



Submission to: Committee Secretariat
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On: Agricultural Compounds and Veterinary Medicines Amendment Bill
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1. Executive Summary

Horticulture New Zealand (HortNZ) takes very seriously any changes to agricultural compound legislation and appreciates the opportunity to provide a submission on the proposed Agricultural Compounds and Veterinary Medicines Amendment Bill. This piece of legislation is extremely important to the future of our growers.

HortNZ supports data protection and the intention of the legislation drafted in the amendment bill. However further data protection provisions are needed along with modification of the text in section 74B to ensure this legislation is implemented correctly to provide optimal benefits to growers.

Specifically, HortNZ:

- endorses the necessity for amending the data protection section of the ACVM Act and agrees the changes are needed to support primary sector productivity and international competitiveness
- proposes the Bill is redrafted to:
 - increase data protection to **5 years** for uses added to new actives
 - allow for new use applications to be made within **5 years** of a new active registration
 - increase data protection for new uses/claims/formulations to **5 years**
 - introduce **5 years** of data protection for reassessments
 - reword section 74B (5 and 6) to encourage registrants to obtain label claims for **crop groups** as opposed to individual plant species
 - requests clarification on how the addition of new pests, weeds, diseases to labels are considered
- supports the submission made by Agcarm in relation to agricultural chemicals
- welcomes the opportunity to be heard in support of this submission

Table 1 Summary of HortNZ's recommendations for data protection periods

Data protection type:	Current (years)	Bill proposal (years)	HortNZ proposal (years)
New active ingredients	5	5 + ≥ 3 uses = total max 8	5 + ≥ 5 uses = total max 10
New claims/uses/formulations	zero	3	Minimum 5
Reassessments	zero	zero	Minimum 5

This submission is supported by all 23 product groups affiliated to Horticulture NZ. All product groups support data protection as outlined in this submission. However, the kiwifruit industry believes that in their industry three years is sufficient data protection for new uses of existing active ingredients and will provide greater choice to their growers.

2. Introduction

HortNZ represents 5,500 commercial fruit, vegetable and berry fruit growers to provide strategic direction and focus, build strong relationships with product groups and associations and works at both a national and regional level across a range of interest areas, including government legislation around agricultural chemical policy.

Horticulture occupies 100,000 ha of productive land. The crops growers produce are exported to discerning customers in over 120 countries. The industry also supplies the majority of domestic fresh and processed fruit and vegetables. The horticulture industry is this country's fourth largest exporter, has a total value of more than \$5 billion and employs over 60,000 people. The Horticulture Industry Strategy "Growing a New Future" plans to increase the value of the industry to \$10 billion (domestic and export) by 2020.

Agrichemical policy has a direct impact on three of the seven key themes identified in HortNZ's industry strategy:

1. **Productivity** – access to the newest advances in agricultural chemicals internationally means growers can achieve greater and better quality yields and be internationally competitive.
2. **Sustainability** – access to new innovations in agricultural chemicals are essential to replace older less sustainable products and ensure New Zealand growers are utilising international best practice to minimise environmental and food safety issues associated with production of horticultural crops. Increased data protection will encourage registration of new products and addition of claims to existing products.
3. **Improved Market Access** - the most significant barriers to expanding New Zealand's horticulture exports are the technical barriers to trade faced due to trading partners' food safety concerns (usually around agricultural chemical residues). To enable continued and expanded market access, growers must be able to utilise new agrichemicals that are favoured by trading partners.

2.1. New Zealand is a small market

The New Zealand Horticultural industry is based on crops which are considered 'minor' internationally making up a very small percentage of the global market¹. When crop protection companies make decisions internationally on where to invest funds, factors

¹ New Zealand represents less than one percent of the global market in agrichemicals.

such as sales volumes, transport costs and regulatory barriers are all important considerations. HortNZ is aware of many examples where the lack of data protection has resulted in decisions not to register compounds. There must be an economic benefit for companies to introduce new products to the market and invest in the development of existing ones. The proposed data protection provisions, while an improvement, still do not provide companies with enough incentive to register new products across a wide range of crops.

Increased time periods are required to ensure registrants have the opportunity for an economic return on investment. Cost of registration (including residue, efficacy, crop safety trials and ACVM and EPA regulatory fees) are significant. The crop protection manufacturers association (Agcarm) submit that the costs of registration is often greater than the profit before generic companies copy the label once data protection lapses – even with the Bills revised time periods. Increased protection is needed to ensure New Zealand growers have access to new chemicals at the same time as international competitors who are both larger markets and have greater data protection provisions.

2.2. Alignment with Trading Partners

HortNZ considers that New Zealand's data protection regime should be aligned with our key trading partners and competitors who have longer data protection periods. Table 2 in the Agcarm submission provides an outline of New Zealand's key trading countries, and their data protection periods.

Five years is the minimum that HortNZ believes is required to justify investment in minor crop claims and to align with international regulators. HortNZ urges the select committee to consider this recommendation taking into account the strong support from both the horticultural and agricultural crop protection industry (as per Agcarm's submission).

2.3. Funding Research and Development

Investment in research and development to register label claims is significant and requires data generation, with a significant portion of trials (e.g. residues and efficacy) carried out in New Zealand. Given the lack of economic return to the crop protection companies, industry often must co-fund trial work required to obtain a label claim for their crop. Many industry groups currently utilise levy funds (generated from grower sales) for this purpose as there are no government funds available to support trial work. This is contrary to many close trading partners such as Australia, the USA and Canada where Government funds are used in a cost sharing model to ensure that crop protection options are available to all growers. This leaves New Zealand growers at a disadvantage as both the funding and data protection systems are inferior to New Zealand's trading partners.

HortNZ believes that providing increased data protection (greater than that proposed in the Bill) will encourage registrant investment and bring new innovative products to New Zealand.

3. Benefits of increased data protection

Benefits of increased data protection include:

- Reduction in off-label use
- Decreased potential for resistance development

- Human health and environmental benefits - reduction in the use of 'older chemistry'
- Faster response to biosecurity issues

The benefits of increased data protection and the subsequent availability of a wider range of chemicals to a wider range of crops, significantly outweigh any disadvantages from decreased competition. Generic companies do not generally have R&D programmes and do not invest in the development of innovative crop protection options. They compete largely on price. HortNZ considers that through increased data protection provisions, growers will have access to a greater choice of crop protection solutions. Growers are willing to invest in high quality innovative options that help them grow crops. This is especially true for chemicals that are more efficacious, require fewer applications and allow access to a wide range of export markets (i.e. where MRLs² are set in importing countries).

HortNZ recognises that large crops who currently attract initial registrations of innovative products will face a longer period of data protection under the proposed legislation. However, crop protection companies will have a longer time period and more registrations from which to recoup their registration costs and this may see a reduction in initial pricing, providing a benefit to growers over the longer term. Given the improved economic proposition from horticulture with data protection, both large and small product groups will benefit from the increased availability of new innovative products and through the addition of new uses to labels.

3.1. Reduction in off label use

Presently many products do not carry label claims for all the crops they are used on and must be used off-label. HortNZ believes that with increased data protection, companies will be more willing to register compounds for smaller crops which currently do not provide a return on investment for the registration process. The benefit of data protection is not just quicker access to products, but access in the first place. In general, generic companies do not undertake trial work once data protection has lapsed, they simply copy the original label. In the past 'older' chemicals often carried generic 'all fruit and vegetables' label claims, with corresponding MRLs set. This is no longer the case and unless registered, growers are forced to use chemicals off label and produce must meet the default MRL (of 0.1mg/kg) in some cases severely restricting how the product can be used. Growers have no label directions and do not have access to GAP³ advice to achieve residues below the default forcing growers to be reliant on older chemistry with generic MRLs.

While off-label use is extremely important to the horticultural industry, HortNZ prefers that chemicals are registered specifically for use on each crop. Adequate (i.e. minimum five years) data protection for new uses would enhance the value proposition for companies and allow registration of new active ingredients and use patterns across as many uses as economically viable. It will provide smaller industry groups with options for new chemistry to replace 'older' chemistry. Some industry groups such as Summerfruit New Zealand and many offshore customers do not allow off-label use for exported crops. The lack of registered products impacts on the ability of growers to develop markets and export crops.

² Maximum Residue Limits

³ Good Agricultural Practice

By increasing data protection for new active ingredients and new uses, there is an increased likelihood that products will be registered, carry a label claim and MRL.

3.2. Resistance management

A key advantage of New Zealand's horticulture industry is the use of Integrated Pest Management (IPM) in production systems to manage resistance. The success of IPM relies on access to a suite of different active ingredients. Resistance in insect, disease and weed populations is a concern and management of this is vital for the future of the industry.

Adequate data protection provisions will assist in ensuring growers have access to a wide range of products to use in IPM systems and resistance management.

3.3. Human Health and Environmental Benefits

Newer active ingredients and formulation types tend to be 'softer' chemistry than those traditionally used and as such have lower hazard classifications which pose less risk to human health, non-target organisms and the environment. Application frequencies and rates are also often decreased. There are many 'softer' chemistry products that could be introduced into New Zealand to replace older chemistry. However, increased data protection is necessary to incentivise companies to register these products across a wide range of crops.

3.4. Biosecurity benefits

Growers are at risk from pest, disease and weed incursions. In recent years there have been a number of incursions impacting on growers. New control tools need to be available to eradicate and manage incursions. Increased data protection would encourage companies to register products and new uses to respond quickly to incursions and manage biosecurity risks.

4. Increased data protection periods

The Bill addresses two (innovative products and new uses / formulations) of the three key areas where HortNZ believes data protection is important. This section provides justifications for increased data protection periods in two areas and arguments for implementing data protection for reassessments (the third area).

4.1. Innovative products

In summary the data protection for new active ingredients are:

- Currently: 5 years
- Bill proposes: 5 + 1 year for every new use up to a maximum of 8 years – provided the new claims are added with in the first three years of initial registration
- HortNZ proposes: 5 + 1 year for every new use or 5 years for the addition of a crop group up to a maximum of **10 years**– provided the new claims are added with in the **first five years** of initial registration

HortNZ considers that the proposed data protection for innovative products is inadequate to encourage the necessary investment from companies. Data protection needs to provide sufficient economic incentive to enable registration costs to be recovered. HortNZ requests that the Select Committee considers extending the data protection to a five plus five (instead of five plus three) year data protection

period. Extending the maximum data protection to 10 years will provide crop protection companies with the opportunity to obtain a return on investment from the registration process.

HortNZ considers that the time period for making an application to add new uses needs to be extended to five years to allow for sufficient time for data generation. When a new compound is introduced into New Zealand, companies initially focus on large crops (e.g. apples, wine grape etc) where a return on investment is possible. This requires significant time and capital investment and the product must get to market quickly to obtain maximise return during the data protection period. The new legislation proposes that to achieve an additional three years of data protection, new claims must be added within the first three years. By default, this means that the trial work required to support the new claims must be completed, analysed and an application submitted prior to the end of the three years.

HortNZ requests that the Select Committee consider the impact of this three year timeframe on the ability to generate data. Residue, efficacy and plant safety trials are required to support additional use claims. These often need to be carried out over consecutive seasons, meaning two or more years is required just to gather field data. Once data is collected it must be analysed, collated into reports and presented to ACVM who carry out data and then technical assessment, and finally (in most instances) set an MRL. The additional uses may also need to be approved by EPA and may require additional data (i.e. toxicity, environmental, worker exposure etc). The regulatory processes can exceed three years. A five year period would also enable consideration of how a product performs in New Zealand on major crops before investing in additional use trials. It would provide a better incentive to justify crop protection company investment to add new use claims.

HortNZ is unclear whether it is the intention of the Bill to provide data protection for new uses from the addition of new crops, new diseases/pests/weeds, new application methods and any other new use of a compound. HortNZ considers the definition of new use in Section 74B(6) to be ambiguous. Section 74B(6) refers to species of plant or animals but not to additional pests or any other parameter. For example, if a product was originally registered for use on scale in kiwifruit and then an application was made within the required timeframe to add thrips to the label, it is not clear if this would count as a new use and data protection be extended by one year. HortNZ requests that text in the legislation is redrafted to make this distinction clear and that new use is considered to be new pest/ disease/ virus/ application method etc.

4.2. New uses and reformulations (non-innovative products)

In summary the data protection provisions for new uses / reformulations of non-innovative products are:

- Currently: zero
- Bill proposes: 3 years
- HortNZ proposes: minimum 5 years

The Bill proposes that data protection for new uses / reformulations should be introduced to encourage registrations in a wide range of crops – particularly minor crops.

4.2.1. *New uses*

Lack of data protection for new uses is currently the main reason why companies do not add new uses to existing labels thereby severely limiting registered options available to New Zealand growers. The capital outlay associated with registration of a new use claim is significant and this needs to be recouped through exclusive market advantage. While appreciating that data protection for new uses has been proposed, HortNZ believes three years is insufficient. Companies would be incentivised to register new uses and reformulations if at least five years data protection was provided (as outlined in Agcarm's submission).

As outlined above, HortNZ requests that clarification is provided on the definition of new use to ensure that the addition of new pests, weeds, diseases, application method etc. are recognised and included as new uses.

4.2.2. *New / reformulations*

HortNZ considers data protection for new uses/reformulations is critical to the future of horticulture. Internationally there are safer formulation types that pose reduced environment and human health risks, provide better coverage of crops and have superior residue and efficacy profiles. However these are often not brought to the New Zealand market as there is no data protection and no incentive to register. The data protection period needs to be extended to five years to incentivise companies to register new formulations in New Zealand.

4.3. Reassessments

In summary the data protection provisions for reassessments are:

- Currently: zero
- Bill proposes: not mentioned / zero
- HortNZ proposes: minimum 5 years

HortNZ is very familiar with the EPA and ACVM reassessment process. During reassessments, HortNZ's experience is that very few registrants submit information and participate in the process. This is understandable, because with no data protection, if one company submits support data this benefits all other competing companies.

If data protection were in place for reassessments it would encourage companies to submit supporting data. Without support, many chemicals under reassessment now and in the future will be lost, or use claims heavily reduced and restricted. When crop protection companies provide supporting data it demonstrates strong product stewardship for the products under scrutiny. HortNZ product groups had to step in during the recent EPA and ACVM OPC⁴ reassessment and fund the drafting of submissions, appearance at public hearings, residue trials, and efficacy data extrapolations in the absence of investment by the registrants. Input into the reassessment process comes at considerable cost. If product groups had not funded reassessment submissions, HortNZ is in no doubt that the majority of these chemicals would have been removed from the market within 6 months or less and these critical control tools would be lost to growers with no time to find alternatives, negatively impacting on production, yields and resistance management.

HortNZ believes that companies who support reassessments and provide information to the regulator must be rewarded in the form of protection for that data. The

⁴ Organophosphate and carbamate group of insecticides

legislation should be aligned with New Zealand's trading partners (and competitors). HortNZ strongly requests that the Select Committee seek advice from MPI and Agcarm on how international regulators provide data protection for reassessments to ensure that a robust system is implemented.

5. Extended protection period – definition of new use

HortNZ supports the mechanism of increasing data protection where new uses are added to a label but is very concerned that the current text in Section 74B (6) where a new use is defined will have perverse consequences. HortNZ strongly requests the select committee considers changing the text in section 74B (5 & 6) that refer to **species of plant** to also allow for acceptance of **crop groups**.

Crop groups are used to facilitate establishment of MRLs. Individual crops are allocated to a crop group based on botanical and taxonomic criteria as well as cultivation practices. Crop groups simplify MRL establishment by using residue data for crops that are representative of the whole group to extend the label claim to all individual crops within that crop group. Crop grouping is used internationally as a mechanism for ensuring that minor crops are included in registrations without the need for additional data generation. If data generation was required for each species of plant before registration was granted, this would be an unacceptable situation for a company and registrations would not proceed. Crop grouping is recognised internationally (including New Zealand) as a key mechanism for extending registrations across crops without the need for additional data generation. Section 7 of the ACVM Information Requirements document "Residue Data for Agricultural Chemical Registration" covers crop grouping in New Zealand which incorporates by reference the Codex standard.

HortNZ is concerned that the current wording of the Bill rewards companies for adding a new individual crop species to the label but does not provide a reward for adding a whole crop group, thereby discouraging registrants from adding crop groups and reducing registered use claims available to growers. For example:

- Using the proposed "species" definition of a new use company 'A' receives full registration for an innovative product and the label claim is for apples. Within three years of the initial approval, the company registers a claim for potatoes, carrots and mandarins. This company would receive maximum data protection for their product by adding **three individual crops**.
- Using a definition that refers to "crop groups" company 'A' receives full registration for an innovative product and the label claim is for apples. The company then registers a claim for the root and tuber crop group (using the same trial data for potato and carrot as would be required for the individual crops). This 'root and tuber' crop group claim covers not only larger crops such as potatoes but also five other minor crops i.e. carrots, kumara, parsnip, beetroot and radish. The company receives the maximum data protection for their product by adding one crop group which includes **six individual crops**. If they also submitted label claims for the citrus crop group (using data from mandarin trials plus two more on lemons), then the crop group 'citrus' would include a further **six individual crops**. By utilising crop grouping, there would be label claims for **12 individual crops** (six root & tuber and six citrus).

The current wording focusses on registration of species only and will result in less uses being registered on labels. Internationally, regulators and companies are working to

obtain labels by crop group in order to include as many minor crops as possible. The current wording of the Bill will force New Zealand out of line with international counterparts and will not benefit growers.

HortNZ also notes that by defining new uses by species, perverse outcomes are likely to occur. For example, kiwifruit is grown from two different species – *Actinida deliciosa* and *Actinidia chinensis*. Registrants currently use the crop name of 'kiwifruit' when registering a product but under the proposed legislation will receive greater data protection if they used species names. There is a high potential for confusion if this occurs. For horticulture crops, the use of the term 'species' in the legislation is not appropriate and consideration should be given to using the term 'crop' in addition to 'crop group'.

5.1. Modifications to section 74B

HortNZ proposes that the Select Committee consider changing the wording of Section 74B (5) and (6) of the Bill to allow for crops and crop groups.

HortNZ proposes changing the text under 74B (5) so that where a crop group is registered, this is sufficient to allow for the maximum data protection period. All crop groups include multiple individual species, therefore by allowing for a single crop group to gain maximum data protection, there will automatically be multiple plant species included. Allowing a crop group is equivalent to accepting maximum data protection for multiple species.

HortNZ's proposes that the text be changed as follows:

*74B Innovative TNP application for full registration
Extended protected period*

(5) The end date that applies under subsection (3) is extended by a period of 1 year for each new use or to the **maximum period of data protection where a crop group is** authorised by the granting of a variation application that ...

(6) *A new use is authorised if the conditions on the registration of a product are varied so as to authorise the product's —*

*(a) use on a **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 **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.*

If these changes to the text are not made, companies will be incentivised to register single crop species rather than crop groups. They will focus on large crops where they can obtain a return on investment from the registration costs and minor crops will be left without registration. By allowing crop groups to fulfil the new use requirement, the legislation will encourage the registration of crop groups providing an overall increase in the number of crops with registered uses. Using the examples outlined above (section 5), allowing for crop groups would provide for registration of 12 individual crops where the current wording would allow for only three.

6. Conclusions

HortNZ:

- commends the work by MPI in recognising the need for increased data protection periods.
- disagrees with the Bills proposed data protection periods and requests increased periods be considered by the Select Committee and the Bill amended before it is reported back to the House including:
 - increase data protection to **5 years** for uses added to new actives
 - allow for new use applications to be made within **5 years** of a new active registration
 - increase data protection for new uses/claims/formulations to **5 years**
 - introduce **5 years** of data protection for reassessments
- provides clarification on how the addition of new pests, weeds, diseases to a label are considered
- asks that section 74B (5 and 6) are refined to ensure maximum benefits to growers of minor crops by adding allowances for crop grouping
- wishes to be heard in support of this submission

HortNZ asks the committee to support this data protection legislation to ensure the New Zealand Horticulture industry is competitive internationally and to ensure the long-term security of New Zealand's horticulture industry. If implemented correctly, this Bill will allow New Zealand growers to increase their competitive advantage both domestically (against imported produce) and internationally. Data protection will allow a wider range of products to be available to more growers – especially those of minor crops to manage resistance, biosecurity incursions and develop products that are more environmentally friendly and pose less risks to human health.