Ministry for Primary Industries
Manatū Ahu Matua

Data Protection for Agricultural Compounds

Regulatory Impact Statement

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Growing and Protecting New Zealand

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Contents

Page

AGENCY DISCLOSURE STATEMENT

This Regulatory Impact Statement has been prepared by the Ministry for Primary Industries (MPI) to analyse options for amending data protection in Part 6 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

The policy proposal responds to the problem that the current data protection regime in the ACVM Act does not encourage registration of new products or uses, and provision of data to support reassessments. It also responds to ACVM stakeholder feedback that the data protection regime in the ACVM Amendment Bill, currently before the House, could be improved.

A quantitative assessment of the net economic impact of any changes is not possible due to a lack of information. Product cost and revenue information is commercially sensitive and not publicly available. Without detailed firm-specific information and analysis, it is not possible to:

- verify the extent to which the current rules are the cause of a particular product or new use not being registered; or
- evaluate the extent to which the development of new products using existing chemistry is being inhibited.

In light of the lack of quantitative data, MPI has relied on information provided in the submissions of ACVM users and suppliers to ascertain:

- the likely effectiveness of various data protection regimes; and
- the impact of various data protection options on short term and medium term competition.

Karen Adair
Director, Food & Regulatory Policy

BACKGROUND AND STATUS QUO

New Zealand market for agricultural compounds and veterinary medicines

1. New Zealand's primary industries make extensive use of agricultural compounds[1] and veterinary medicines. The agricultural and horticultural sectors are the primary purchaser of agricultural compounds but other groups also make extensive use of them, such as forestry and land management (including domestic gardens and central and local government public land). Veterinary medicines are used to treat production and companion animals. In 2012, MPI surveys showed that animal health and pest control costs accounted for about 15% of farm working expenses for sheep and beef, and 6% for dairy.[2]

2. Around 300 companies have approximately 3,200 different products registered for sale in New Zealand under the Agricultural Compounds and Veterinary Medicines Act (the ACVM Act). Many of the brand name suppliers are locally registered subsidiaries of major brand name companies.

Table 1: Average number of applications MPI grants by registration type

Registration type	**Average number of granted applications per annum (2013-2015)**
Innovative applications	37
Non-innovative applications	138
Provisional applications	71
New use applications	71
Reassessments	20

3. New Zealand's agricultural compounds and veterinary medicines expenditure is estimated at around $520 million per year with $250 million on agricultural compounds and $270 million on veterinary medicines.[3] This has been estimated to represent about 0.5% of global sales each year. The value and number of competing products in individual product markets varies. The majority of products have small markets and low sales. Covec Consultancy Ltd estimated that a large proportion of products have annual sales of less than $50,000, and only around 30 to 40 have sales that exceed $1 million per annum. [4]

[1] Agricultural compounds include veterinary medicines, agricultural chemicals, vertebrate toxic agents, fertilisers and animal feeds.
[2] www.mpi.govt.nz
[3] Irvine R and Denne T "Data Protection for Agricultural Compounds and Veterinary Medicines", Covec Ltd (2009)
[4] Ibid.

The ACVM Act's regulatory process for registering a new product, use or reformulation, or a reassessment

4. The ACVM Act prohibits the sale, manufacture, import or use of agricultural compounds in New Zealand unless the compound is a registered trade name product or exempt from registration. The ACVM Act manages risks to trade, public health, agricultural security and animal welfare by ensuring ACVM use complies with domestic food residue standards and consumers have sufficient information to make informed decisions.

5. Applications for registration, or provisional registration, as a trade name product are considered by the Director-General of MPI (the Director-General) pursuant to sections 9 (1) or 26 of the ACVM Act. Applications receive a full risk assessment based on the intended use of the product. Registration applications are generally granted subject to specific conditions to manage any risks associated with the agricultural compound.

6. Once a product is registered, an applicant may apply to the Director-General pursuant to section 9 (2) to vary any condition on the product, which could include the uses of that product, or its formulation. For example, an applicant may originally register a product for use on apple trees, then seek a variation to allow it to also be used on plum trees. Another example could be a product being registered to treat mildew, with a variation sought to use it to treat *Pseudomonas syringae pv actinidiae* (Psa).

7. The Director-General may also reassess a product's registration if significant new information becomes available, or there has been a significant change in use.

8. Agricultural compounds that are hazardous substances or new organisms must also be approved by the Environmental Protection Authority (EPA) under the Hazardous Substances and New Organisms (HSNO) Act 1996. Hazardous substances or new organism may have their controls on use extended, or be reassessed under the HSNO Act.

Data protection

9. ACVM suppliers applying to register, or provisionally register, a particular trade name product in New Zealand must support their application with data on the product's features, such as chemistry and manufacturing, plant or animal safety, efficacy and the likelihood of residues remaining when used on crops or animals for human consumption. Some of this data will be New Zealand-specific to show how the product performs in New Zealand conditions. This data can cost between $10,000 and $500,000 to develop.[5]

10. Data protection prevents MPI from disclosing this supporting data or using it to assess other applications to register similar products during the protected period. Under the ACVM and HSNO Acts, data protection begins when an application to register an innovative trade name product is received under the ACVM Act and continues for five years after the registration decision.

[5] Irvine R and Denne T "*Data Protection for Agricultural Compounds and Veterinary Medicines*", Covec Ltd (2009)

11. In 2012 the Government decided [EGI MIN (12) 27/11 refers] to:

    a. extend data protection for "innovative" products in certain circumstances. Innovative products are those that contain an active ingredient not previously registered in New Zealand; and
    b. confer data protection on "non-innovative" products, including reformulations and new uses of these products. Non-innovative products are products that contain active ingredients previously registered here.

12. The ACVM Amendment Bill, currently before the House of Representatives, gives effect to these decisions. Submissions on the Bill to the Primary Production Committee revealed that there is now consensus between those ACVM suppliers and users who submitted that data protection should be increased beyond what is proposed in the ACVM Amendment Bill. In light of this, MPI has re-evaluated the policy.

Current data protection arrangements

ACVM Act Process	Nature of the product	Current ACVM and HSNO Act protection
Application for registration (s9 (1)) or provisional registration (s26)	Innovative product containing an active ingredient not previously registered in New Zealand	5 years
	Non-innovative product containing an active ingredient previously registered in New Zealand	0
New use or reformulation of an existing registered product (achieved by varying the condition of the original products registration (s 9(2))	Innovative use or significant reformulation	0
	Non-innovative use or reformulation	0
Reassessment (s29) (s30)	Reassessment	0
Other relevant legislation		Official Information Act 1982; Patents Act 1953; Patents Act 2013

13. Data protection is different to patent law in that it does not confer market exclusivity. Patents enable the holder of a patent to restrict other parties from using their idea without their approval. Data protection does not stop other parties from generating their own data and registering a competing product.

Approaches of other jurisdictions

14. New Zealand implemented data protection for agricultural compounds (previously called pesticides and animal remedies) in 1995 to meet its obligation under the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Article 39.3 of the TRIPS Agreement requires signatories to provide some form of data protection for agricultural chemicals that involve new chemical entities but does not set a minimum period of protection.

15. Approaches to data protection vary significantly across different comparable jurisdictions, such as Australia, Canada, the USA, Korea and Japan, with most comparable jurisdictions having at least 10 years' protection for products containing new active ingredients (innovative) and new uses for products already containing existing active ingredients (innovative use or significant reformulation).

PROBLEM DEFINITION

16. ACVM suppliers value data protection because it prevents subsequent applicants from free-riding on the costly research of the original applicant. Generating supporting data is expensive and New Zealand's market size is small, making the business case for developing data and registering a product marginal for some products. This is particularly so in the case of smaller horticultural and agricultural sectors.

17. ACVM suppliers have long argued that the current data protection regime inhibits the supply of products to the New Zealand market. Suppliers argue that the current data protection regime in the ACVM Act and HSNO Act does not provide a sufficient data protection period to enable registrants to recoup data development costs. The types of registrations where data protection has been identified as an issue include:

    a. registration of new innovative products;
    b. registration of new uses for innovative and non-innovative products;
    c. registration of reformulations of registered products; and
    d. reassessments of existing registered products.

18. ACVM users have identified a number of consequences that flow from not having access to agricultural compounds and veterinary medicines, including:

    a. fewer options to manage pests and diseases and enhance productivity, resulting in:
        i. increased pesticide and antimicrobial resistance;
        ii. insufficient tools to support integrated pest management; and
        iii. adverse environmental, food safety and occupational health and safety impacts associated with newer and safer products not becoming available;
    b. increased off-label uses, creating trade risks associated with breaching the default Maximum Residue Limit (MRL);
    c. weak competition in the market as substitute products are not introduced to compete with existing registered products;
    d. low productivity and international competitiveness, particularly for smaller sectors; and
    e. lower levels of investment in research and development and greater innovation.

19. User stakeholders have identified a number of agricultural compound and veterinary medicine products that are available to their competitors in countries such as Australia, Canada, the USA, Korea and Japan.[6]

[6] Irvine R and Denne T "*Data Protection for Agricultural Compounds and Veterinary Medicines*", Covec Ltd (2009)

POLICY OBJECTIVES

20. The policy objectives are to ensure that the ACVM Act's data protection regime:

    a. supports primary industry productivity and international competitiveness by encouraging:

        i. registration of innovative agricultural compounds;
        ii. registration of non-innovative agricultural compounds and reformulations;
        iii. registration of new uses for registered agricultural compounds;
        iv. provision of data to support reassessments; and

    b. promotes competition in New Zealand agricultural compound and veterinary medicine product markets.

21. In addition, the ACVM Act's data protection regime must meet the following critical success factors:

    a. be consistent with New Zealand's international obligations;
    b. be supported by users and suppliers of agricultural compounds; and
    c. be simple and cost effective for government and industry.

Optimal data protection period

22. The objective of data protection is to give the original applicant time to recover the costs of developing the supporting data before suppliers of competing 'generic' products can use their data to enter the market.[7] An optimal data protection period will occur where the benefits of encouraging development and registration of new product and uses equals the cost of delaying competition.[8]

23. Any fixed period of protection is somewhat arbitrary given that costs are not uniform and different products have different pay-back periods.[9] Any fixed period will over-compensate in some cases and under-compensate in others. Determining the appropriate data protection period requires a value based trade-off between competing objectives, drawing on the perspectives of ACVM suppliers and users.

[7] "*Impacts of proposed data protection for Agvet chemicals*", Centre for International Economics (2002).

[8] Henry Grabowski, "Follow-on Biologics: Data Exclusivity and the Balance between Innovation and Competition." *Nature Reviews: Drug Discovery* 7 (2008). Recent break-even lifetime analysis of new biological entities in the medical field identified break even points of between 12.9 and 16.2 years (at discount rates of 11.5% and 12.5% respectively).

[9] Linfong Tzeng, "Follow-on Biologics, Data Exclusivity and the FDA" Berkley Technology Law Journal [Vol. 25:135] (2010), 155.

OPTIONS

24. The options are:

    a. Option 1: Maintain the status quo of five years data protection for innovative products in the ACVM Act
    b. Option 2: Continue with the data protection regime proposed in the current ACVM Amendment Bill; or
    c. Option 3: Revise the data protection regime in the ACVM Amendment Bill to align with the views of ACVM users and suppliers.

25. The following table outlines how these options would work in each of the ACVM registration categories.

Data protection options

ACVM Act Registration Category[10]	Nature of the product/use	Option 1: Status quo	Option 2: ACVM Amendment Bill	Option 3: Further increases to data protection
Application for registration (s9 (1)) or provisional registration (s26)	Innovative (new active ingredient)	5 years	5 years, extendable to 8 years.	10 years
	Non-innovative or reformulation	0 years	3 years	5 years
New use for a registered product (achieved by varying the condition of the original products registration (s 9(2))	Innovative use	0 years	0 but 1 year would be added (up to a maximum of 3) to the base protection period for the original innovative application for each additional use registered within a 3 year period	Protected for duration of the original registration; or five years (whichever is longer)[11]
	Non-innovative use	0 years	3 years	5 years
Reassessment (s29) (s30)		0	0	5 years

[10] Note: protection only applies to confidential supporting information. Confidential supporting information is information which relates to trade secrets and commercially valuable information provided in support of an application to MPI.

[11] Note: MPI proposes that under this option, applications that would be eligible for data protection would include applications that result in a variation in conditions on the registration to permit a change in:

    a. the purposes for which an agricultural compound can be used; or
    b. how the agricultural compound is applied

Other reform options not assessed

26. MPI has not considered a compulsory compensation regime that would require other firms in the market to compensate the original registrant/data-holder for the cost of providing the data required. Evidence from the USA and Australia is that such arrangements are complex, difficult to administer and enforce, and costly for industry and regulators.

27. MPI has considered the non-regulatory options associated with its existing co-funding programmes. This regulatory impact statement is focused on revisions to the ACVM Amendment Bill in the House. Co-funding options already exist under the Sustainable Farming Fund and the Primary Growth Partnership. MPI has previously worked with 12 grower groups and six agrichemical companies to:

    a. make the registration process more efficient, less costly and more achievable to small industry groups;
    b. register some new agrichemicals for participating minor crops to allow producers to reduce reliance on older, less environmentally friendly options

28. MPI and the Ministry for the Environment (MfE) have not considered widening the scope of data protection under the HSNO Act further than innovative products and new uses. The ACVM Act is seen as the more appropriate mechanism for implementing data protection, due to its more narrow focus on registering products and uses, rather than substances and conditions.

IMPACT ANALYSIS

29. The table below assesses the options against each of the policy objectives based on fit with the objective and ranks each option against each other on the objectives. The comment section assesses the impact of data protection on registrations and competition.

Objective	Option 1: Status quo	Option 2: (as per ACVM Amendment Bill)	Option 3: Larger protection increase
Encourage registration of new products	✓ – 3 ACVM suppliers submitted that longer data protection is necessary	✓ – 2 ACVM suppliers submitted that longer data protection is necessary	✓ – 1 ACVM suppliers submitted that this should be sufficient
Encourage registration of non-innovative products and reformulations	✓ – 3 ACVM suppliers submitted that longer data protection is necessary	✓ – 2 ACVM suppliers submitted that longer data protection is necessary	✓ – 1 ACVM suppliers submitted that this should be sufficient
Encourage registration of new uses	✓ – 3 ACVM suppliers submitted that longer data protection is necessary	✓ – 2 ACVM suppliers submitted that longer data protection is necessary	✓ – 1 ACVM suppliers submitted that this should be sufficient
Encourage provision of data to support reassessments	✓ – 3 ACVM suppliers submitted that longer data protection is necessary	✓ – 2 ACVM suppliers submitted that longer data protection is necessary	✓ – 1 ACVM suppliers submitted that this should be sufficient
Encourage competition	✓ – 1 Short term: short duration and narrow scope creates weak barriers to entry for generic suppliers Medium term: substitute products/uses not registered, inhibiting creation of new competitive markets for generics to enter once data protection expires	✓ – 2 Short term: relatively short duration and narrow scope creates moderate barriers to entry for generic suppliers Medium term: substitute products/uses not registered, inhibiting creation of new competitive markets for generics to enter once data protection expires	✓ – 3 Short term: relatively long durations and wide scope creates strong barriers to entry for generic suppliers Medium term: many more substitute products/uses are registered, creating new competitive markets for generics to enter once data protection expires
Not inconsistent with international obligations	✗ – 3 Consistent with TRIPS Agreement but inconsistent with Trans-Pacific Partnership	✗ – 2 Consistent with TRIPS Agreement but inconsistent with Trans-Pacific Partnership	✓ – 1 Consistent with TRIPS Agreement and Trans-Pacific Partnership
Supported by users and suppliers	✗ – 3 ACVM users and suppliers submitted that longer data protection is necessary	✓ – 2 ACVM users and suppliers submitted that longer data protection is necessary	✓ – 1 ACVM users and suppliers submitted that this length of data protection should be sufficient
Simple and cost effective for government and industry	✓ – 1 Simple and easy to implement	✗ – 3 More complex and harder to implement	✓ – 2 Simpler than option 2 and easier to implement

Key:
– ✓ indicates that a criteria meets the objective ✗ indicates that a criteria does not meet the objective
– **1, 2 or 3** indicates the ranking against the criteria, with **1** being most preferred and **3** being least preferred

Impact of data protection on willingness of suppliers to register new products and support reassessments

30. When suppliers have longer to recoup data development costs, they are more likely to register new products and uses, and continue to support reassessed products. Key benefits of this include:

    a. more options to manage pests and diseases and enhance productivity, resulting in:
        i. lower pesticide and antimicrobial resistance;
        ii. more effective tools to support integrated pest management;
        iii. fewer adverse environmental, food safety and occupational health and safety impacts as newer and safer products become available;
    b. less off-label use, creating fewer trade risks associated with breaching the default maximum residue limit rates;
    c. stronger competition in the market as substitute products are introduced over time to compete with registered products;
    d. higher productivity and international competitiveness, particularly for smaller sectors; and
    e. higher levels of investment in research and development and greater innovation.

Impact on competition in the short-term

New products and uses

31. Assessing the impact of data protection on competition is challenging in New Zealand. Data protection theory suggests that data protection can, for the duration of the protection period, decrease competition in individual product markets and potentially result in monopoly outcomes and lower consumer welfare, such as higher prices, less choice, less supply security and lower service levels. In the case of reassessments, data protection could force "generic" competitors out of a market.

32. The monopoly created by data protection is, however, relatively confined. Data protection does not prevent new entrants from entering and competing on price or service if there is a viable business case. There are a range of options available to mitigate against reduced competition, including:

    a. individual competing suppliers developing their own data;
    b. individual competing suppliers contracting with the data owners to rely on their data; or
    c. some combination of user, supplier or government funding.

33. If no supplier is willing to register an active ingredient or use, then a market for a type of active ingredient or use may not develop and therefore no competition may occur. If there are few substitute products, this will result in a worse competitive outcome for the end users.

Reassessments

34. A particular risk exists in relation to reassessments. That is the risk that when an agricultural compound is reassessed, generic suppliers which cannot provide data are:

    a. de-registered until the data protection period expires; or
    b. regulated with stricter conditions while the participating supplier operates with less strict-conditions.

35. While this risk is real, if no company is willing to provide data, all suppliers of a type of agricultural compound under reassessment may be forced to leave the market, or accept stricter conditions.

Impact on larger sectors

36. Larger sectors that can attract registration of new products or uses could be adversely affected by the anti-competitive effects of the new policy in the short run as it could take longer for competitors to enter the market. However, this impact may be off-set by registrants introducing products at lower prices as a result of having longer to recoup data development costs. Changing data protection rules will not affect the significant number of products already available to these larger sectors, and may encourage registration of newer products for these sectors. ACVM users representing larger sectors were supportive of increased data protection.

Impact on smaller sectors

37. Smaller sectors may be impacted by less competition associated with longer data protection. However, these sectors are likely to be impacted more by not having access to new and existing ACVMs as they affect sectors' ability to operate and maintain production. The costs associated with increased data protection may be more than offset by the introduction of new products and uses and, over the medium term, increased competition in the supply of these products. ACVM users that represent smaller sectors were generally supportive of increased data protection.

Impact on competition in the medium term

38. Over the medium term, it can be expected that increased registrations will translate into increased competition as data protection lapses and generics enter the new markets created by the new registrations. This should in turn result in competitive outcomes and higher consumer welfare, such as lower prices, greater choice, more supply security and higher service levels.

CONSULTATION

39. Data protection for agricultural compounds has been the subject of numerous rounds of consultation in 2006[12], 2009[13], and 2011[14]. ACVM suppliers were all in favour of greater data protection than is proposed in option 2 or option 1. The majority of horticultural user stakeholders preferred greater data protection than is proposed in option 2 or option 1. A key group of agricultural user stakeholders preferred the data protection offered in line with option 2.

40. In October 2015, the Primary Production Committee consulted on the ACVM Amendment Bill (option 2). Nine submissions were received representing all major ACVM users and suppliers. The consultation revealed that there was now consensus amongst ACVM users on the need to provide greater levels of data protection than option 2.

CONCLUSION

41. MPI's preferred option is option 3 for the following reasons:

    a. Option 3 will better encourage registration of more new products and uses and provision of data to support reassessments than option 1 or option 2.

    b. The net impact of option 3 on competition is unclear. It is ranked lower than option 2 or option 1 due to the short term impacts, but in the medium term more registrations of products will increase substitutes and provide more markets for generics to enter, which will significantly enhance medium and long term competition.

    c. Option 3 is consistent with New Zealand's international obligations and will bring New Zealand into alignment with the approach taken to data protection by overseas comparable countries, while option 2 and option 1 would not.

    d. ACVM user and supplier stakeholders indicated a preference for greater data protection than is offered under option 1 or 2.

42. Overall MPI considers that the benefits of increased registrations of new products and uses and more competition in the medium term are likely to outweigh the negative impact on competition in the short term.

[12]The former New Zealand Food Safety Authority, Environmental Risk Management Authority, and Ministry of Economic Development; now Ministry for Primary Industries, Environmental Protection Authority, and Ministry of Business, Innovation and Employment)

[13]Data Protection for Agricultural Compounds - NZFSA Public Discussion Paper No 07/09, July 2009

[14]Data Protection for Agricultural Compounds: Summary of Submission – MPI Information Paper No: 2012/11

IMPLEMENTATION

43. The proposals will be given effect by repealing and replacing Part 6 of the ACVM Act. Consequential amendments will be needed to the HSNO Act to ensure alignment. MPI will implement the new provisions under the ACVM Act. The Environmental Protection Agency (EPA) will implement the proposals under the HSNO Act.

44. MPI and the EPA will develop guidance material on the changes in discussion with affected parties, including other interested government agencies. There will be additional administrative costs including:

    - one-off implementation costs (over $100,000)
        - updating of forms, information requirements and guidance documents for both internal and external stakeholders;
        - communications for applicants on the new rules via publications and/or workshops; and
        - updating the database to allow for capture of, and reporting on, data protection information.

    - ongoing operational costs
        - an increased number of applications will require screening to determine whether they are eligible for data protection. Alternatively, where an applicant is trying to "piggy back" off another product, it will need to be determined whether they can do so (whether there is data protection for the referenced product);
        - monitoring of data protection periods and associated products for both internal and external use;
        - processing queries by registrants about whether MPI used its data to process other applications; and
        - managing the interface with the HSNO Act.

45. All ACVM registrations are cost recovered, so no additional Crown funding will be required. MPI will monitor the impact on its costs through its memorandum accounting and will evaluate whether any revision to costs will be necessary. At this stage the impact is not expected to be significant and, given the strong level of industry support for increased data protection, increase cost recovery is unlikely to be controversial with ACVM suppliers.

MONITORING, EVALUATION AND REVIEW

46. MPI will monitor the changes in registrations by application type and will be able to observe whether the policy changes impact registrations. This will help inform whether the objectives of promoting registration of new products and uses has been achieved. It will also help inform whether it has resulted in increased research and development in New Zealand. MPI will survey user stakeholders to evaluate the impact of changes on market competitiveness and whether the expected benefits for users were realised.

47. In its role as regulatory steward, MPI will continue to monitor the need for legislative amendments to the ACVM Act. This could potentially include amendments to the data protection regime if necessary. Any proposals to amend the ACVM Act would be consulted with stakeholders.

APPENDIX 1: APPROACHES OF SELECT JURISDICTIONS TO DATA PROTECTION FOR AGRICULTURAL CHEMICALS

48. Please note that due to differences in terminology, application and legal systems it is difficult to provide an accurate comparison on data protection regimes. The following table is therefore only indicative and should not be relied upon as definitive.

Application type		EU[15] data protection periods	Australia[16] data protection periods	USA[17] data protection periods	Canada[18] data protection periods for pest control products	New Zealand data protection periods
First registration	Innovative registration – new active ingredient not previously registered	10 years exclusive data protection (except for low-risk plant protection products which attract 13 year protection)	10 years exclusive data protection for new active ingredient 10 years exclusive data protection for innovative product	10 years extendable to 13 years with new minor uses 1 additional year for each 3 minor use applied for within the first 7 years to a maximum total of 13 years 15 years compensable protection	10 years exclusive data protection for new active ingredient 1 additional year for each 3 minor uses applied for within the first 7 years to a maximum total of 15 years	5 years exclusive data protection
	Non-innovative registration – contains an existing active ingredient previously registered	10 years exclusive data protection (except for low-risk plant protection products which attract 13 year protection)	5 years exclusive data protection for agricultural chemicals 3 years exclusive data protection for veterinary chemical products	10 years extendable to 13 years with new minor uses 1 additional year for each 3 minor use to a maximum total of 15 years to a maximum total of 13 years 15 years compensable protection	12 years compensable protection	0
New use registration	Registration containing an active ingredient previously registered	3 months for each additional minor use registered within first 5 years, up to a maximum total of 13 years (or 15 years for low-risk plant protection products)	5 years exclusive data protection for agricultural chemicals 3 years exclusive data protection for veterinary chemical products	10 years extendable to 13 years with new minor uses 1 additional year for each 3 minor use to a maximum total of 15 years to a maximum total of 13 years 15 years compensable protection	12 years compensable protection	0
	Change of conditions on a registration containing active ingredient previously registered	2.5 years exclusive data protection for “reviews and renewals”	5 years exclusive data protection for agricultural chemicals 3 years exclusive data protection for veterinary chemical products	*Unclear*	12 years compensable protection	0
Re-assessment	Re-assessment of existing products	2.5 years exclusive data protection for “reviews and renewals”	8 years exclusive data protection	*Unclear*	10 years exclusive data protection	0

Note on compensable data protection

49. Some jurisdictions provide compensable data protection regimes. Compensable data protection systems enable ‘generic’ product owners to apply to the applicant to use their data to register their products. These systems usually employ mediation and arbitration systems where agreement cannot be reached.

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15 Chapter V – Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009:

16 Section 37 – Agricultural and Veterinary Chemicals Code Act 1994

17 Section 3 – Federal Insecticide, Fungicide, and Rodenticide Act

18 Clause 17 – Pest Control Products Regulations