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**Submission on:** **Agricultural Compounds and Veterinary Medicines  
Amendment Bill**

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**Submission from:**

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# Agricultural Compounds and Veterinary Medicines Amendment Bill

## 1. Introduction

- 1.1 Agcarm welcomes the opportunity to comment on the Agricultural Compounds and Veterinary Medicines Amendment Bill (the Bill).
- 1.2 This Bill implements decisions made within the Regulatory Impact Statement (Data Protection for Agricultural Compounds) document, released by Cabinet in 2012.
- 1.3 At the time of release of the Regulatory Impact Statement, Agcarm welcomed acknowledgement by the Government that increased data protection was needed to encourage businesses to register new and innovative products needed by the New Zealand agricultural sector, but did not support the minimal change proposed. Based on what is outlined in the Bill, Agcarm submits that this stance remains, and that the data protection being offered must be further increased.
- 1.4 Agcarm agrees with the government that increased data protection will encourage registration of new products, thus enhancing our agriculture sector, particularly smaller industries, to be competitive internationally. However, it is essential that any changes to the legislation must take account of our international agricultural trading competitors levels of data protection, the critical role agriculture has in our economy, the need to incentivise products with lower hazard classifications, and the need to provide new and innovative products to replace products no longer in use, or where resistance is occurring.
- 1.5 The tabling of this Bill in Parliament has been a long process, and Agcarm advises the Select Committee to carefully consider Agcarm's points within this submission, and the need for extended data protection beyond what is being offered within the Bill to ensure long-term security for our agricultural sector.
- 1.6 **Agcarm would like to be heard in support of our submission.**

## 2. Recommendations

- 2.1 Agcarm recommends that the Bill is redrafted by the Select Committee to allow for longer data protection than is being offered. The Committee should carefully consider the benefits of further increasing the data protection outlined in the Bill, in particular the following points:
  - Alignment with our trading partners and agricultural competitors
  - Encouragement of registration of products for minor species
  - Management of resistance – both crop and animal
  - Environmental benefits
  - Increasing the range of tools for pest management and biosecurity incursions
  - Encourage Research and Development Investment
- 2.2. Agcarm is of the firm opinion that the additional protection outlined in the Bill for innovative products must be further extended from 5 to 10 years, thus bringing New Zealand in line with our trading partners, and to provide confidence to Agcarm members on registering new and innovative products that will benefit our economy, animal health, and our environment.
- 2.3 Agcarm submits that the government implements 10 years data protection to enable a 'fair and reasonable' regulatory regime for companies which invest significant resources to develop a new product. The development process includes research and testing to assemble a data package, paying regulatory fees and for marketing the new product. Ten

years data protection will incentivise companies to develop new products for the New Zealand market place.

- 2.4 Currently there is minimal incentive to develop new uses and formulations of existing products. Although the Bill indicates up to an additional 3 years for new uses and reformulations, Agcarm submits that this is extended to 5 - 10 years. Extensions require trials to generate data and information for regulatory authorities, and extended data protection is needed to encourage companies to invest in product extensions.
- 2.5 In addition, Agcarm submits that Reassessments are considered within the legislative amendments, for a minimum of 5 years protection, and preferably 10 years.
- 2.6 Table 1 highlights Agcarm’s recommendations for data protection within New Zealand.

**Table 1 – Agcarm Data Protection Recommendation**

	Current	Proposed	Agcarm (Industry) seeking
Innovative Trade Name Products	5 years	5 years	10 years
Non-innovative Trade Name Products/New Uses	zero	0-3 years	5 - 10 years
Reassessments	zero	zero	5 - 10 years

- 2.7 Agcarm submits that in whatever form the Bill takes, the Select Committee must be confident that they have provided the best data protection framework possible that will allow New Zealand’s agricultural sector, especially minor industries, to remain competitive internationally now and into the future.

### 3. General Comments on Data Protection

As stated, Agcarm’s core recommendation is that the Bill should be amended to further increase the length of data protection being offered. Agcarm submits that the Select Committee must consider the following reasons and examples for increasing data protection, when considering this Bill at Committee, and prior to reporting back to the House of Representatives.

#### 3.1 Innovative Trade Name Products

- 3.1.1 Agcarm submits that 10 years protection is accorded for confidential information provided in support of applications to register innovative trade name products. The Amendment Bill provides for 5 years, which is no different than what is already provided in the current legislation.

#### **Reasoning:**

- i. Availability of the best global technologies is vital for New Zealand agriculture to continue to boost productivity, maintain environmental best practice, and to remain competitive with other agricultural producers.

- ii. Five years data protection is insufficient to encourage an environment of innovation for companies which invest in the development of active ingredients and associated products.
- iii. For a new agrichemical and vet medicine, the package of supporting studies may extend to hundreds of thousands of pages of written material. The data package, therefore, represents a very significant investment in intellectual capital by the applicant company, and one that could potentially be of considerable value to competitors.
- iv. As per Table 2, p.6, 10 years data protection for new actives is the international norm, and aligns with our major trading partners such as Australia, China, Japan, the United States, and the European Union.
- v. Ten years data protection will encourage companies to invest in products for the minor species and crop market, such as citrus, avocados, stone fruit, and animal species such as deer and goats.

### **3.1.2 Actual Examples (Note that to protect privacy, company names have been removed)**

- i. We are looking at a market which is dominated by one product. This product is an organophosphate and it has been used for 20 plus years. We would like to develop a product using an alternative (and more acceptable) chemistry but we have been hesitant to do this because we know that within a couple of months of registering our product there will be a number of copies of it in the marketplace. This would not allow us to recoup the cost of developing the product, generating residue data and establishing Maximum Residue Limits (MRLs), so we haven't moved forward with researching alternatives. The lack of data protection is the reason why this specific market has only ever had one Organophosphate product registered.
- ii. While foliar applied Actigard (acibenzolar-methyl) is now fully registered on kiwifruit for Psa control, the soil application method requires further trial work for efficacy, application method and crop safety. With only 5 years data protection from the launch date of the foliar claim, data protection will have expired by the time the data is generated to support the soil claim, which will allow generic formulations to enter the market with both the foliar and soil label claims by cross referencing a company's data. The lack of data protection means the company cannot support a business case to invest time and money perusing the soil label claim, which would help Kiwifruit growers control Psa and protect a vital New Zealand export industry.

## **3.2 New Uses/Reformulations**

- 3.2.1 Agcarm submits that 5- 10 years data protection is accorded on new uses and formulations. The Bill confers a maximum of 3 years, which is too short a period to encourage investment in new uses and reformulations, as the policy objective states is a core policy objective of the Bill.

### ***Reasoning:***

- i. There are no incentives for companies to develop new uses and reformulations. For example, use of a pesticide that is registered for apples to include kiwifruit, the extension of a vaccine used in cattle to sheep, or the development of a new formulation to improve efficacy, and safety when handling.
- ii. Ten years data protection will provide an incentive to develop new applications, especially in respect of minor crops and minor animal species. This incentive would equally apply to New Zealand and multi-national companies.

- iii. Extensions require trials, usually carried out in New Zealand, to generate information for the regulatory authorities. The trials cost money and to encourage testing within New Zealand, it is this data where protection is necessary.
- iv. Significant national benefits would accrue if 5-10 years data protection were given to applications involving new uses of existing formulations

### 3.2.2 Actual Examples (Note that to protect privacy company names have been removed)

- i. *We have a number of generic products which do not have approval for use on expanding new crops – e.g. fodder brassicas, fodder beets, forage herbs such as plantain. Under the current situation we would not spend the money to generate the crop efficacy, crop safety and crop residue studies because another party could copy it immediately. Currently many of these products are being used off-label. While this is not illegal, these products are all grazed by stock, so clear labelling on the appropriate use rate and grazing withholding period is necessary.*
- ii. *Aquatic weeds have become a problem over recent years. Companies are reluctant to develop new information to support applications for the use of products such as glyphosate to control aquatic weeds, due to the lack of data protection.*
- iii. *The best example for us is that we want to increase the crop use on existing products. It tends to be products that have more than one alternative copy in the market. Hence, we are reluctant to share the spoils, so it does not happen. This is very pertinent nowadays when considering grazing with holding period in fodder and pasture for products that have actually been used in these crops. Residue studies are not cheap and under our current data protection regime, there is very limited return on investment.*
- iv. *As an example, we have products for fodder brassicas and fodder beet. The new formulations have the potential to help grow these crops, but more importantly would provide farmers reassurance that the use is not going to compromise their livelihood nor indeed cripple Fonterra with a residue scare. To take these formulations forward we require data protection, otherwise there is no point in progressing.*
- v. *A major crop protection company wished to register a new formulation with higher use rate than the current label rate, reflecting field use rates (label use rate in ryegrass is 800 ml/ha and field use rate is 3.2 L/ha). The company has generated local residue and efficacy data to support the higher use rate and only the company has a global feeding study to support the setting of a local MRL for the formulation in ryegrass, as ryegrass does not currently have an MRL for the formulation. The global company is not motivated to progress the higher use rate of the formulation on the label and the submission of an MRL for ryegrass without data protection, as generic formulations would be able to cross reference their local residue data and global feeding study with no compensation to the company. With 10 years data protection, the company will be motivated to submit the residue and feeding study data required. This will help overcome potential residue issues for grazing stock (milk and meat), which is a major concern for New Zealand food producers.*

### 3.3 Reassessments of Existing approved compounds

- 3.3.1 Agcarm submits that 5 - 10 years data protection is accorded to reassessments to align New Zealand with our global agricultural competitors. There is currently no protection provided for data supplied to the regulator for the purposes of a reassessment, with the Bill providing **no change** from the status quo (i.e. no data protection).

## Reasoning

- i. During the reassessment of an existing product, regulators may require additional data. However, without sufficient protection in New Zealand, this proprietary information may not be supplied as competing companies will benefit from the data. This may place the continued use of important agrichemicals into doubt.
  - ii. No data protection for reassessments, reduces the quality of data and information available for the regulator to make an informed decision. This could lead to unnecessary controls being imposed, uses lost, or the product being removed from the market.
  - iii. A data owner may decide to withdraw from the New Zealand market in preference to other markets where data protection occurs, as there is a greater chance of obtaining a return on investment.
  - iv. Examples of reassessments by the EPA include 1080, endosulfan, dichlorvos and diazinon.
- 3.3.2 Agcarm submits that the Select Committee reconsider the need to implement data protection for reassessments in the amended legislation. Provision of data protection for reassessments will align New Zealand with our trading partners, and encourage companies to provide data to our regulators.

## 4. Why New Zealand needs 10 Years Data Protection

### 4.1 Alignment with our Trading Partners

- 4.1.1 In tabling the amendment Bill, the government appears to have disregarded the level of protection offered by many of our key trading partners and competitors. Australia for example, has recently increased its data protection to 10 years. This enables it to align with other countries such as the United States, EU members, and China. Table 2 provides an outline of comparable countries to New Zealand, and what data protection they are offering.

**Table 2 – Data Protection in our Trading Partner countries**

Country	Number Years	Country	Number years
Japan	15+	Brazil	10
Korea	15	Singapore	10
EU members	10 + 5	Australia	10
Chile	10	China	6 - 10
Columbia	10	New Zealand	5 + 3 (as per Bill)
USA	10	Mexico	5

- 4.1.2 Data protection is well-established in the agrichemical regimes of all Organisation for Economic Co-operation and Development (OECD) countries. The aim being to:
- prevent unauthorised access by others
  - prevent the use of data by the regulator in a way that might benefit others ('cross-referencing'); and
  - establish a specific period of time for the owner to realise the value of the investment (the 'protection period').
- 4.1.3 The short fall in New Zealand's data protection when compared to overseas food producers, places our agricultural industry at an unfair disadvantage. This is especially so when it comes to the small size of our market, and the need to encourage product registration for our minor species.

4.1.4 The Government has set an ambitious target of doubling our primary industry exports in real terms from \$32 billion in June 2012 to over \$64 billion by 2025. This is only nine years away, and extended data protection will assist in enabling this target, with Agcarm members being incentivised to register new and innovative products that will further enhance animal health and crop performance outputs.

## **4.2 Encourage and Increase Registrations for Minor Uses**

4.2.1 Farmers and growers, particularly of minor crops and minor species, are missing out on technologies available overseas due to New Zealand's weak data protection regime. Because of this, a wide variety of crops and animals that are important to New Zealand's economy, have very little choice on product availability.

4.2.2 Minor crops include citrus, squash, sweet corn, kumara, tamarillos, field tomatoes, avocados, berry fruit and stone fruit. Also, minor species such as deer and goats.

5.2.3 The scale of the majority of the New Zealand fruit and vegetable production is minor, making a up a very small percentage of the global market where there is superior data protection. For example, several Agcarm members frequently receive requests to introduce these products available overseas for use on minor crops in New Zealand. Unfortunately, there is little being done to introduce these products despite the demand. The reason is that New Zealand is a very small market globally, and there is no data protection for the work.

4.2.4 As an example, for new innovative, not yet registered products companies are looking at additional crop claims to extend the period of data protection (e.g. across a range of vegetable crops). Some of these are relatively minor and they would not proceed to generate the data if there was no additional data protection period.

## **4.3 Support the Strategies for Resistance Management – Crops and Animals**

### **Crop Protection**

4.3.1 On the crop protection front, pesticide resistance is being cited as one of the main global concerns for the future of a successful agricultural industry. A loss of pesticide options could have important economic and environmental consequences for New Zealand.

4.3.2 Pesticide resistance happens when a genetic mutation occurs within an otherwise sensitive pest population (insect, pathogen or weed) that allows some individuals to survive in the presence of a particular pesticide. Repeated use of the pesticide selects the resistant individuals until they predominate in the population. If those individuals have a high degree of resistance that is stable over time then the ability of the pesticide to control the pest in the field will be lost. Resistance can develop in most agricultural pest groups and its management requires an understanding of pest genetics, mode of action of the pesticide and factors that influence resistance selection.

4.3.3 Part of the strategy for managing pesticide resistance, is the use of a variety of different products. This includes novel and new products, with different ingredients. Because of the limited data protection in New Zealand there is a real risk that the products required to manage pesticide resistance, will not be introduced onto the market. By extending data protection to 10 years, this will assist New Zealand with ensuring the management of pesticide resistance within our agriculture systems.

### **Antimicrobial Resistance (Animal Health)**

- 4.3.4 According to the MPI's Antimicrobial Resistance (AMR) Direction Statement, AMR is generating world-wide concern and there are a number of global initiatives currently underway to understand the epidemiology of AMR. In parallel, there are global concerns that as AMR increases in animals' antimicrobials will become less effective for both therapeutic and prophylactic use.
- 4.3.5 Antimicrobial resistance is when microbes are resistant to one or more antimicrobial agent. In this context, "antimicrobial" is a general term for drugs, chemicals, or other substances that either kill or slow the growth of microbes. Substances that are considered antimicrobials include surface disinfectants, antibiotics, parasiticides, anti-fungal and anti-viral agents.
- 4.3.6 One of the key endeavours outlined by MPI in their AMR statement, is facilitating new antimicrobials to enter the market with novel modes of action that may be effective against resistant microbes.
- 4.3.7 Under the current data protection regime manufacturers find minimal encouragement to register new products in New Zealand. However, extended data protection will provide the necessary incentives to see new antimicrobials enter the animal health market.

## **4.4 Enhance Environmental Benefits**

- 4.4.1 One of Agcarm's core objectives is to promote product stewardship and the responsible use of products. Over the years the agrichemical industry has been very proactive in reducing the risk of agrichemicals through two means – introducing actives with lower hazard classification and developing formulations with less hazardous properties. This in return reduces potential "risks" to human health, non-target organisms and the environment. Use rates and the number of applications are also reduced, as is the potential for pest resistance.
- 4.4.2 Numerous examples exist of products with 'softer' more environmentally chemistry that could be introduced into New Zealand to replace other products which have been reassessed by the EPA, and may no longer be available for use, or will be removed from the market place in the near future.
- 4.4.3 As highlighted previously, without stronger data protection manufacturing companies are reluctant to register these products as there is no return on investment, hence 'older' chemistries continue to be used as there are no, or limited alternatives due to the lack of data protection.

## **4.5 Support Biosecurity**

- 4.5.1 New Zealand remains under intense pressure from pests and diseases which threaten our economy and environment, despite investing heavily in biosecurity and pest management systems. The government and science community has indicated that action is needed to develop new approaches, and to improve existing tools to protect the country's environment and economy.
- 4.5.2 There have been a number of exotic pest incursions over recent years, and new products are needed at short notice to mitigate impacts on our native biodiversity and agricultural production. In addition, pests established within New Zealand have spread to other parts of the country, leading to regional economic and environmental harm. Examples being varroa mite, psyllid, theileria and Chilean needle grass.

4.5.3 To eradicate and manage these pests and diseases, new products are required. Extended data protection will encourage companies to research and produce new products that will assist in the management of harmful pests newly established, or spread, within New Zealand.

#### **4.6 Encourage Research and Development, along with Innovation**

4.6.1 Amongst the Government's growth agenda is a boost to lift levels of Research and Development (R & D) spend, along with a lift in innovation. A strong focus on R & D, helps to diversify and strengthen the New Zealand economy and ensure New Zealand companies remain competitive internationally. That in turn helps lift New Zealand's export revenues, job numbers, and the incomes of New Zealand families.

4.6.2 Science and technology solutions are critical to meeting growing demand for food, maintaining market competitiveness and adapting to and mitigating climate change. Agricultural research helps generate new technologies and improved policies - key drivers of growth in agricultural productivity and resilience.

4.6.3 Agcarm members are strong supporters of Research and Development, with an informal estimate of over \$50 million being spent annually across the agricultural sector on searching for new and innovative products. With enhanced data protection, this spend would increase, further benefitting New Zealand. Companies are reluctant to over capitalise in R & D, when there is limited or no protection for the end product.

4.6.4 The implementation of 10 years data protection, will be beneficial for New Zealand agriculture as it will encourage the introduction of modern, innovative, and potentially lower risk science and health technologies into New Zealand.

### **5. Patents vs Data Protection**

5.1 Amongst the New Zealand public, there is often confusion about the link between patents and data protection.

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

5.3 Patent and data protection are two distinct intellectual property rights. Patent protection is the reward you receive for disclosing your invention (investment in innovation) by preventing another party from using that invention in any form, for a defined period of time, while data protection is the reward you receive for the cost and risk associated with generating data on the required health, efficacy, and environmental safety studies.

5.4 It is important to clarify this misunderstanding as it is easy to reach an incorrect view that a 20-year patent negates the need for data protection. A patent does not protect the data required for market approval, but only the invention. Appendix 2 outlines the patent protection and data protection framework.

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

- 5.6 Markets for products develop over many years and at varying times around the world. It can take many years before innovator companies see a market opportunity to bring a new active to New Zealand, which represents less than one percent of the global market in agrichemicals and animal health products.
- 5.7 Decisions about introducing an active ingredient to New Zealand are often made after a new active has come off patent or at the end of the 20-year patent period. New Zealand's minimal data protection is therefore a key influencer on the decision to introduce the active ingredient into our country.
- 5.8 Doubling the data protection to 10 years for new actives would further encourage the registration of active ingredients new to New Zealand. This would benefit New Zealand agriculture in three ways:
- Bringing new technology to NZ farmers.
  - Increasing the pool of active ingredients that can be used to minimise the development of pest resistance to pesticides and antibiotics.
  - Increasing the pool of products for subsequent approval/registration by generics companies (after the patent and 10-year data protection period has expired).

## **6. There is No Reputable Opposition to Increased Data Protection**

- 6.1 Agcarm has had discussions with a number of groups involved in the manufacture of agricultural compounds and veterinary medicines, along with stakeholders within the primary sector, and is yet to encounter any industry association, company or individual that is actively opposed to extended data protection. The likes of Federated Farmers (as per their submission) and their membership, is in favour of increased data protection as a means of encouraging innovation and the registration of new and more effective products for our farmers.
- 6.2 Generic Producers Support Extended Data Protection**
- 6.2.1 It has been mentioned that increased data protection will lead to an increase in the cost of products for the end user, along with disadvantaging generic companies. Agcarm submits that this slant is incorrect.
- 6.2.2 Generic companies support data protection as they cannot manufacture a generic of a product that has not been registered in New Zealand, because of an insufficient data protection.
- 6.2.3 The argument that extended data protection will act against generic competition can be disproved by looking across the Tasman. The reality is that Australia is considered to have substantial generic competition, where 5 years data protection is currently given for label extensions and 10 years for products with new active ingredients. This level of data protection has not prevented healthy generic competition.
- 6.2.4 As per competition, purchasers of agricultural compounds will not support products which are overpriced, and will look for other solutions. Extended data protection will not give registrants an opportunity to set any price. Any increase in data protection will have no impact on products which are already registered. Data protection is not retrospective, so there will be no change on the many hundreds of already registered active ingredients.
- 6.2.5 Generic companies are in support of data protection. A number of the companies carry out their own product extension (which requires data needing protection), and all rely on pioneer companies to register new chemistries and label extensions which others can eventually copy.

## 7. Specific Comment on the Amendment Bill

### 7.1 Modification to Section 74B (5) and (6)

- 7.1.1 To encourage the maximum benefit for growers from data protection it is recommended that the text in s. 74b (5) and (6) is amended to allow for crops and crop groups, as well as animal species. As the text reads, crop protection manufacturers will be incentivised to register single crop species, rather than crop groups. This will have a detrimental effect on the registration of products for minor crops, as manufacturers will favour registering products for larger crops only, due to there being a greater return on investment.
- 7.1.2 Agcarm submits that the Select Committee review the wording in s.74b (5) and (6) to ensure that the maximum value from extended data protection is realised. The suggested text is as follows:

s. 74B (6)

*(a) use on a ~~species of plant or animal~~ crop or crop group or individual animal species on which the product could not be used under the conditions as they were before the variation was granted.*

*(b) labelling for use on a ~~species of plant or animal~~ crop or crop group or individual animal species on which the product could not be labelled for use under the conditions as they were before the variation was granted.*

## 8. Conclusion

- 8.1 As the peak industry representative for Crop Protection and Animal Health within New Zealand, Agcarm welcomes the progression and support by the Government for additional data protection. The amendments proposed in the draft Bill are seen as a step forward and will no doubt assist in the encouragement of new products entering the New Zealand market.
- 8.2 In simple terms data protection is simply the commercial recognition that the high cost of data for agricultural registration and veterinary medicines (which is often very different, far more complex and very expensive compared to data used to generate a patent) should be compensated for by a period of exclusive market access.
- 8.3 Agcarm is of the opinion that though well intentioned, the length of data protection being offered in the Bill needs to be reconsidered by the Select Committee, and the Bill amended to increase data protection to the level outlined in this submission. This being:
- 10 years for innovative trade name products
  - 5 - 10 years for non-innovative and new uses
  - 5 - 10 years for reassessments
- 8.4 In particular we urge the Committee to carefully consider the need to:
- keep New Zealand agriculture competitive internationally
  - allow a wide range of product availability to manage resistance and biosecurity incursions
  - encourage the registration of products for minor species
  - register new products to replace products that are no longer in use
  - encourage products that pose less risk to our environment and human health
  - support research and development, along with innovation

## **9. About Agcarm**

Agcarm is the industry association for manufacturers and suppliers of crop protection and animal health products. For further information see [www.agcarm.co.nz](http://www.agcarm.co.nz).

A full list of our current members is provided in Appendix 1.

The products that our members produce protect public health, improve animal welfare and help environmental management. They:

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

## **APPENDIX 1:**

### **Agcarm Membership**

Agcarm represents around 85 percent of the crop protection and animal health industry within New Zealand. Our companies are both local and globally linked, producing products that enable our farmers and growers to supply high-quality food and fibre into domestic and international markets, along with keeping our animals and pets healthy.

#### **Animal Health Manufacturers**

- Bayer Animal Health
- Boehringer Ingleheim
- Donaghys
- Elanco Animal Health
- Merial Ancare
- MSD Animal Health
- Zoetis NZ

#### **Crop Protection Manufacturers**

- ADAMA New Zealand
- AgriNova NZ Ltd (trading as Grochem)
- BASF New Zealand
- Bayer CropScience
- Donaghys
- Dow Agrosciences
- Dupont
- Etec Crop Solutions
- Key Industries
- Monsanto Australia
- Nufarm
- Sinochem
- Syngenta Crop Protection
- Zelam

#### **Distributors**

- Ashburton Trading Society
- Farmlands Co-operative
- Horticulture
- ICD Group
- New Zealand Farm Source
- PGG Wrightson Ltd
- Venture Exports

#### **Corporate Associates**

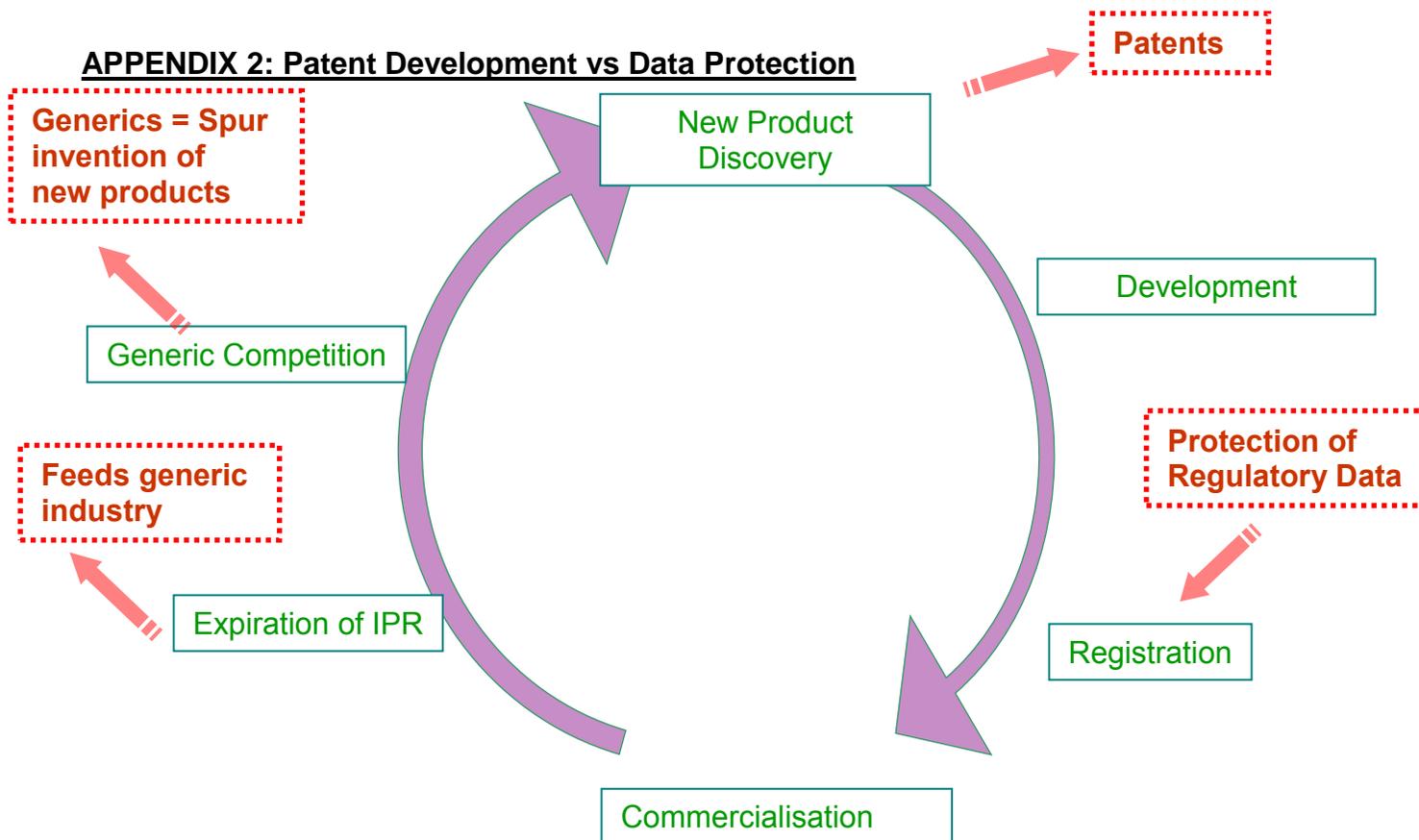
- AgriMedia
- Argenta
- Eurofins Agrosciences Services
- Medicines New Zealand
- Peracto New Zealand
- Philstic Labels
- Rural Contractors

#### **Individual Associates**

- Hill Laboratories
- RxVet Limited

- Mantissa Corporation
- Agworld
- Ag Services
- Pipfruit New Zealand
- Market Access Solutionz
- Renovo Technologies
- NZ Sports Turf Institute
- Molloy Agricultural Spraying
- Connell Brothers
- Competitive Advantage
- Intuit Animal Health Consultants

## APPENDIX 2: Patent Development vs Data Protection



### Discovery

Researchers identify candidate molecule for use in product development. Patent protection sought.

- Application filed when a candidate molecule is identified.
- Exclusive use in production and research for the patent term.
- Minimum term in TRIPS Agreement is 20 years.
- Not all molecules which are patented become final products

### Development

Researchers establish effectiveness and safety of various formulations including the patented active ingredient.

- Development of a new agricultural chemical costs in excess of \$256 million.
- Development time usually exceeds 9 years.
- 1 out of 140,000 molecules makes it from laboratory to field.
- Over 120 tests are performed on each new product to ensure safety and efficacy

### Registration

Companies seek approval to sell the new compound from government regulators and protection of regulatory data.

- Regulatory data are tests and studies generated by companies to prove the safety and efficacy of a product.
- Government regulatory approval is needed to sell/make the products.
- The clock starts ticking for data protection on the day of registration