or special review decisions.

Proprietary interests in these data will be protected for specified periods of time:

1. 10 years of exclusive protection from the date of first registration of a TGAI, extendable by one year for each addition of three minor uses to the label, to a maximum of 5 additional years.
2. 12 years mandatory compensable protection status for data submitted for use expansions, new formulations, and data requested and considered by the PMRA in the context of re-evaluation and special review. Compensable protection status starts only once the exclusive protection status of a database has lapsed. During this time an applicant can gain the right to rely on a registrant's database by entering into a negotiated commercial agreement with the owner of the data. Compensatory access is mandatory - the owner of the compensable database will be obliged to negotiate with an applicant and, if necessary, binding arbitration may be used for a final resolution of access and compensation issues.

OECD

The OECD Monograph Guidance document specifies that Regulatory Authorities should not use the contents of Monographs as a basis for their regulatory decisions unless the data package upon which a particular Monograph was based has been

provided to the Authority or the owner of the data has granted permission for use of the summary evaluation in a Monograph in lieu of the data:

“The summaries and evaluations contained in this monograph or review report are, in most cases, based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation in this Monograph or review report unless they have received the data on which the summaries and evaluation are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose or alternatively either the applicant has received permission from the data owner to use the summary and evaluation contained in this Monograph or review report in lieu of the data or the registration authority requires mandatory compensation for use of the data.”

Appendix Two: Market Definition Example

Below is a brief hypothetical example that outlines some of the main factors that need to be considered in carrying out a market definition.

Consider the following scenario within which there are four different agricultural compounds sold by four different suppliers:

- Products X, Y and Z are registered for use on crop A.
- Product X is substantially more expensive than the other products but is more effective, safer and easier to use.
- Product W is not registered for use on crop A, but is very similar to Products X, Y and Z and is also effective on crop A.
- As a condition of ERMA approval, Products X and Y are not to be used in certain areas (eg near certain plant species) because they may lead to specific adverse environmental impacts in those areas.

Determining whether some or all of these products are in the same market requires evaluating a number of difference aspects. For instance, although Product X is more expensive, growers may be indifferent between using it and the other products because of its specific advantages (ie more effective, safer and easier to use). To the extent that a small but significant increase in the price of X would lead to growers switching to other products, X could be considered to be in the same market as these products because it is effectively substitutable. Conversely, if this price increase did not lead to buyers of X switching to other products, X could be considered to be in a different market.

To the extent that growers are able to use product W on crop A 'off-label' without incurring any additional costs or without being subject to any onerous additional regulations or barriers (eg restrictions in export markets) W may be in the same market as X, Y and Z. However, if the off-label use of W would effectively prevent growers from being able to sell crop A in end markets, W may not be in the same market.

Regarding the use of Products X and Y, if the areas that these are not able to be used in are relatively minor and are not the same as the areas where crop A are grown, X and Y could be considered to be in the same geographic market as Z. However, if X and Y are unable to be used in many large areas where crop A is grown, X and Y may not have the same geographic market as Z, although there will be some overlap. The areas where Z is the only product entitled to be used may constitute a separate geographic market as it may be profitable for the producer of Z to be able to raise its price significantly because most growers would not be able to switch to X or Y. Thus, X and Y would not be effective substitutes for Z and could not be considered to be in the same geographic market.