

**Requirements and guidelines for a particular batch shelf life extension permit for a registered veterinary chemical product**

**Guideline 48**

**Contents**

**1. INTRODUCTION ..... 1**

1.1. Batch extension of shelf life is given effect by a permit ..... 1

1.2. Guideline scope..... 1

1.3. Application category, fee and timeframe ..... 2

**2. REQUIREMENTS ..... 2**

2.1. General requirements..... 2

2.2. Application requirements ..... 2

2.3. Data requirements ..... 3

2.4. Data modules ..... 4

**3. LABEL OVERSTICKERS ..... 5**

**Revision history ..... 5**



## 1. INTRODUCTION

Veterinary chemical products may reach their expiry date whilst remaining within specifications and are therefore suitable for use beyond the original label expiry date. The purpose of this guideline is to outline the procedures and requirements for assessment of applications to extend the shelf life of a particular batch or batches of a registered veterinary chemical product.

Application for a general extension of the product shelf life must be made under Category 14.

If the APVMA has recently granted an extension of the product shelf life, the registrant may make an application to extend the shelf life of a particular batch to reflect the new shelf life of the product.

The APVMA will not grant an extension of shelf life that is more than 50% of the existing approved shelf life. The maximum extension that the APVMA will grant is 12 months.

If granted, the extension of shelf life of a particular batch will only apply to stock stored under the conditions specified on the label and the product will have typically been held at the wholesale level of distribution.

### 1.1. Batch extension of shelf life is given effect by a permit

Section 91(2) of the Agvet Code, which deals with supply of date-controlled chemical products, states:

*91(2) If the container of a date controlled chemical product has attached to it a label containing an expiry date, a person must not, without reasonable excuse, after that date, supply, or cause or permit to be supplied, the product that is in the container unless:*

- (a) The person is authorised to do so by a permit: or*
- (b) The person does so on a date that, despite the date on the label, is earlier than the date that is required to be contained on the label as a condition of the registration of the product.*

Therefore, a person must not supply a date controlled chemical product beyond the expiry date displayed on the approved label unless authorised to do so by an APVMA permit issued under section 112 or section 114 of the Agvet Code.

This means that an application for extension of shelf life of a particular batch of a product is an application for the issue of a permit. The relevant application category is Category 23. The issued permit will allow the registrant to use an appropriate label oversticker.

### 1.2. Guideline scope

This guideline applies only to products which are not immunobiological products. Specific requirements and guidelines for immunobiological products are set out in Guideline 49.

### 1.3. Application category, fee and timeframe

Application must be made under Category 23. Category 23 is a modular category, therefore the applicable fee and timeframe depend on which of the modules are required for assessment of the application.

To calculate the statutory timeframe for an application, the longest assessment period for the specific data modules should be added to the timeframe for the relevant finalisation module.

Further information is set out in *Category 23* in Volume 2: Category requirements and guidelines.

## 2. REQUIREMENTS

### 2.1. General requirements

The product that is the subject of an application for an extension of shelf life for a particular batch, must:

- be registered and have an existing APVMA approved shelf life of at least 12 months; and
- have been manufactured and undergone pre-release quality control testing in premises for which the APVMA has issued a licence or been recognised under the Manufacturers' Licensing Scheme, to manufacture and test the product.

### 2.2. Application requirements

The Category 23 application form is available on the APVMA website.

Applications must include:

- a list of the batches pertaining to the application, including: batch numbers, dates of manufacture, original expiry dates, proposed expiry dates, storage locations (eg warehouse addresses) and storage conditions
- a copy of the product release and expiry specifications
- the initial (pre-release quality control) test results of all listed batches
- the current test results of samples of the listed batches close to the expiry time at each storage location
- for the active constituents: analytical method details and validation data, including representative sample chromatograms (where applicable), or reference to previously assessed validated analytical methods (eg application number and analytical method number where available); and
- the draft label over sticker.

If the APVMA has recently granted a shelf life extension to the registered product, only the following should be included with the application:

- a list of the batches pertaining to this application, including: batch numbers, dates of manufacture, original expiry dates, proposed expiry dates, storage locations (eg warehouses) and storage conditions; and
- the draft label over sticker.

### **2.3. Data requirements**

The following data requirements and conditions must all be met:

- the samples must be drawn from warehouse<sup>1</sup> stock that was stored under the conditions specified on the label and the storage conditions have been documented or otherwise assured
- all registered product expiry specification parameters must be tested and conformance with the limits demonstrated
- the samples must have been analysed at an APVMA-licensed, or recognised laboratory
- testing must be conducted using validated analytical methods or reference made to previously assessed methods
- the approved shelf life of the registered product must be based on stability data the APVMA has assessed. For registered products where this is not the case, applicants should also make an application for shelf life confirmation (see MORAG Category 14)<sup>2</sup>; and
- the results should be obtained as close as practicable to the existing expiry dates of the batches and allow prediction to the proposed expiry dates.

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<sup>1</sup> Retailers are generally not suitable unless acceptable storage condition data can be provided for all stock locations.

<sup>2</sup> Registrants should contact the APVMA to verify that stability data have previously been supplied to support the approved shelf life of the registered product.

## 2.4. Data modules

**Example 1:** Application is made to extend the shelf life of three batches of a veterinary product for 12 months longer than the currently-approved 36 month shelf life of the product. The submission includes supporting data for the particular batches of product.

The following modules are expected to apply:

Module	Description	Fee	Timeframe
Module 1	Screening	\$460	
Module 2.4	Chemistry – Level 4	\$180	3 months
Module 11.4	Finalisation	\$145	2 months
<b>Total fee:</b>		<b><u>\$785</u></b>	
<b>Timeframe:</b>			<b>5 months</b>

**Example 2:** Application is made to extend the shelf life of one batch of a veterinary product. The APVMA has recently granted a 12-month extension of shelf life for the product and the applicant wishes to over-sticker the labels of one existing batch of the product with an amended expiry date to reflect the new approved shelf life. The applicant has provided scientific argument, including warehouse storage location and conditions for the particular batch, to justify the application.

The following modules are expected to apply:

Module	Description	Fee	Timeframe
Module 1	Screening	\$460	
Module 11.4	Finalisation	\$145	2 months
<b>Total fee:</b>		<b><u>\$605</u></b>	
<b>Timeframe:</b>			<b>2 months</b>

**Note:** The APVMA will endeavour to process all permit applications to extend the shelf life of a particular batch of product well within the legislated timeframe.

### 3. LABEL OVERSTICKERS

To reflect the adjusted expiry date, registrants must apply a label over sticker to the relevant batches. The permit conditions will provide the specific wording of the label over sticker.

As a guide, a label over sticker will contain the amended/adjusted expiry date of not greater than (the proposed new shelf life) months after the date of manufacture and the statement:

“Extension of shelf life has been approved by the APVMA under permit PER...”.

**Note:** Overstickering of labels must occur at an APVMA-licensed, or recognised facility that is licensed to label a finished product.

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### Revision history

Revision date	Description of revision
1 June 2002 1 <sup>st</sup> edition	<ul style="list-style-type: none"><li>• first edition</li></ul>
1 December 2007 2 <sup>nd</sup> edition	<ul style="list-style-type: none"><li>• complete revision of content and layout</li></ul>