



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



CONTINUATION FRAMEWORK

Discussion Paper

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CHAPTER 1

INTRODUCTION

1.1 Background

The Australian community has an expectation that the agricultural and veterinary (agvet) chemicals registered for use in Australia are safe and effective, meeting standards equivalent to those required in comparable countries. The objective of the Code scheduled to the *Agricultural and Veterinary Chemicals Code 1994* (the Agvet Code)¹ is to provide a national framework for the regulation of agvet chemicals in Australia, so as to ensure their quality, safety to people and the environment and that they are effective. The Agvet Code also recognises the importance of international trade to Australia's primary industries. The regulatory framework facilitates overseas confidence in the safety of Australia's agricultural produce by ensuring that agvet chemicals used in Australian primary production are safe and consistent with internationally accepted standards.

In 2011 the Australian Government agreed to several reform measures to strengthen the regulatory framework for agvet chemicals including the delivery of contemporary legislation. One of the reforms includes the introduction of a mandatory re-registration regime (referred to as 'continuation' in the Australian context) to ensure the ongoing safety of agvet chemicals. The continuation scheme will systematically consider the entire chemical inventory and has been designed to minimise impacts on affected businesses.

1.2 Purpose

This document describes the implementation and administration of the continuation scheme including:

- an explanation of continuation
- how the continuation scheme will operate
- a description of the key elements of the continuation scheme

- how the continuation period for an agvet chemical will be decided
- how the APVMA will prioritise the assessment of Australia's existing chemical inventory

1.3 Scope

This document describes the operational arrangements for the continuation of approval and registration scheme proposed in the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011, which was released on 15 November 2011. The document is intended to inform discussion and aid consultation on the government's agvet chemical reform agenda. Any feedback in relation to this discussion paper will be forwarded to the Department of Agriculture, Fisheries and Forestry (DAFF) which is responsible for the development of the Agricultural and Veterinary Chemicals Legislation. It is intended that a revised framework document will be made available following the outcomes of the government's current consultation process and passage of the amendment bill.

1.4 Context

A brief overview of the history of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) is included at Appendix 1. At the commencement of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) in March 1995 a national system for the reconsideration of existing registrations and approvals of agvet chemicals was introduced. The reconsideration scheme (referred to as chemical review) provides a mechanism to examine new information that may arise post-registration about the hazards and risks associated with the ongoing use of registered agvet chemical products. The scheme also provides a mechanism for appropriate regulatory action to be taken where such information is found to be scientifically valid and to identify issues of concern. New information in relation to registered agvet chemicals and their effects on plants, animals, people and the environment may become available through many avenues, including advancements in scientific methodology or knowledge and information gained through experience with their use.

Unlike some other regulatory systems, such as the United States (US) and the European Union (EU), the NRS has not had a 're-registration' component. The current chemical review arrangements have provided a responsive mechanism to deal with new information and concerns as they arise, but do not intend to systematically reconsider the entire chemical inventory. Once an agvet chemical is registered it remains so, subject to an administrative renewal process, unless impacted by the outcomes of a chemical review.

The operation of chemical review is underpinned by nominations based on scientifically valid information (information that is known to exist), which are prioritised for further consideration based on the evidence of and/or risk of potential undue harm. Information on the current chemical review program, including the chemicals that have been nominated for review, are under review, or for which a chemical review has been completed, is available from the APVMA website (www.apvma.gov.au/products/review/index.php).

The new continuation scheme complements but does not replace the chemical review arrangements already in place. The chemical review arrangements will continue to allow the APVMA to conduct a full scientific re-evaluation of registered chemicals at any time. The new continuation scheme will provide a mechanism for the systematic consideration of the entire agvet chemical inventory.



CHAPTER 2

CONTINUATION— AN OVERVIEW

Under the Continuation of Approval and Registration scheme (continuation) approval holders and registrants will be required to apply to the APVMA and provide certain information at prescribed intervals in order for their approval or registration to continue.

The underlying principle of the continuation scheme, as defined by the current drafting, is that active constituent approval and product registration should continue unless the APVMA has reason to doubt that the active constituent or chemical product would be safe or effective when considered against the relevant statutory tests. Where scientifically valid evidence is found to exist that gives the APVMA reason to doubt these things, the continuation scheme provides that this be further investigated through the referral of those agvet chemicals to the existing chemical review process. Within the chemical review process the validity of the evidence and its relevance to the authorised uses in Australia will be further considered and any necessary regulatory action will be taken in accordance with the existing prioritisation system (see Appendix 2).

In operation, the continuation scheme will provide for the systematic consideration of whether any new scientifically valid information exists about approved active constituents and registered agvet chemical products that may affect the APVMA's ongoing satisfaction of those approvals or registrations. In this way the continuation framework will complement the existing chemical review process, providing an avenue through which relevant information may be identified.

Importantly, the chemical review process will continue to operate independently of the continuation scheme and respond to nominations for chemical review through the existing prioritisation system. Should valid evidence of potential undue harm become available outside the continuation scheme, the associated approvals and registrations may be reconsidered at any time.



CHAPTER 3

CONTINUATION OF APPROVAL AND REGISTRATION SCHEME

Since the commencement of the NRS active constituent approvals have continued in perpetuity unless impacted by the outcomes of a chemical review. The circumstances for agvet chemical product registrations have been similar, subject to an administrative process of renewal each year. Under the continuation scheme a defined end date for active constituent approvals and product registrations will be determined and these authorisations will only continue where the APVMA has granted a continuation application made by the active constituent approval holder or product registrant.

3.1 Statutory test for continuation

The draft legislation sets out the matters to be considered in the continuation assessment process. These matters include, but are not limited to, human health and safety, environmental safety, international trade and efficacy. The draft legislation requires that continuation be granted where the APVMA is satisfied that the statutory tests for continuation have been met.

Where an approval holder or product registrant makes a continuation application the draft legislation requires that the APVMA must continue the approval or registration if it is satisfied that:

1. the approval holder or registrant has provided the necessary information, and that this information is consistent with that held in the APVMA record or register
2. there is no reason to doubt that the continued use of the constituent or product in accordance with the approved instructions for its use:

- i. would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
 - ii. would not be likely to have an effect that is harmful to human beings; and
 - iii. would not be likely to have an unintended effect that is harmful to animals, plants, things or to the environment; and
3. any moneys outstanding in regard to the active constituent or product have been paid.

The draft legislation also requires that the APVMA must continue the approval or registration if it is satisfied, where relevant, that it has no reason to doubt that the use of the product in accordance with the approved instructions for its use would:

- i. not unduly prejudice trade or commerce between Australia and places outside Australia; and
- ii. be effective.

These matters constitute the statutory tests for continuation.

In determining its satisfaction with the statutory tests for continuation, the APVMA will focus its attention on whether any matters that were relevant to prior assessments have changed, and whether any new scientific information has become available since the authorisation was granted, or subsequently affirmed, that may affect its ongoing satisfaction against the relevant statutory tests. The APVMA's considerations in this regard may only be founded on scientifically valid and robust evidence and will involve:

- validating the particulars held in the APVMA Record for Active Constituents and Register of Chemical Products
- identifying relevant information about the active constituents and chemical products
- considering the relevance of that information to the authorised uses of relevant registered agvet chemical products in Australia
- considering whether the information demonstrates that reasonable grounds exist that the chemical could pose an unacceptable risk of undue harm in relation to the statutory tests or that the product may be ineffective.

Approval holders or registrants will not be required to generate new data under the continuation scheme. All approval holders and registrants have a pre-existing statutory obligation to provide the APVMA with any new information they become aware of that may affect the APVMA's ongoing satisfaction as soon as practicable, including any reports of adverse experiences¹. Approval holders and registrants will however be required to provide information about the particulars of approval or registration to confirm that agvet chemical products being supplied to the marketplace are consistent with what the APVMA authorised. Approval holders and registrants will also be required to make declarations about compliance with any relevant conditions of approval or registration.

3.2 Possible outcomes

The draft legislation provides that continuation applications will be subject to a preliminary assessment phase. During this phase the APVMA must validate the information about the relevant particulars and/or conditions of approval or registration that the approval holder or registrant (the applicant) provides against the details held in the APVMA record. Should the particulars of approval or registration not be validated, the applicant will have an opportunity to rectify any information found to be invalid by remaking the continuation

¹ This statutory obligation is created by section 161 of the Agvet Code.

application, or seeking to have the relevant particulars varied through the normal registration application processes. Continuation applications that do not pass the preliminary assessment phase must be refused by the APVMA.

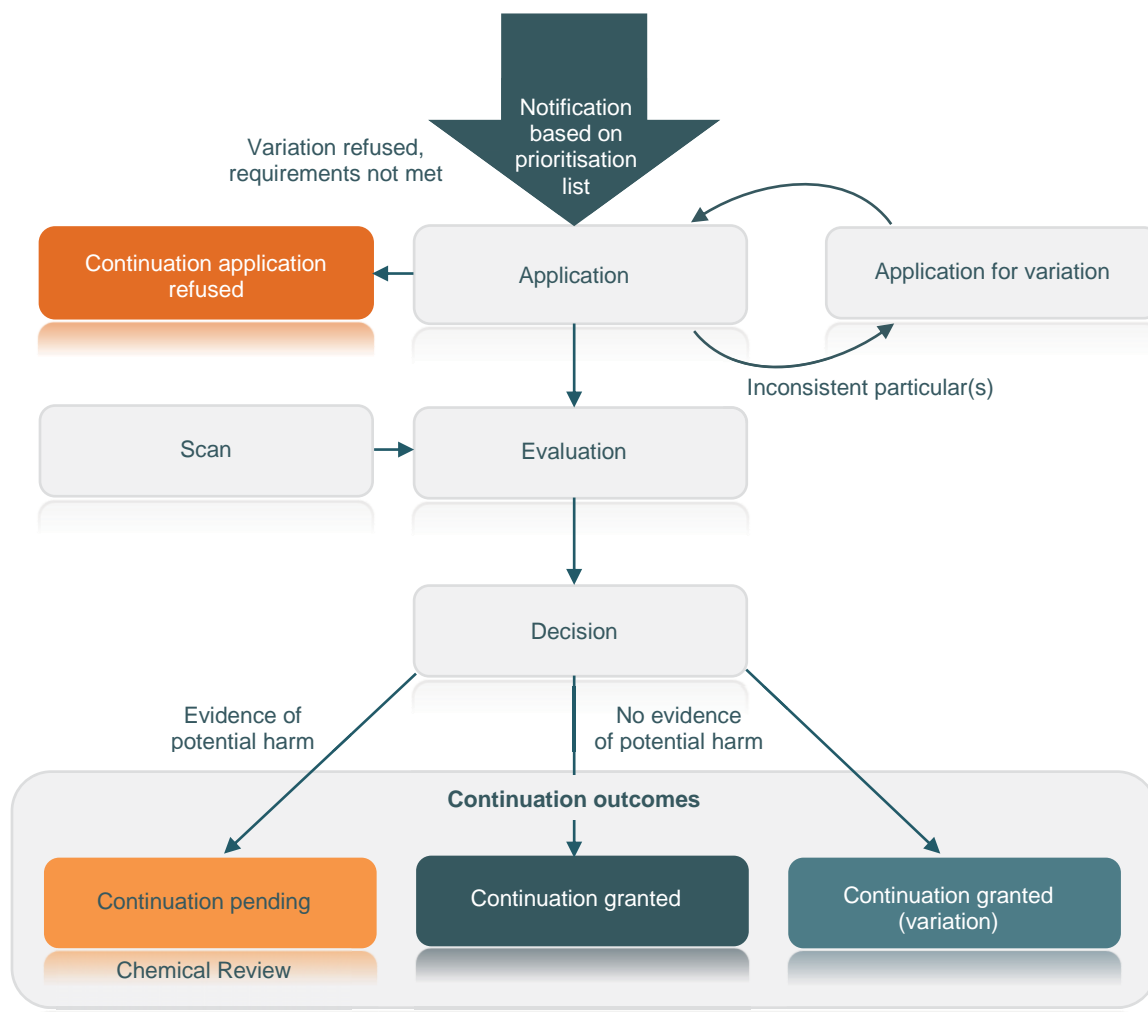
Where a continuation application made by an approval holder or product registrant passes the preliminary assessment phase, the draft legislation provides that the APVMA's consideration may result in one of three outcomes:

1. the APVMA must grant the application if it is satisfied of the statutory tests for continuation
2. if the APVMA is not satisfied of the statutory tests for continuation, but could be if the relevant particulars and/or conditions of approval or registration were varied, it may vary the particulars or conditions so that it may grant the application for continuation
3. if the APVMA is not satisfied of the statutory tests for continuation it may refer the active constituent or registration to the chemical review process for further consideration.

The proposed Australian continuation scheme is depicted in Figure 1. Further information on the operation of the scheme is provided below and in Section 4.

Figure 1. Proposed Australian Continuation Scheme

Note: Where an application for continuation is not received the approval or registration will expire



Where the particulars of approval or registration are validated and the APVMA is satisfied that there is no valid reason to demonstrate that its existing satisfaction against the statutory tests should not hold, continued approval or registration will be granted for a specified period (7-15 years). If the APVMA's assessment identifies reasonable grounds founded in evidence to demonstrate that its existing satisfaction against the statutory tests may not hold, further investigation and consideration of the available evidence will occur through referral to the chemical review process, unless the APVMA's satisfaction can be maintained through it making a minor variation to the relevant particulars or conditions. An explanation of how this variation power may be applied is provided in scenario 1.

Scenario 1. Continuation of registration granted with minor variations

A variation may be appropriate where a chemical is known to react with packaging materials other than those lined with epoxy resin. In such a case a condition requiring the use of epoxy resin-lined packaging could be applied in order for the APVMA to be satisfied of the statutory tests for continuation. In such circumstances the draft legislation provides that the APVMA must notify the approval holder or registrant and provide them with an opportunity to make a written submission about the proposed course of action.

Where an agvet chemical is referred to the chemical review process, the affected approval holders and registrants may be required to provide further information and scientific data to allow the APVMA to appropriately investigate the identified areas of concern. Such a requirement will be made as part of the usual chemical review processes. Whilst a chemical review consideration is being undertaken, the continuation application is suspended until a decision on that chemical review is made. The approval or registration will remain valid until that occurs.

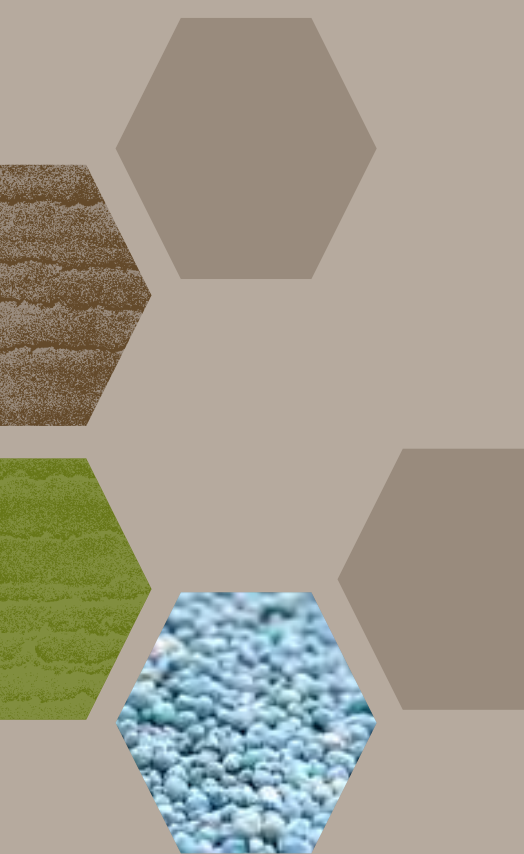
The continuation framework provides that any decision of the chemical review is also taken to be a decision on the continuation application. Where the decision of the chemical review affirms approval and/or registration the continuation application will be granted. If the decision of the chemical review is to cancel the approval and/or registration, continuation of the approval or registration will not be granted.

Further information on the key elements (steps) of the continuation scheme is provided in Section 4.

It is important to note that the continuation framework set out in the draft legislation does not replicate or duplicate the existing chemical review processes. Chemical reviews will continue to operate independently of the continuation scheme and respond to nominations for chemical review through the existing prioritisation system (see Appendix 2). Consequently where relevant evidence of potential undue harm becomes available outside the continuation scheme, the associated approvals and registrations may be reconsidered at any time.

The continuation scheme will however provide for the systematic consideration of whether any new scientifically valid information exists about approved active constituents and registered agvet chemical products that may affect the APVMA's ongoing satisfaction of those approvals or registrations. In this way the continuation framework will operate in synergy with the existing chemical review process, providing an

The continuation scheme complements the existing checks and balances of chemical review, and enhances consumer confidence that agvet chemicals supplied and used in Australia are safe.



additional avenue through which relevant new information may be identified.

Approval holders and registrants may choose not to participate in the continuation scheme by not making a continuation application when required. Where a continuation application is not made, the relevant approvals and registrations will expire. It is an offence to supply unregistered agvet chemical products to the marketplace. As such, subject to a defined phase out period, agvet chemical products not continued will be withdrawn from the marketplace.

3.3 Operation of the scheme

At the commencement of the continuation scheme, the draft legislation requires that the APVMA determine the date on which a continuation application is required (an expiry date) for all approved active constituents and registered products. The APVMA will develop a priority list for continuation of approval and registration, which will be made publicly available. It will also notify approval holders and registrants when they are required to make a continuation application. The prioritisation methodology used to determine the expiry date for each active constituent and chemical product is described in Section 5.

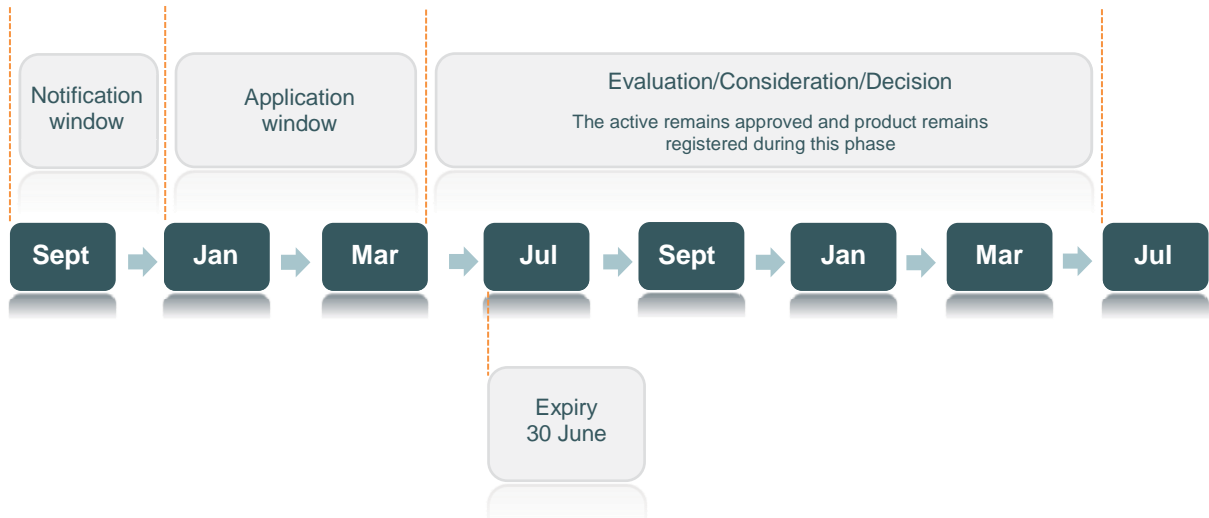
Once the scheme is in operation the date on which subsequent continuation applications would be required for each active constituent and product will be determined through the continuation evaluation process. The draft legislation provides that the period must be between 7 and 15 years.

Where a continuation application is required approval holders and registrants may apply to have their active constituent approvals and their product registrations continued. Applications passing the preliminary assessment phase will progress to evaluation. During the evaluation phase any new information that is identified will be considered to determine its relevance to the use of the constituent or product in accordance with the approved instructions for its use in the Australian circumstance. This assessment will determine which of the three outcomes depicted in Figure 1 will apply to the continuation application.

The draft legislation provides that the date on which a continuation application is required (the expiry date) must be the last day of a calendar month and that applications for continuation, when required, must be made no earlier than six calendar months and no later than three calendar months before that expiry date (the application window). In operation the APVMA would determine 30 June each year to be the expiry date for the active constituents and chemical products scheduled for consideration through the continuation process in each year. Consequently the application window would be 1 January to 30 March. This operating timetable

is depicted in Figure 2. Where a continuation application has been made for an active approval or product registration, those approvals and registrations will not expire while the application is under assessment. The assessment timeframe for continuation applications will be determined in the Regulations.

Figure 2. Continuation Scheme Operating Timetable





CHAPTER 4

KEY ELEMENTS OF THE CONTINUATION OF APPROVAL AND REGISTRATION SCHEME

4.1 Notification

Approximately nine months before a continuation application is required the APVMA will notify the relevant active constituent approval holders and product registrants that a continuation application is required. The notification will specify the application window and the information about the relevant particulars and/or conditions of approval or registration that are required with the application.

If an acceptable continuation application is not received by the APVMA within the application window the active constituent approval or chemical product registration will not be continued and the approval or registration will expire. The draft legislation includes provision for late applications to be made up to the point at which the approval or registration expires in certain circumstances that will be set out in the Regulations, subject to a prescribed late fee.

Should an approval holder or registrant fail to make an acceptable application within the application window, but wish to continue to market the affected active constituent or chemical product, the only option available is to apply for a new approval or registration (with a new approval number) through the normal registration application processes. Such an application will be subject to the data requirements and assessment

methodologies relevant at the time of the application and will be considered by the APVMA in cognisance of any new information or decisions arising from the continuation assessment process.

4.2 Application—preliminary assessment

When making a continuation application approval holders and registrants will be required to provide certain information about the relevant particulars and/or conditions of approval or registration—this is specifically provided for in the draft legislation. It is expected that this requirement will include making a formal declaration of compliance with any conditions of approval or registration and information about the following particulars²:

- composition and purity of active constituents
- constituents of chemical products (formulation and composition)
- product specifications
- site of manufacture (and licence information where relevant)
- method of manufacture.

In the preliminary assessment process these particulars will be confirmed (validated) against the APVMA Record of Approved Active Constituents or Register of Chemical Products (as appropriate) and other records in the relevant APVMA file. The APVMA may extend the particulars of interest to include any of the particulars detailed in the Record of Approved Active Constituents or Register of Chemical Products if considered necessary.

Where the particulars of approval or registration are validated and any other relevant requirements are met, the continuation application will pass preliminary assessment and progress to the evaluation phase. Where the preliminary assessment of the application identifies inconsistencies between the particulars held on the APVMA's record and those submitted in the application, the APVMA will identify the areas of inconsistency in a notice. As indicated earlier should the particulars of approval or registration not be validated, the approval holder or registrant will have an opportunity to rectify any information found to be invalid by³:

- amending and remaking the continuation application; or
- seeking to have the relevant particulars varied through the normal registration application processes and subsequently remaking the continuation application.

In circumstances where particulars inconsistent with the APVMA record are identified during the preliminary assessment, the APVMA notice will specify a date by which any associated variation application must be made and/or the continuation application must be resubmitted. If an approval holder or registrant does not meet this date, the application for continuation is refused. A continuation application must pass the preliminary assessment phase to proceed to the evaluation phase.

4.3 Application for variation

If an approval holder or registrant elects to seek to have the particulars held on the APVMA record varied to meet their contemporary circumstance they may do so by making the appropriate variation application through the usual registration application processes. Where an approval holder or registrant elects to make a

² Note: The draft legislation includes new penalties for the provision of false or misleading information.

³ Note: The submission of particulars not matching those held on the APVMA record may trigger a compliance audit of the active constituent or chemical product. Approval holders and registrants have a pre-existing obligation to ensure that the particulars held on the APVMA record are current and that the agvet chemicals they supply to the marketplace conform to those particulars.

Continuation positions the APVMA to proactively look for new scientific knowledge about a chemical and its effects which will complement existing intelligence scanning operations.

variation application and does so by the date set out in the APVMA notice, consideration of the continuation application will be deferred until the variation application is determined⁴. Variation applications will be considered under contemporary assessment methodologies and data requirements.

If a variation application made by an approval holder or registrant to address any inconsistencies in the particulars identified by the APVMA at the preliminary assessment is granted by the APVMA, and the continuation application is remade, consideration of the continuation application will resume. The information about the particulars provided in the continuation application should be consistent with the Record of Approved Active Constituents or the Register of Chemical Products. Provided all other requirements are met the application will progress to evaluation.

If a variation application (made by the an approval holder or registrant to address inconsistencies identified by the APVMA at the preliminary assessment) is refused or withdrawn, and the approval holder or registrant chooses not to amend the original continuation application so that it is consistent with the APVMA records, the active constituent or product will not be continued.

4.4 Scanning for new information

To inform the APVMA's assessment of continuation applications, the APVMA will conduct an information scan to identify any new information relevant to its assessment against the statutory tests about the active constituent(s) and associated chemical products under consideration. It is anticipated that this process will usually commence in the year prior to consideration of the continuation applications and will continue up until the evaluation and decision phases.

Examples of the type of information that may contain facts relevant to the APVMA's assessment against the statutory tests for continuation include:

- national and international regulatory decisions and standards
- international regulatory scientific assessments and reports
- adverse experience reports
- Poisons Information Centre reports
- compliance intelligence
- high quality peer-reviewed scientific literature

⁴ Note: The draft legislation amends the provisions relating to registration application processes. Under the new provisions a defined elapsed time for applications will apply. This will mean that each application will have a clearly defined end point at which a decision must be made. The new arrangements will safeguard against the potential for any gaming of the system by not addressing requirements in a timely fashion to draw out the period taken to determine an application.

- information submitted to the APVMA in compliance with existing statutory obligations
- information obtained by state and territory agencies in their administration of control-of-use functions.

Regulatory decisions made by comparable international regulators with similar roles and functions to the APVMA can provide a useful source of information on advancements in scientific knowledge about a chemical and its effects, particularly where those regulators have conducted contemporary scientific assessments for existing chemicals. However a number of factors may differ between Australia and the foreign country that may influence the relevance of those assessments, including:

- differences in the use of the agvet chemical
- differences in environmental and agronomic factors
- differences in the properties of the products supplied in the different countries
- differences in the way decisions or assessments are made.

The APVMA takes these factors into account in its consideration of the relevance of the information. Differences in these parameters mean that a decision taken by a comparable overseas regulator may not be replicated within Australia. It is also important to note that agvet chemicals are sometimes withdrawn from overseas markets by the supplier for marketing or financial reasons. For example in the context of more attractive alternatives, or changing agricultural practices that negate the need for the chemical, the return earned from sales may not justify the costs of maintaining the authorisation. In such cases, where there is no adverse regulatory decision, the APVMA would consider whether any information is available that is relevant to its consideration against the statutory tests for continuation. As noted earlier, the APVMA's consideration of continuation applications may only be founded on scientifically valid and robust evidence. Consequently the voluntary withdrawal of an agvet chemical from a foreign market does not of itself constitute relevant information for the purposes of the APVMA's consideration of continuation applications.

The information scan conducted as part of the continuation scheme will complement the existing intelligence scanning operations of the APVMA chemical review program. As noted earlier should valid evidence of potential undue harm become available outside the continuation scheme, the associated approvals and registrations may be reconsidered at any time.

Summaries of the findings from each information scan conducted by the APVMA under the continuation scheme will be made publicly available at the completion of the APVMA's consideration of the related continuation applications.

4.5 Evaluation

During the evaluation phase the APVMA will consider the specific relevance of any information identified through the information scan to the active constituents and chemical products approved and registered in Australia. As noted earlier, in making its assessment the APVMA's attention will focus on whether any matters of relevance to prior assessments have changed and whether any new scientific information has become available since the authorisation was granted or subsequently affirmed that may affect its ongoing satisfaction against the relevant statutory tests.

4.6 Decision

Where continuation applications have passed the preliminary assessment phase and no relevant information is identified through the evaluation process that causes the APVMA to doubt whether the continued use of the active constituent or chemical product in accordance with the approved instructions would be safe or effective within the parameters of the statutory tests for continuation, the draft legislation provides that the APVMA must grant the continuation application. Should relevant information be identified that gives the APVMA

...a system designed to be fair and transparent, providing the applicant with the opportunity for rebuttal, enhancing the rigour of the decision-making process.

reason to doubt whether it may be satisfied of the statutory tests, the draft legislation provides for two potential decision outcomes:

1. referral of the active constituents or chemical products to a chemical review where further detailed investigation (scientific assessment) is undertaken (potentially requiring generation of data to inform the APVMA's considerations); or
2. variation of the relevant particulars and/or conditions of approval or registration to mitigate the identified concern(s) so that the APVMA may be satisfied.

Should a circumstance arise in which compelling evidence is identified through the continuation process demonstrating that active constituents or chemical products pose imminent undue harm to public health, occupational health and safety or to the environment, the APVMA may utilise its existing powers (e.g. suspension, cancellation or recall) to appropriately manage the relevant products in the marketplace⁵.

In circumstances where the decision is that the active constituent or chemical product will be referred to chemical review or that the particulars will be varied so that the APVMA may remain satisfied, the draft legislation provides that the APVMA must notify the approval holder or registrant of the proposed outcome and provide them with an opportunity to make a written submission about the proposed course of action. Should the applicant provide this submission within the prescribed 28 day period, the APVMA must reassess the application having regard to the submission.

Where the evaluation identifies that the APVMA could be satisfied if the particulars (including labels) and/or conditions of approval or registration were varied, the APVMA will carefully consider whether the matters of concern should be addressed in this manner, or whether the nature of the concern warrants further investigation through the chemical review process. It is anticipated that the particulars and/or conditions of approval or registration will only be varied where the APVMA is satisfied that it is unlikely that further investigation through the chemical review process would yield a different outcome. Examples of the sorts of variations that may be made through the continuation process include:

- updating signal headings and associated statements to meet contemporary requirements
- updating of modes of action to meet contemporary requirements
- updating first aid instructions and safety directions so that the APVMA may remain satisfied they are adequate in the contemporary circumstance, or
- adding or varying a condition to specify certain packaging requirements.

⁵ The draft legislation also provides the APVMA with additional powers to suspend or cancel an approval or registration if that is considered necessary to prevent imminent risks to public health or occupational health and safety.

Following its consideration of any written submission made by the approval holder or registrant, the APVMA will make a final decision and communicate that decision to the approval holder or registrant. If the decision is to vary the relevant particulars and/or conditions of approval or registration, the notice will state that the APVMA has varied the particulars and/or conditions. If the decision is a referral to a chemical review, the notice will set out the proposed timing of the review and the obligations of the approval holder or registrant. The priority for chemical review referrals arising from the continuation scheme will then be determined using the existing prioritisation framework (see Appendix 2). During the period of referral to a chemical review the approval or registration will continue. The draft legislation provides that the decision made through the chemical review process is taken to be a decision in relation to the continuation application.

A decision made on a continuation application to vary the relevant particulars and/or conditions of approval or registration may be subject to merits review through an application made to the Administrative Appeals Tribunal (AAT). A decision made as a result of a chemical review to vary the particulars and/or conditions of approval or registration, or to suspend or cancel the approval or registration may be subject to merits review through an application made to the AAT.

If the final decision on a continuation application is to continue the approval or registration, the APVMA will determine the period of continued approval or registration (see below).

The design of the continuation scheme is such that data protection provisions are not required. An approval holder or registrant will only be required to generate and submit new scientific data within the chemical review process to inform the further investigation of matters of concern identified through the continuation assessment process. Separate data protection provisions apply within the chemical review process.

4.7 Continuation period

The draft legislation provides that a continuation period of 7-15 years may be determined by the APVMA. In granting a continuation application the APVMA has determined that it remains satisfied that any risks associated with the chemicals supply and use are adequately mitigated by the instructions contained on the label and regulatory arrangements that otherwise apply to the chemical. This means that while agvet chemicals may exhibit different hazard profiles, the level of risk associated with their use in accordance with the approved instructions has been determined to be acceptable. As such, where the APVMA has determined that it is satisfied against the relevant statutory tests, that satisfaction is analogous. For this reason the continuation period determined by the APVMA will generally be 15 years, except for defined classes of active constituents or chemical products with particular characteristics warranting a shorter continuation period.

The classes of agvet chemicals for which a shorter continuation period (less than 15 years) may be determined could be those:

- with particularly hazardous properties (e.g. chemicals that are highly volatile, mobile or persistent), and
- for which the authorised use (in accordance with label instructions) presents exposure risks that must be carefully managed (e.g. fumigants, vertebrate pest control agents, sheep dips).

While at the time of approval or registration, or subsequent affirmation of approval or registration (through the chemical review or continuation processes), the APVMA has determined that the risks of the use of such agvet chemicals are mitigated by the approved instructions and other regulatory requirements (e.g. user training/licensing requirements), the nature of the necessary risk mitigation tools required for safe and effective use may warrant more frequent positive investigation to determine whether any new scientific information has become available that may affect the APVMA's satisfaction against the statutory tests. The continuation scheme provides the avenue through which such investigation may occur. The classes of products affected could include those already prescribed as Restricted Chemical Products by the Regulations.

The methodology used to determine the continuation period for any new (novel) active constituents and associated product registrations will be the same as that described above. If the APVMA grants approval of a new active constituent and/or registers an associated product, generally the initial continuation period will be set at 15 years.

For the efficient operation of the continuation system it may be desirable for the continuation period of all active constituents of the same name and all chemical products containing that constituent to be aligned. In particular this would facilitate efficiencies in the information scan and evaluation phases (as well as efficiencies within the chemical review process should the continuation evaluation result in a decision to refer the chemical to chemical review). Such alignment would mean that if the APVMA grants approval of an additional source of an existing active constituent, or registers a new chemical product containing an existing active constituent (a 'generic' active constituent or product)⁶, the date on which a continuation application would be required for that active constituent or product would align with the period determined for other active constituents of that name (and associated products). Scenario 2, details how this concept could be applied.

Scenario 2. A consistent continuation period applied for all active constituents of the same name and all chemical products containing that constituent.

Active constituent X (and related agvet products) is subject to continuation. All applications are granted in 2015 and a continuation period expiring in July 2030 is set. A new agvet product containing active constituent X then seeks registration in April 2022. On granting the application for registration, the continuation period for this product would be July 2030 to align with the related chemicals.

Should valid evidence of potential undue harm become available outside the continuation scheme, the associated approvals and registrations may be reconsidered through a chemical review at any time.

4.8 Auditing of information

To ensure the accuracy of information submitted as part of the scheme, the APVMA will undertake post-application auditing and other compliance monitoring activities. Should the APVMA identify that false or misleading information was provided within an application for continuation, appropriate action will be taken. This may include prosecution and/or product suspension or cancellation.

⁶ A 'generic' active constituent or product is one that is an image or copy of a previously approved active constituent with the same name, or a previously registered product containing that active constituent.



CHAPTER 5

PRIORITISATION OF THE EXISTING CHEMICAL INVENTORY

At the commencement of the continuation scheme, the draft legislation requires the APVMA to determine the date on which a continuation application is required (an expiry date) for all approved active constituents and registered products. In effect, this requires the APVMA to prioritise the entry of the existing chemical inventory into the scheme.

In developing a methodology for prioritising the entry of the existing chemical inventory into the scheme, the APVMA has been cognisant that the existing chemical review process has, since the commencement of the NRS, considered nominations for chemical review through the existing risk-based prioritisation system. That system responds to potentially adverse information that is known to exist using a scoring process that takes account of the identified concern that led to the chemicals' nomination and the potential risk of undue harm (see Appendix 2). Consequently where relevant information about the safety and effectiveness of approved active constituents and registered chemical products is known to exist, such information either has been considered, is under consideration, or will be considered through the chemical review system—and this will continue into the future⁷.

For those agvet chemicals that are not the subject of chemical review consideration at any point (including within the prioritisation process), the APVMA has no information to suggest that its satisfaction against the relevant statutory tests should not hold.

⁷ Information on the current chemical review program, including the chemicals that have been nominated for review, the chemicals that are under review, and those for which a chemical review has been completed is available from the APVMA website at www.apvma.gov.au/products/review/index.php.

The prioritisation system addresses concerns about chemicals no longer available in overseas markets and orders chemicals into the scheme on the basis of the potential risk that information unknown to the APVMA may exist.

The proposed continuation scheme will operate in synergy with the existing chemical review process by providing an avenue through which new relevant information may be proactively identified (i.e. information other than that already known to exist) systematically across the entire chemical inventory. Should the APVMA identify relevant information that is potentially adverse to its ongoing satisfaction against the statutory tests through its continuation assessment, the draft legislation provides that further consideration of that information must occur through referral to the chemical review process, unless the APVMA's satisfaction could be maintained by making a minor variation to the relevant particulars or conditions.

5.1 Methodology

New information in relation to registered agvet chemicals and their effects on plants, animals, people and the environment may become available through many avenues, including advancements in scientific methodology or knowledge and information gained through experience with their use, both domestically and internationally. Because information becomes available through these avenues:

- the greater the period that has elapsed between the original regulatory risk assessment for an agvet chemical, the more potential there is (the greater the risk) that new information of relevance to the APVMA's ongoing satisfaction against the statutory tests may exist, and
- in circumstances where Australia is the only jurisdiction in which a chemical remains authorised, the less potential there is (the greater the risk) that new information of relevance to the APVMA's ongoing satisfaction against the statutory tests may be known to regulatory authorities, the regulatory community, or the companies marketing the chemical in Australia.

For these reasons the APVMA's proposed approach for prioritising the existing chemical inventory into the scheme is to:

1. first consider those active constituents (and hence chemical products containing that active constituent) for which Australia is the only jurisdiction in which they remain authorised (Group 1—international regulatory status), then
2. subsequently prioritise the remaining chemicals into the scheme based primarily on the chronological age of entry of each active constituent (and hence chemical products containing that active constituent) to the marketplace, with the oldest chemicals considered first (Group 2—chronological age).

Secondary considerations such as the potential for impurities of toxicological significance in active constituents, the nature of the authorised use and associated exposure potential of chemical products, as well as market status (quantum of sales) will be applied within each group to ensure chemicals with the most significant hazard and exposure potential are given priority, while ensuring a sustainable work flow (see Section 5.2 and Figure 3 for further information).

The chemicals considered in the first group will not be considered again in the second group. The subsequent consideration of chemicals through the continuation process will occur in accordance with the continuation period determined by the APVMA as part of its decision on each continuation application (see Section 4.7).

The APVMA considers that this approach to prioritising the existing chemical inventory into the scheme provides a transparent and predictable mechanism that is risk-based. Other prioritisation methodology options were considered, including those based on intrinsic chemical hazard. However when considered in the context that the APVMA's satisfaction against the relevant statutory tests relates to the acceptability of the risks of supply and use in accordance with the approved label instructions, such hazard-based approaches did not provide an effective means of considering and managing risk across the existing chemical inventory. The APVMA is also cognisant that the Exposure Draft Explanatory Guide⁸ establishes the policy intent that the continuation period will be determined on the basis of "...*the risk associated with the active constituent and the risk associated with the product use...*" (p.15). The intended approach for prioritising the entry of the existing chemical inventory into the scheme is consistent with this risk-based rationale.

5.2 Application of the methodology

International Regulatory Status (Group 1)

The prioritisation of chemicals into the continuation scheme based on international regulatory status (Group 1) will ensure that chemicals for which Australia is the only jurisdiction in which they remain authorised (i.e those for which no approvals remain in the major international agvet chemical markets) are scrutinised for whether any new information, otherwise not known to the APVMA, exists that is potentially adverse to the APVMA's ongoing satisfaction against the relevant statutory tests. Should such relevant information be identified, the continuation process will facilitate referral of that chemical to the chemical review process for further consideration where necessary.

For the purposes of the APVMA's consideration, the major chemical markets will be considered to include the European Union (EU), the United States of America (US) and Canada. Active constituents that are approved in Australia but not authorised as an active constituent within an agvet chemical product by the relevant regulators in these jurisdictions will be identified by the APVMA through liaison with those responsible authorities.

Once the APVMA has identified the chemicals for which Australia is the only jurisdiction in which their authorisation remains, its initial prioritisation will identify any chemicals for which the authorisation ceased in those foreign jurisdictions due to identified concerns of potential relevance to the statutory criteria in Australia. Where chemicals are identified for which such concerns exist, the APVMA will prioritise their entry into the continuation scheme using a scoring process similar to that currently used to prioritise chemical reviews (see Appendix 2)⁹. Consideration of these chemicals in this way through the continuation scheme will

⁸ *Exposure Draft (Explanatory Guide), DRAFT Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011* (Version 1: 16 November 2011) is available from the DAFF website at www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals.

⁹ Note: If the identified concerns are significant and/or there is apparent potential for the use of the chemical in Australia in accordance with the approved instructions to pose undue harm, the chemical may be immediately referred to the chemical review process.

facilitate the appropriate assessment of the relevance of the concerns identified in those foreign jurisdictions to the Australian approval, and the risks of use associated with the authorised use of the chemical in Australia, as well as whether any additional information of relevance to the APVMA's ongoing satisfaction against the statutory tests exists (see Section 4.4 for further information on how such information would be considered). Chemicals will be prioritised into the continuation scheme in this way even if they have previously been nominated for chemical review and are already prioritised on the chemical review nominations list.

The remainder of the chemicals for which Australia is the only jurisdiction in which their authorisation remains will be prioritised into the continuation scheme based primarily on their chronological age of entry to the marketplace (see below). Secondary considerations, such as the potential for impurities of toxicological significance in active constituents, the nature of the authorised use and associated exposure potential of chemical products, as well as market status (quantum of sales) will be applied where necessary to ensure the chemicals with the most significant hazard and exposure potential are given appropriate priority and that annual intakes of continuation applications and associated assessment workloads are sustainable.

Chronological age (Group 2)

The prioritisation of chemicals not captured in Group 1 into the continuation scheme via the chronological age methodology (Group 2) will ensure that the remainder of the existing chemical inventory is systematically probed for any new information otherwise not known to the APVMA which, if relevant and potentially adverse to the APVMA's ongoing satisfaction, may be referred to the chemical review process.

The date on which an active constituent (and any associated products) first entered the marketplace will be taken to be the date on which an active constituent by that name (and/or a product containing that active constituent) was first authorised for supply and use in Australia as an agvet chemical. The key factors to be considered by the APVMA in determining the chronological age of the chemical inventory include:

- the year or date on which entry to the marketplace first occurred
- the year or date on which the initial regulatory risk assessment was undertaken
- whether the approval or registration has been subsequently affirmed (through a chemical review) and if so the date and nature of the associated considerations (whether or not the chemical review considered all aspects of the approval or registration).

The APVMA will ascertain the date on which an active constituent (and any associated products) first entered the marketplace through consideration of:

- APVMA records including the Record for Active Constituents and Register of Chemical Products
- state and territory records for chemical authorisation
- Poisons Scheduling records, or if necessary
- the date of entry into *The Pesticides Manual*¹⁰ or similar document.

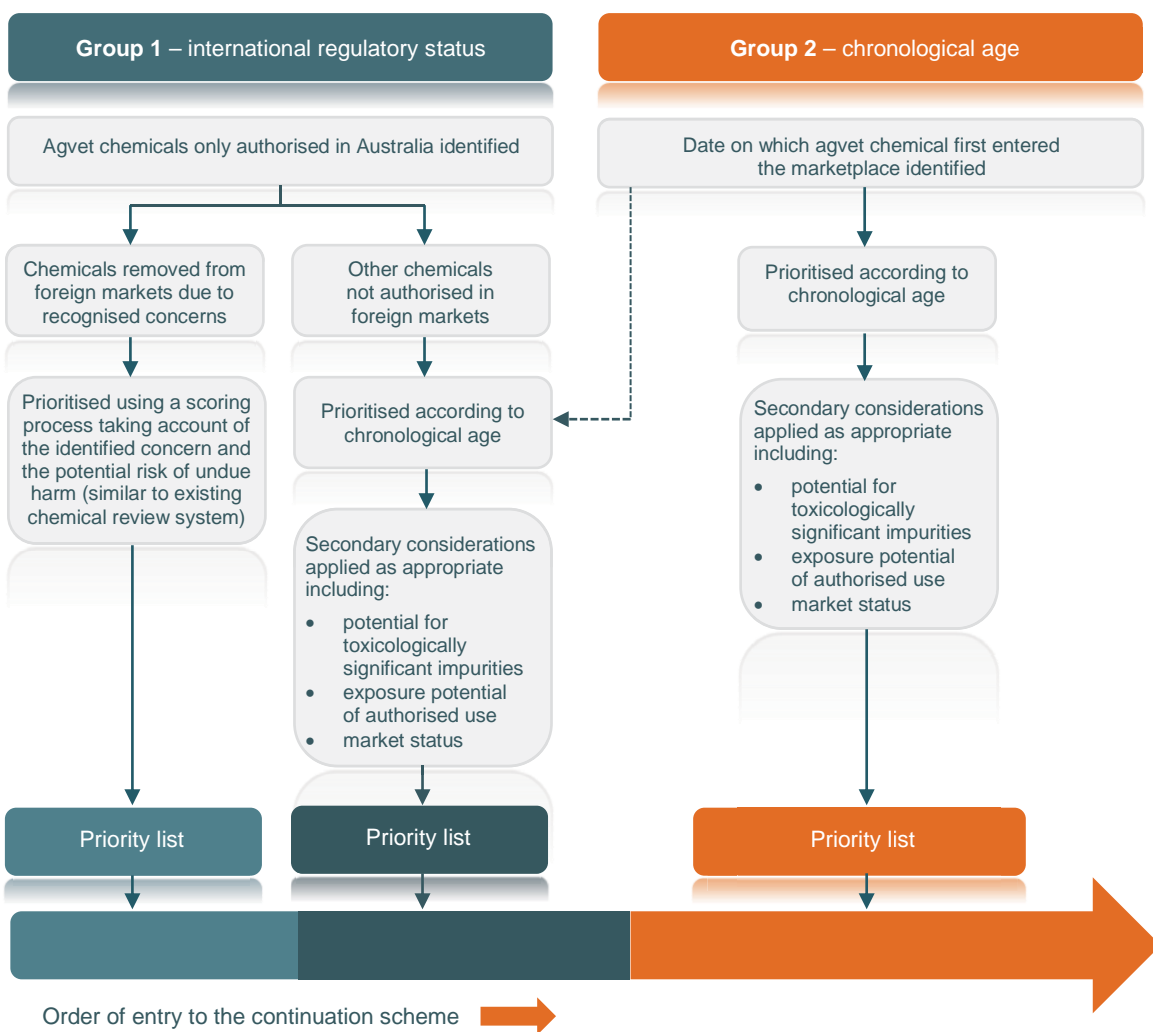
The date of first entry of an active constituent into the marketplace will be taken as the date that applies to all active constituents with the same name and all chemical products containing that active constituent. As such, the consideration of all active constituents with the same name and all chemical products containing that active constituent will occur concurrently through the continuation process to avoid the duplication of regulatory effort.

¹⁰ The Pesticides Manual: *A World Compendium*. British Crop Protection Council (www.pesticidemanual.com).

Similar to the prioritisation of the Group 1 chemicals, secondary considerations such as the potential for impurities of toxicological significance in active constituents, the nature of the authorised use and associated exposure potential of chemical products, as well as market status (quantum of sales) will be applied where necessary to ensure the chemicals with the most significant hazard and exposure potential are given appropriate priority and that annual intakes of continuation applications and the associated assessment workloads are sustainable.

The proposed methodology for prioritising the existing chemical inventory into the continuation scheme is depicted diagrammatically in Figure 3.

Figure 3. Proposed Methodology for Prioritisation



Management of chemical products with multiple active constituents

Agvet chemical products containing multiple active constituents will be considered at the time the first active constituent they contain enters the scheme. The registrants of these chemical products are not required to make a further continuation application when the other active constituent(s) present in the product enter the continuation scheme. However should the subsequent consideration of those other active constituents through the continuation scheme identify information that is relevant to the APVMA's ongoing satisfaction of the constituent or product against the statutory tests, the product will be captured in the associated chemical review process due to the presence of the active constituent and may be affected by the outcomes of that chemical review process.

Implementation

It is proposed that the continuation scheme will be implemented over a four year period, with phased intakes of continuation applications in the first three years whilst the APVMA's assessment capacity and capability is being developed. It is anticipated that full intake capacity will be achieved in the fourth year of operation (see Table 1).

The number of approved sources for an active constituent and the number of chemical products containing each active constituent vary. In order to achieve the intake targets and ensure a manageable and sustainable work flow, whilst also ensuring that the chemicals with the most significant hazard and exposure potential are given appropriate priority, the APVMA will apply the secondary considerations described above.

To enhance the efficiency with which the APVMA is able to systematically consider the existing chemical inventory through the continuation process, some active constituent groups with chemical similarities (e.g. vitamins or phenoxy herbicides) may be considered together. Some grouping of common mixtures of active constituents (such as those in household insecticides) may also occur. It is not anticipated that this would significantly affect the prioritisation order.

As noted earlier at the commencement of the continuation scheme the draft legislation requires the APVMA to determine the date on which a continuation application is required (an expiry date) for all approved active constituents and registered products. It also requires the APVMA to notify each approval holder or registrant of that date. A schedule for the consideration of the entire chemical inventory through the continuation scheme will be made publicly available. Consequently the order in which the existing chemical inventory will be considered through the scheme will be clear and transparent to all interested parties.

Table 1: Proposed phased implementation

YEAR OF OPERATION	APPROXIMATE NUMBER OF AGVET PRODUCTS TO BE CONSIDERED
1st	100
2nd	500
3rd	1000
4th onwards	1200

APPENDIX 1

HISTORY OF THE NATIONAL REGISTRATION SCHEME—AN OVERVIEW

Since 1945 agricultural and veterinary chemical products (agvet chemicals) in Australia have been regulated by state and territory legislation. In the 1950s the Commonwealth became increasingly involved in the regulation of agvet chemicals through the National Health and Medical Research Council (NHMRC), involvement in poisons scheduling, the setting of maximum residues limits (MRLs) and the promotion of nationally consistent standards. This involvement increased further in the 1980s with the establishment of the Australian Agricultural and Veterinary Chemicals Council (AAVCC), which provided clearances for agvet chemicals that were used by the states and territories as the basis of product registration. However the registration of agvet chemicals was a state and territory responsibility until the 1990s.

Following the *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*¹¹, in 1991 the Commonwealth, states and territories agreed to establish the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The establishment of the NRS involved the creation of a single national Commonwealth authority, now named the APVMA¹², with responsibility for the regulation of agvet chemicals up to and including the point of retail sale. The states and territories retained responsibility for the control of use of agvet chemicals past the point of retail sale. The NRS commenced full operation in March 1995.

At the commencement of the NRS existing state and territory product registrations were adopted under the new national arrangements. This was on the basis that those registrations would satisfy the statutory tests for safety and effectiveness of the new national scheme due to their assessment under the previous state and territory registration schemes. Approximately 5000 chemical products were transitioned to the NRS on this basis.

¹¹ Commonwealth of Australia, *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*, Australian Senate Publication Unit, Canberra 1991.

¹² The authority was first named the National Registration Authority (NRA). The name was changed to the Australian Pesticides and Veterinary Medicines Authority (APVMA) in 2003.

APPENDIX 2

EXISTING SYSTEM TO PRIORITISE CHEMICALS NOMINATED FOR CHEMICAL REVIEW (RECONSIDERATION)¹³

Agvet chemicals nominated for review by the APVMA are given an order of priority according to the level of concern that led to the nomination. This priority is based on advice received from APVMA's external advisory agencies: the Australian Government Department of Sustainability, Environment, Water, Population and Communities, the Office of Chemical Safety within the Australian Government Department of Health and Ageing, as well as from the APVMA's own experts in residue chemistry and target animal/plant safety and efficacy. Chemicals prioritised for review are listed in the Priority Candidate Review List (PCRL)¹⁴.

The APVMA and its external advisory agencies use a scoring process to prioritise nominated chemicals for review, based on key criteria of concern including, human health (toxicology & occupational health and safety), environment, residues & trade, target crop & animal safety and efficacy. The priority for each chemical nomination is determined by assessing it against each of the criteria and evaluating the outcomes. The PCRL provides an indication of the chemicals with the higher levels of concern or chemicals which have been assessed as of concern by multiple agencies.

This existing risk-based prioritisation system will continue to be applied to all chemicals referred to chemical review, whether as an outcome of the continuation process or through other mechanisms.

Human health (Toxicology and Occupational Health and Safety)

Chemicals that are nominated for review are assessed for their effect on human health against the following criteria:

1. Special concerns
 - demonstrated or potential adverse effects in humans
2. Potential acute and chronic risk
 - scheduling of the chemical
 - exposure to the chemical from food
3. Regulatory action taken overseas (eg Canada, EU, UK, USA)

¹³ This information on the existing prioritisation system for chemical review is published to the APVMA website at www.apvma.gov.au/products/review/nominated/prioritisation.php.

¹⁴ The current priority list is available from the APVMA website at www.apvma.gov.au/products/review/a_z_reviews.php.

4. Toxicity
 - non-hazardous substances
 - hazardous substances
 - other toxicity (health hazard)
5. User exposure
 - industrial exposure in Australia
 - form of concentrated chemical (includes formulated products)
 - exposure to working strength chemical (mixing/loading/application)
 - frequency of application
 - post application exposure (handling of treated crops & animals)

Environment

Chemicals that are nominated for review are assessed for their effect on the environment against the following criteria:

1. Environmental exposure
 - form and method of application
 - volume of use (kg per annum)
 - scale of use (ha per annum)
 - persistence (soil or aquatic half life)
 - bioaccumulation potential
 - mobility/leaching potential
2. Environmental toxicity
 - aquatic toxicity
 - terrestrial bird/mammalian toxicity
 - terrestrial plant toxicity
 - other non-target organisms
3. Sensitivity of receiving environment
4. Demonstrated adverse effects
5. Regulatory action taken overseas on environmental grounds

Residues and trade

Chemicals that are nominated for review are assessed for their impact on residues and trade against the following criteria:

1. Absence of Maximum Residue Limits (MRLs)
2. Reported incidents of residue violations
3. Reported incidents of adverse effects on trade
4. Compatibility with other countries' MRLs
5. International regulatory action
6. Residues resulting from use according to the label and the appropriateness of existing directions (e.g. hydroponics vs. field use)

Note: Dietary exposure is considered under human health

Efficacy

1. Lack of efficacy (confirmed report/s of serious incident/s of chemical failure, substantial incidents of chemical failure)

Target animal and crop safety

1. Reported incidents of phytotoxicity and adverse interactions with target crops
2. Reported incidents of adverse effects to treated target animals

