Protection of Confidential Information about Trade Name Products

ACVM guidance

IN THIS DOCUMENT

1 Background

The ACVM Amendment Bill was passed by Parliament and came into force on 8 November 2016. This amendment extended the period of protection for confidential information given in support of an application to register an innovative trade name product (TNP) and also expanded the scope of confidential information protection coverage to include confidential information supplied in support of applications to register non-innovative TNPs and use.

The amended Agricultural Compounds and Veterinary Medicines Act 1997 can be found on the New Zealand legislation website.

2 What has changed?

Summary of Changes		Previous provisions	New provisions
New Registrations	Innovative Trade Name Products*	5 years protection	10 years protection**
	Non-innovative Trade Name Products	No protection	5 years protection
New Provisional Registrations	Innovative Trade Name Products	5 years protection	5 years protection The protected period can be extended to 10 years from the date of refusal/granting of an innovative TNP registration, if it is the same innovative trade name

			product. Note: the confidential information protected in this section only relates to the confidential information submitted with the provisional registration application, and the application for registration must be received prior to the 5 years expiring.
	Non-innovative Trade Name Products*	No protection	5 years protection The protected period can be extended to 5 years from the date of refusal/granting of a non-innovative TNP registration of the same non-innovative trade name product. Note: the confidential information protected in this section only relates to the confidential information submitted with the provisional registration application, and the application for registration must be received prior to the 5 years expiring.
Variations to Registrations for one or more of the following situations: a) a purpose listed in the definition of an agricultural compound; b) rate at which the product is applied; c) when the product must or must not be applied; d) how the product is applied; e) the withholding period for the product.	Innovative Trade Name Products	No protection	Either the longer of two periods of: a) end date for the protected period for confidential information supporting an innovative TNP application that resulted in the registration of the product (i.e. 10 years); or b) 5 years from the granting or refusing the variation.
	Non-innovative Trade Name Products	No protection	5 years protection
Reassessment of Registrations	Trade Name Products	No protection	5 years protection

***** Innovative Trade Name Product (i.e. A1 product) refers to a product containing an innovative active ingredient, which means that the active ingredient is not in any previous registered product registered either under section 21, or a pesticide registered under the Pesticides Act 1979, or an animal remedy licensed under the Animal Remedies Act 1967. Any application which is formally received as an A1 (i.e. passed screening), , will remain as an A1 throughout the assessment process and will be entitled to 10 years data protection once registration is granted or refused. This will remain the case even if a different product containing the same innovative active(s) is formally received and registered during the assessment period of the originator A1 application.

** Confidential information protection commences on the date of granting or refusing of an application.

3 What does the applicant need to do?

Applicants must identify all confidential information supplied to MPI in support of an application eligible for protection of confidential information, using the form:

Identification of Confidential Information for the Purpose of Data Protection

B1 applications (i.e. application for a new product that is identical to existing registered product) and B2 applications where the only difference between the new product and an existing registered product is the trade name and registrant, do not require an Identification of Confidential Information for the Purpose of Data Protection form to be provided.

If confidential information is being provided by a third party (for example, manufacturing information provided separately to ACVM by the manufacturer of the product), the third party must provide a completed form with the confidential information submitted to ACVM. ACVM expect the third party to complete sections 1, 3, 4 and 5 of the Identification of Confidential Information for the Purpose of Data Protection form. It is the responsibility of the registrant to communicate this requirement to the third party.

The completed form(s) must be supplied with all appropriate applications. If the completed form(s) are not supplied, then the applicant will be requested to provide it before their application can progress to screening.

4 How does MPI receive confidential information?

Applicants are required to submit all information in support of an application electronically (please refer to the E-File Guidance to Applicants document available on our website).

MPI prefers all application documentation to be submitted by the MPI secure ShareFile system. Documentation can also be supplied by email to approvals@mpi.govt.nz (if file size is less than 25MB), or by supply of information on physical media (CDs, DVDs, USB sticks) by post/courier to:

Approvals Operations
Branch Planning, Systems & Support | Regulation and Assurance Branch
Ministry for Primary Industries | Pastoral House 25 The Terrace | PO Box 2526 | Wellington | New Zealand

After formal receipt of an application (i.e. passed screening), additional protected confidential information may also be provided by the applicant during the appraisal process when requested under s11 of the Act.

5 How does MPI handle confidential information?

Section 73 of the ACVM Act specifies the meaning of confidential information:

(1) In this Part, confidential information means information received by the Director-General that -

(a) is provided in support of an innovative TNP application, a non-innovative TNP application, or an application to authorise a new use or method of use; and

(b) is confidential information about the trade name product that is the subject of that application.

(2) For the purposes of subsection (1)(b), confidential information includes -

(a) trade secrets; and

(b) information with a commercial value that would, or would be likely to, be diminished by disclosure of the information.

Section 74A states the Director-General must protect confidential information during the protected period.

(1) The Director-General must, during the protected period that applies to confidential information,-
   (a) Take reasonable steps to ensure confidential information is kept confidential to the Director-General; and
   (b) Not use the confidential information in determining whether or not to grant any other innovative TNP application, non-innovative TNP application, or application to authorise a new use or method of use.

MPI adheres to the New Zealand Government Security System as outlined by the Protective Security Requirements (PSR). The New Zealand Government Security Classification System identifies official information that requires extra protection against unauthorised or accidental disclosure and limits access to that information and equipment through a series of procedural and/or physical barriers.

New Zealand Government security classifications fall under one of two categories:

> Policy and Privacy information, where compromise could affect the security or interests of individuals, groups, commercial entities, government business and the community.
>
> The classifications under this category are colour coded black and are:
>
> - IN-CONFIDENCE
> - SENSITIVE

The majority of confidential information received from applicants in support of applications for registration holds the IN-CONFIDENCE classification.

6 Under what circumstances can protected confidential information be disclosed?

The Director-General may disclose or use confidential information during the protected period in specific circumstances, as set out in section 74H of the Act:

(3) The Director-General may disclose the information, or use it in determining whether to grant an application other than the application to which the information relates or related, if—

> (a) the applicant who made the application to which the information relates or related has consented in writing to the disclosure or use of the information; or
> (b) the Director-General forms the opinion that the disclosure or use is necessary to protect the health or safety of members of the public.

(4) The Director-General may disclose the confidential information to 1 or more of the following persons or organisations if the Director-General is of the opinion that they will take reasonable steps to ensure that they will not disclose the information to any other person:

> (a) a government department or statutory body for the purposes of that government department or statutory body:
> (b) an adviser for the purposes of obtaining advice about the agricultural compound to which the information relates:
> (c) the World Health Organization:
> (d) the Office International des Epizooties:
> (e) the Food and Agriculture Organization:
> (f) a regulatory agency of a country that is a party to the Agreement Establishing the World Trade Organization adopted at Marrakesh on 15 April 1994 (commonly known as a WTO country):
> (g) a prescribed person or organisation or a person or an organisation within a prescribed class or prescribed classes of persons or organisations.

(5) For the purposes of subsection (3)(a), a person other than the applicant may grant consent to the disclosure or use of the confidential information if—

> (a) the applicant has notified the Director-General in writing that the person may grant consent (and the applicant has not withdrawn that permission); or
> (b) the applicant's rights in respect of the information have been transferred to the person and the applicant or the person has notified the Director-General in writing of the transfer.

7 How does MPI notify the applicant of which confidential information is protected?

MPI will provide a written acknowledgement that the applicant has identified certain information as confidential as of a particular date. This will include all confidential information supplied when the application was lodged, and all confidential information supplied during the processing of the application.

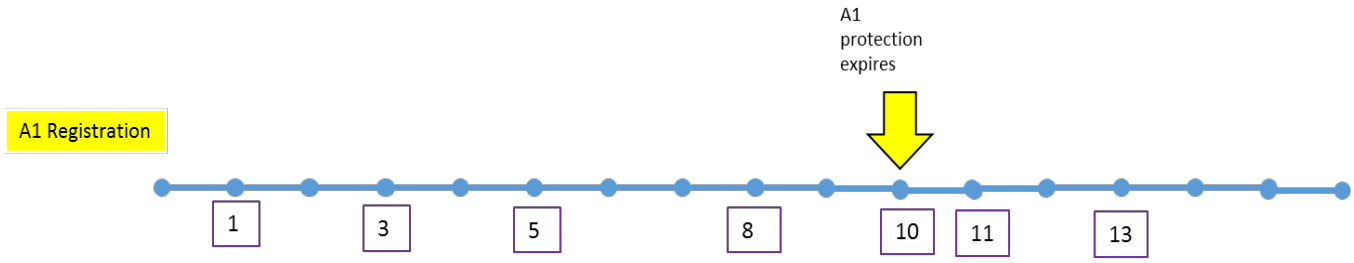
The acknowledgement will be provided as an MPI marked copy of the 'Identification of Confidential Information for the Purpose of Data Protection' form supplied with the application. This will then be sent to the applicant with the approval documentation.

8 Examples of applications where confidential information is protected

Some common examples are shown:

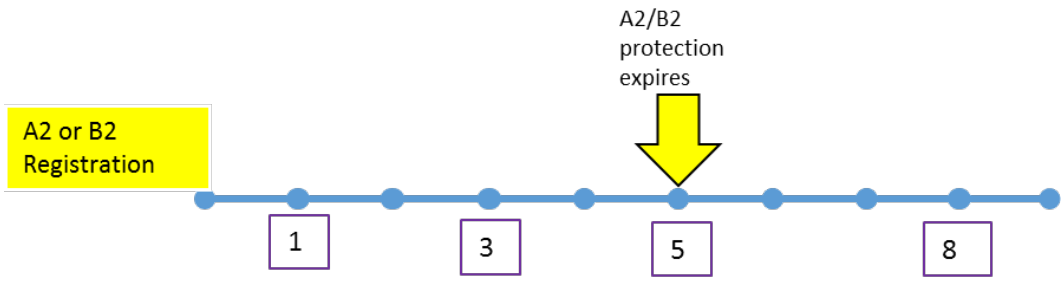
8.1 INNOVATIVE TNP FOR FULL REGISTRATION

Application Type	Confidential Information Protection Period
New Registration	
A1 New product with new active ingredient Confidential information supplied for an innovative trade name product containing a new active ingredient.	Protected period starts when application is received, ends 10 years after the date the application is granted or refused.



8.2 NON-INNOVATIVE TNP FOR FULL REGISTRATION

Application Type	Confidential Information Protection Period
New Registration	
A2 New product containing known active ingredient with new risk profile Confidential information supplied for a new product that does not contain a new active ingredient.	Protected period starts when application is received, ends 5 years after the date the application is granted or refused.
B2 Similar to a registered TNP	Protected period starts when application is received, ends 5 years after the date the application is granted or refused.



8.3 PROVISIONAL REGISTRATION FOLLOWED BY NEW REGISTRATION

New Provisional Registration	
Provisional Registration (innovative - new active ingredient) - Confidential information supplied for a provisional registration of an innovative product.	Protected period starts when application is received[1], ends 5 years after the date the application is granted or refused **Note:** The protected period can be extended to 10 years from the date of refusal/granting of an innovative TNP registration, if it is the same innovative trade name product.
Provisional Registration (non-innovative) - Confidential information supplied for a provisional registration of a non-innovative product.	Protected period starts when application is received, ends 5 years after the date the application is granted or refused. **Note:** The protected period can be extended to 5 years from the date of refusal/granting of a non-innovative TNP registration, if it is the same non-innovative trade name product.

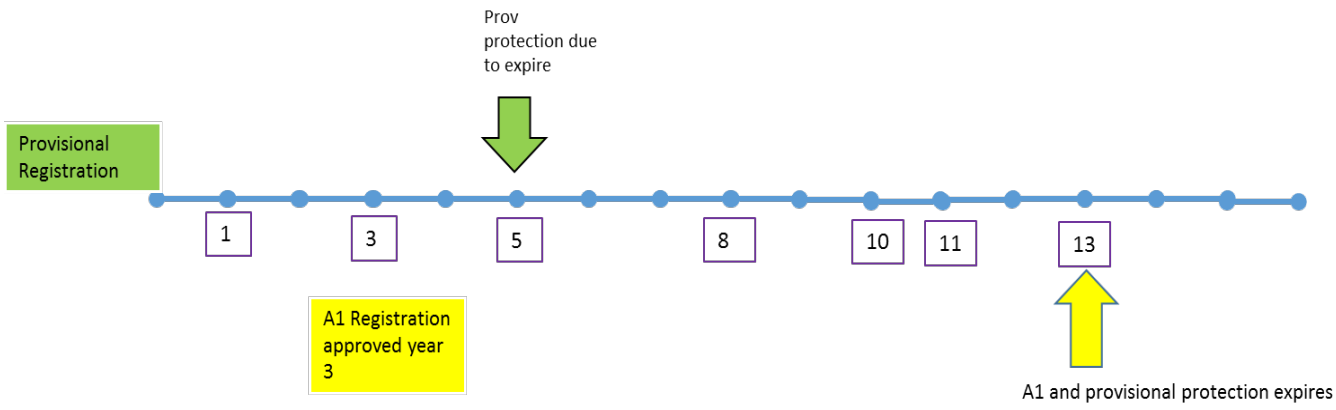
The Act states that for an innovative TNP application for provisional registration (section 74C), the protected period continues until the end of the protected period (i.e. 10 years) for confidential information supporting an innovative TNP application subsequently made under section 9(1) if:

- The application under section 9(1) is for the same trade name product; and
- The confidential information given in support of the application under section 26 is also given in support of the application under section 9(1); and
- The confidential information supporting the application under section 9(1) is received before the 5 years expires.

The same principle applies for a non-innovative TNP application for provisional registration. The Act states that for a non-innovative TNP application for provisional registration (section 74F), the protected period continues until the end of the protected period (i.e. 5 years) for confidential information supporting an innovative TNP application subsequently made under section 9(1) if

- The application under section 9(1) is for the same trade name product; and
- The confidential information given in support of the application under section 26 is also given in support of the application under section 9(1); and
- The confidential information supporting the application under section 9(1) is received before the 5 years expires.

Example: Innovative TNP with Provisional Registration, followed by A1 registration:

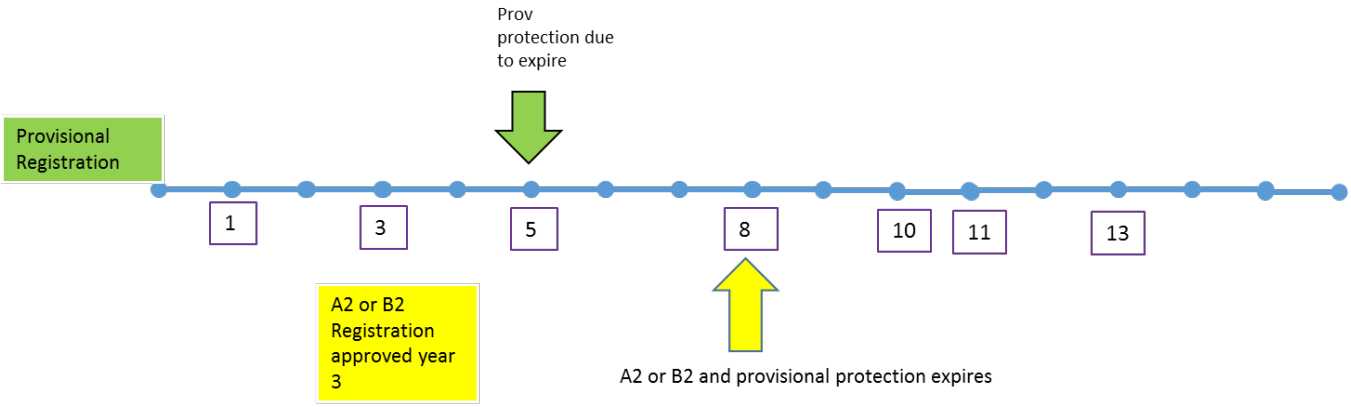


The confidential information protection period that began on the granting of the provisional registration of an innovative TNP expires after 5 years. If no new product registration is made within that 5 year protection period the confidential information protection expires.

If a new product registration is made at year 3 (i.e. A1 application), then the confidential information protection expiry date on all confidential information supplied (provisional and A1) is 10 years from the new product registration approval date.

The maximum confidential information protection period possible therefore is 15 years (10 + 5) in this situation.

Example: Non-Innovative TNP with Provisional Registration, followed by an A2 or B2 registration:



The confidential information protection period that began on the granting of the provisional registration of a non-innovative TNP expires after 5 years. If no new product registration is made within that 5 year protection period the confidential information protection expires.

If a new product registration is made at year 3 (i.e. B2 application), then the confidential information protection expiry date on all confidential information supplied (provisional and B2) is 8 years from the new product registration approval date.

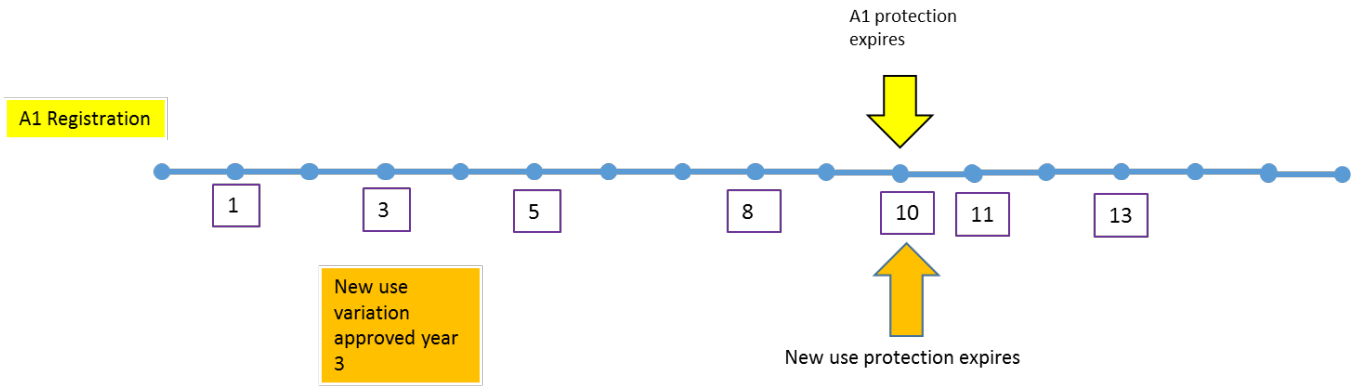
The maximum confidential information protection period possible therefore is 10 years (5 + 5) in this situation.

8.4 NEW INNOVATIVE TNP REGISTRATION FOLLOWED BY VARIATION APPLICATIONS

Variations (New Uses) to Innovative TNP Registration	
Confidential information supplied for a new use or method of use for an innovative product: **C4: AC/VM/VTA:** Extension of use to include an additional situation or target host **C5: AC** Addition of another disease, pest or weed; **VM** Addition of another disease/condition; **VTA** Addition/variation to the use situation for an existing target species **C6: AC/VTA** Change of application rate or timing; **VM** Change of dose regime **C7: AC** Change or addition of a method of application; **VM/VTA** Change to or addition of method of administration **C8:** Change in withholding period	Protected period starts when application is received. Ends either the **later** of the two periods of: a) end date for the protected period for confidential information supporting the innovative TNP application that resulted in the registration of the product (i.e. 10 years); or b) 5 years from the granting or refusing the variation.

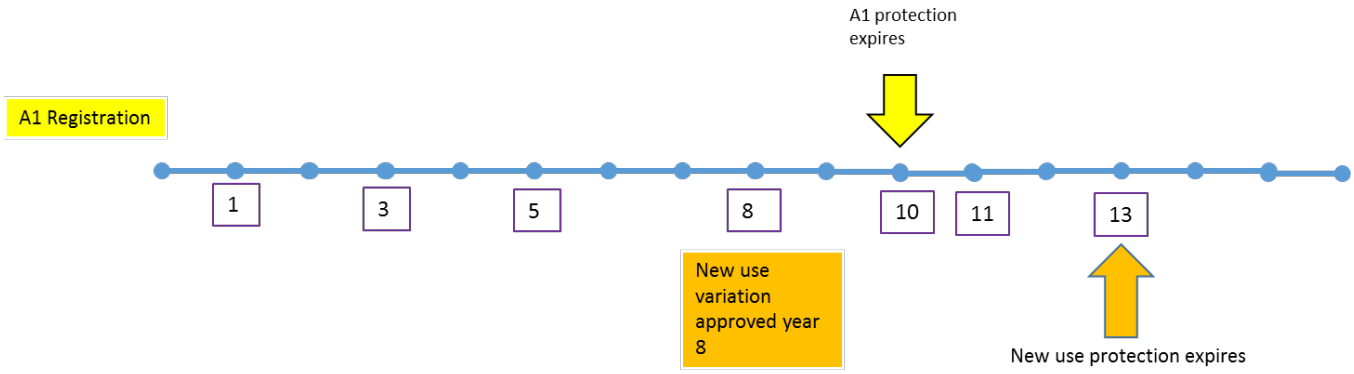
AC = agricultural compound, VM = veterinary medicine, VTA = vertebrate toxic agent

Example: Innovative TNP with New Product (A1) Registration, followed by a variation at year 3:



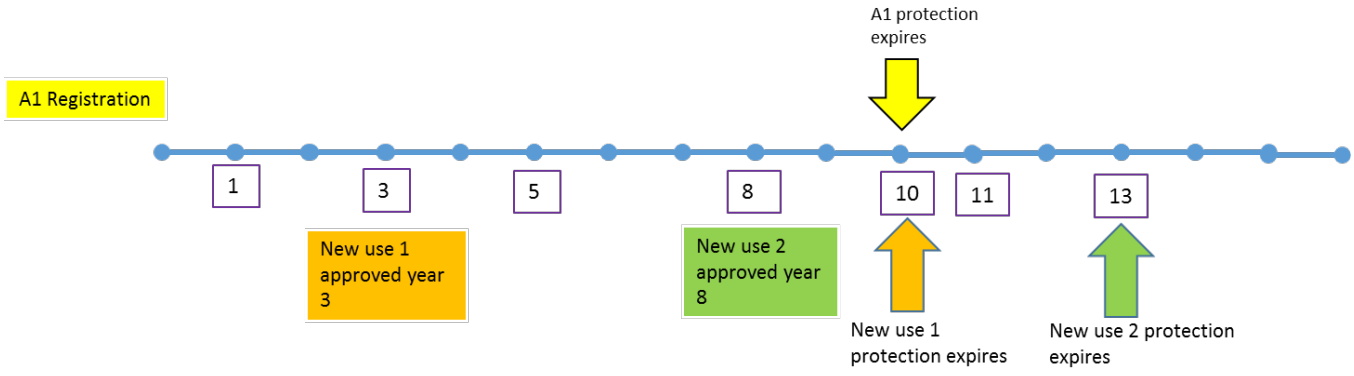
The confidential information protection period that began on the granting of the A1 registration of an innovative TNP expires after 10 years. If a new use variation is made at year 3 (i.e. C4 application), then the confidential information protection expiry date on all confidential information supplied (A1 and C4) is still 10 years from the new product registration approval date, and 7 years from the variation approval date.

Example: Innovative TNP with New Product (A1) Registration, followed by a variation at year 8:



The confidential information protection period that began on the granting of the A1 registration of an innovative TNP expires after 10 years. If a new use variation is made at year 3 (i.e. C4 application), then the confidential information protection expiry date on all confidential information supplied for the A1 is still 10 years from the new product registration approval date, and the confidential information protection expiry date on all confidential information supplied for the variation is 5 years from the variation approval date.

Example: Innovative TNP with New Product (A1) Registration, followed by a variation at year 3 and a variation at year 8:



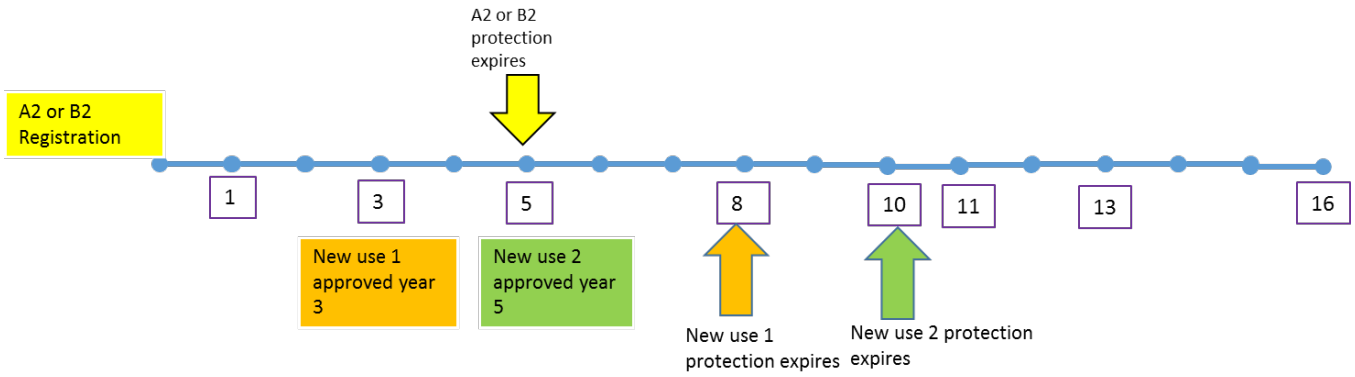
The confidential information protection period that began on the granting of the A1 registration of an innovative TNP expires after 10 years. If a new use variation is made at year 3 (i.e. C4 application), then the confidential information protection expiry date on all confidential information supplied (A1 and C4) is still 10 years from the new product registration approval date, and 7 years from the first variation approval date. The confidential information

protection expiry date on all confidential information supplied for variation 2 is 5 years from that variation approval date.

8.5 NEW NON-INNOVATIVE TNP REGISTRATION FOLLOWED BY VARIATION APPLICATIONS

Variations (New Uses) to NON-Innovative TNP Registration	
Confidential information supplied for a new use or method of use for an Innovative product: **C4: AC/VM/VTA:** Extension of use to include an additional situation or target host **C5: AC** Addition of another disease, pest or weed; **VM** Addition of another disease/ condition; **VTA** Addition/ variation to the use situation for an existing target species **C6: AC/VTA** Change of application rate or timing; **VM** Change of dose regime **C7: AC** Change or addition of a method of application; **VM/VTA** Change to or addition of method of administration **C8:** Change in withholding period	Protected period starts when application is received. Ends 5 years from the granting or refusing the variation.

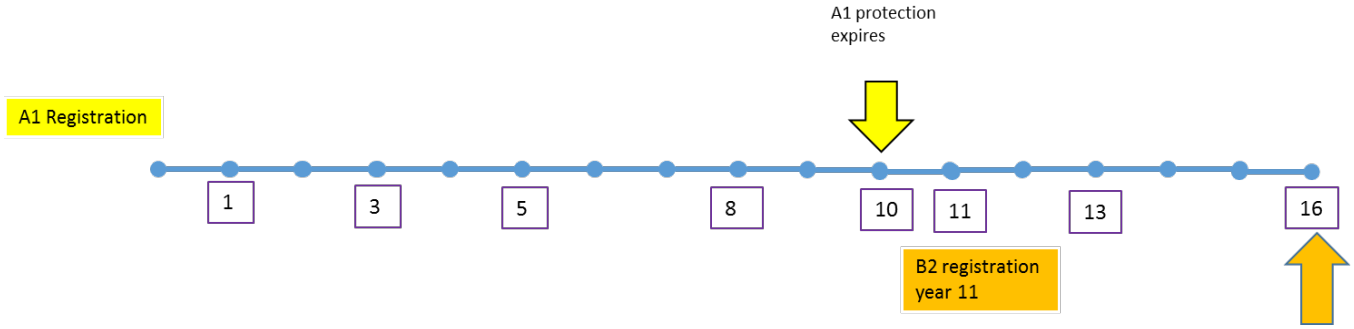
Example: Non-Innovative TNP with New Product (A2 or B2) Registration, followed by a new use variation at year 3 and a new use variation at year 5:



8.6 NEW TNP REGISTRATION FOLLOWED BY B1 OR B2 APPLICATIONS

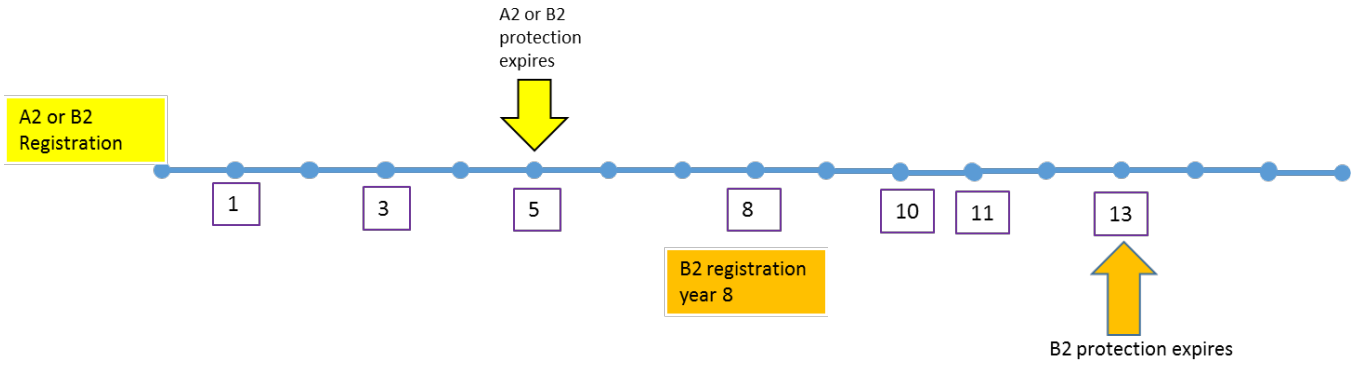
New Registration	
A1 New product with new active ingredient: Confidential information supplied for an innovative[2] trade name product containing a new active ingredient.	Protected period starts when application is received, ends 10 years after the date the application is granted or refused.
A2 New product containing known active ingredient with new risk profile: Confidential information supplied for a new product that does not contain a new active ingredient.	Protected period starts when application is received, ends 5 years after the date the application is granted or refused.
B2 Similar to a registered TNP	Protected period starts when application is received, ends 5 years after the date the application is granted or refused.

Example: Innovative TNP with New Product (A1) Registration, followed by a B2 registration at year 11:



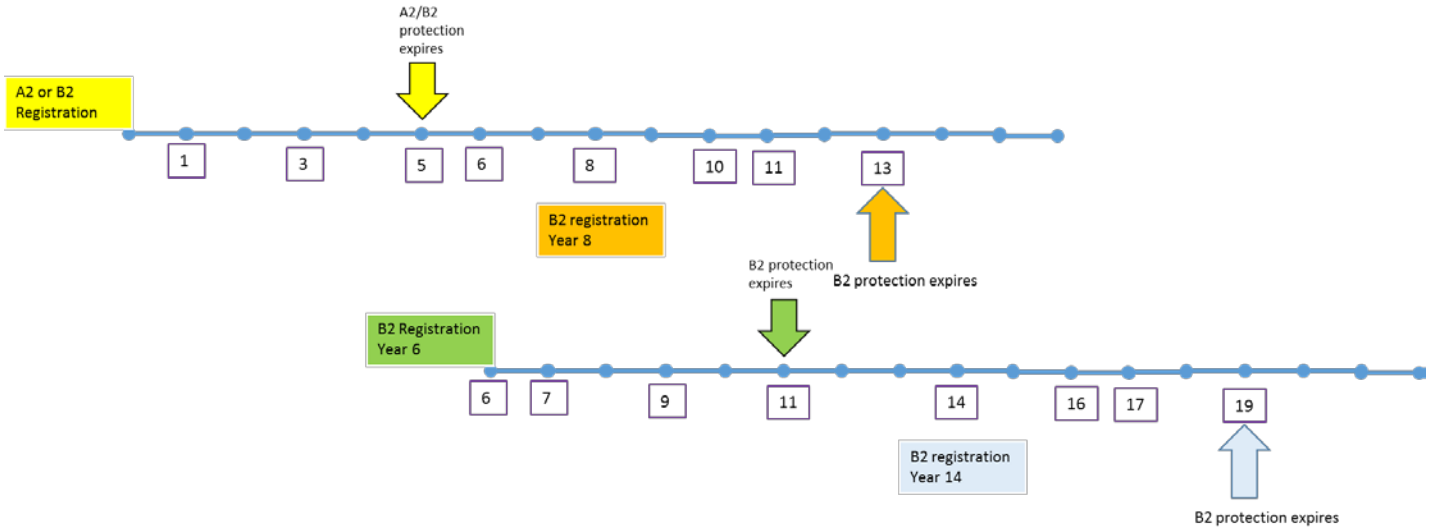
The confidential information supplied in the A1 registration can only be cross-referenced after the protection period expires at 10 years from the registration approval. The B2 registration will receive confidential information protection for 5 years on all confidential information supplied in that application, but not for any confidential information cross-referenced from the pioneer (A1) registration.

Example: Non-Innovative TNP with New Product (A2/B2) Registration, followed by a B2 registration at year 8:



The confidential information supplied in the A2 or B2 (Company A) registration can only be cross-referenced after the protection period expires at 5 years from the registration approval. The subsequent B2 registration made by company B will receive confidential information protection for 5 years on all confidential information supplied in that application, but not for any confidential information cross-referenced from the earlier A2 or B2 registration.

Example: Non-Innovative TNP with New Product (A2/B2) Registration, followed by multiple B2 registrations:



The confidential information supplied in the A2 or B2 registration can only be cross-referenced after the protection period expires at 5 years from the registration approval. The subsequent B2 registrations made by other companies will receive confidential information protection for 5 years on all confidential information supplied in that application, but not for any confidential information cross-referenced from the earlier A2 or B2 registrations.

8.7 VARIATION APPLICATIONS WITH OR WITHOUT NON-NEW USE CONFIDENTIAL INFORMATION

MPI only processes one application for a TNP at a time. An application may be for a new product registration, or to vary the conditions on a product. As a result an application may be of a single application type (e.g. C4 extension of use to include a new species, or a C3 change in shelf life), or may be of a multi-application type (C1, C2, C3, C5).

If an application containing a number of variations with the new use (e.g.C5 new use addition of new pest and C1 change in formulation and C2 change in manufacturing process) is submitted, then **only** the confidential information supplied in the new use variation is protected.

However, if an application containing a number of variations without a new use, such as C1: change in formulation, C2: change in manufacturing process, C3: change in shelf life/packaging or C9: administrative change is submitted, then **no** confidential information protection applies.

8.8 REASSESSMENTS

Reassessment of a Registration	
Reassessment	Protected period starts when confidential information is received, ends 5 years after the date the application is granted or refused.

The confidential information supplied in support of a reassessment receives 5 years' confidential information protection.