Reform Proposal to Improve the Efficiency of Label Approval and Regulation

COAG Early Harvest Reform 8
‘Regulatory Box’ Labelling Reform

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1. PURPOSE

The legislative framework for the regulation of agricultural and veterinary (agvet) chemicals requires the specific approval of individual product labels before the chemical products may be supplied to the marketplace. During the final stages of the 2008 Australian Government Productivity Commission Study of Chemicals and Plastics Regulation the COAG Ministerial Taskforce on Chemicals and Plastics Reform asked the relevant Australian Government agencies to bring forward a number of ‘early harvest’ reforms to improve the efficiency and effectiveness of chemicals and plastics regulation. The APVMA proposed a number of reforms, including a labelling reform proposal which was identified as “Reform 8: Agricultural and Veterinary Chemical Labelling Reform – Regulatory Box”. The early harvest package was agreed by COAG at its meeting on 3 July 2008.

This document outlines the proposed labelling reform, which is intended to:

- facilitate improved regulatory efficiency for the labelling of agricultural and veterinary (agvet) chemicals by clearly distinguishing a labelling hierarchy for the information required by APVMA legislation, other legislation and the registrant;
- establish clear responsibilities for the accuracy and appropriateness of the components of label content;
- ensure that the regulatory burden associated with the APVMA’s assessment of agvet chemical labels is commensurate with the risk posed by the respective label components.

2. BACKGROUND

The labelling provisions of the Agricultural and Veterinary Chemicals Code (the Agvet Code)\(^1\) and the Agricultural and Veterinary Chemicals Code Regulations 1995 (the Agvet Code Regulations) are broad and all encompassing. In approving a label the APVMA is required to determine the particulars that are to be contained on the label and obtain a copy of the label in the form that it will be presented to the marketplace. The effect of these provisions is that the APVMA has to examine and effectively “approve” matters that are not specifically related to its risk assessment about the safe and effective handling and use of the product.

The APVMA believes that its quasi-approval of such matters, including some items required by legislation other than the Agvet Code, is duplicative and unnecessary. Similarly, the APVMA believes that it does not add value in terms of risk management when it approves inclusions on a label for which its regulatory input (and risk assessment) are not required, particularly where those inclusions do not contradict necessary instructions or warnings or have potential to otherwise compromise the overall functionality of the label.

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\(^1\) The Agvet Code is a Schedule to the Agricultural and Veterinary Chemicals Code Act 1994.
Approved labels generally contain three broad elements:

1. Information required by the APVMA, namely the instructions it determines and other matters that the Agvet chemical legislation requires to be included on labels;

2. Information required by other legislation but not controlled by the APVMA such as Poisons Scheduling and Dangerous Goods Classification\(^2\); and

3. Information that the registrant, for commercial reasons, requires to appear on the label such as logos (Company, DrumMuster and WormBoss), warranty information and other suitable promotional material associated with product stewardship.

Under the current arrangements the APVMA has found that in practice the distinction between these key elements is often blurred. Regulatory approval is required for all label changes as:

- Section 21 of the Agvet Code\(^3\) has the effect of requiring the APVMA to determine the size and type of the label as well as certain particulars to be contained on the label and to place a label of the determined size and type on the relevant file; and

- Section 81 of the Agvet Code\(^4\) provides that a registered chemical product may only be supplied where the label attached to the container (the marketed label) is identical to the label approved by the APVMA unless the supply is otherwise authorised by permit (or in effect a new label has been approved through an application to vary the label or approve a new label under Section 29 of the Agvet Code).

In practice these arrangements have the potential to impose a burden on registrants and on the APVMA as they ultimately mean that the APVMA receives applications to alter labels where no risk assessment is required. Applications to update a Dangerous Goods classification (as required to comply with legislation administered by other jurisdictions) is one example as that label content is administered and regulated by other authorities. Applications to change company contact details and trade mark acknowledgements are other examples – there are many others.

To date the APVMA has issued three permits that allow for specified changes or additions to be made to labels without the need for an application to be made to the APVMA for their approval, permits 6868, 9284 and 9523. In addition three standard conditions are currently routinely applied to label approvals that facilitate a level of flexibility with product labelling with respect to information that must by necessity vary (see Table 1 for more information). The labelling permits have greatly improved the efficiency of labelling regulation, significantly reducing the number of applications made to the APVMA for administrative label amendments.

It is now proposed to consolidate these reforms and further improve the efficiency of the regulation of agvet chemical labelling by more clearly distinguishing the

\(^2\) These matters are regulated by other Authorities and addressed by Acts other than the Agvet Code.

\(^3\) Section 21 of the Agvet Code deals with how approval of a label is effected.

\(^4\) Section 81 of the Agvet Code deals with supply of registered chemical products with an unapproved label.
information on the label for which APVMA regulatory approval is required and better managing or eliminating the authority’s authorisation or approval of other label information. The APVMA believes that the regulatory efficiency of label approval can be enhanced in this manner without any compromise to environmental protection, public health, the protection of users of agvet chemicals, product efficacy, or to trade.

Table 1 - APVMA Permits and Standard Conditions referred to in this label reform proposal.

<table>
<thead>
<tr>
<th>Number</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permit 6868</td>
<td>Permit for supplying a registered chemical product with a label which is not identical to the approved label</td>
</tr>
<tr>
<td>Permit 9284</td>
<td>Permit to allow the supply of a registered chemical product with an additional label component consisting of promotional material</td>
</tr>
<tr>
<td>Permit 9523</td>
<td>Permit to supply a registered chemical product with a label that is not identical to the approved label only in respect of net contents</td>
</tr>
<tr>
<td>Standard Condition 2</td>
<td>Shelf life - label contains an expiry date</td>
</tr>
<tr>
<td>Standard Condition 6</td>
<td>Label must contain a date of manufacture and batch number</td>
</tr>
<tr>
<td>Standard Condition 7</td>
<td>Label must contain a date of manufacture, batch number and expiry date no greater than 2 years after the DOM</td>
</tr>
</tbody>
</table>

3. PROPOSAL

The three broad labelling elements outlined above fall into a hierarchy that may be used to distinguish their mode of regulatory approval. It is proposed that under that hierarchy:

a) APVMA required information would continue to be controlled by application to the APVMA (APVMA Regulatory Box);

b) Information required by other legislation would be controlled by condition of label approval (Other Legislation Box); and

c) Registrant desired information would be controlled by permit (Registrant Box).

The proposal, which is presented diagrammatically in Attachment 1, would effectively broaden the type of changes that could be made to product labels without application to the APVMA. In particular it would streamline the process of updating the information included on agvet chemical product labels that is required by other legislation as well as changes of an administrative nature or to information not specifically required and assessed by the APVMA. It would also reduce the time and effort required to assess the label when a product is first considered for registration by more clearly defining the aspects of concern to the APVMA.

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Please note that although Attachment 1 refers to the information as falling into one of three boxes this is for classification purposes only – there will not be a requirement to segregate all information on the label physically into three boxes based on the above hierarchy. Placement of information on the label will remain as currently described in the Ag Labelling Code and Vet Labelling Code, which are published in the APVMA’s Manual of Requirements and Guidelines (MORAG). A further explanation of the three labelling components is provided below.

### 3.1 APVMA Regulatory Box

This is the instructions and other information that is required by the Agvet Code and Regulations to appear on the label. The wording of this information is determined by the APVMA as a result of its assessment of the supporting data and information supplied in the application for registration and/or label approval.

In registering a chemical product or use the APVMA must be satisfied that the use of the product in accordance with the instructions it approves:

1. 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
2. would not be likely to have an effect that is harmful to human beings; and
3. would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
4. would not unduly prejudice trade or commerce between Australia and places outside Australia;

The APVMA must also be satisfied that use in accordance with the approved instructions would be effective.

In approving a label for a chemical product the APVMA is required to be satisfied that the label will contain *adequate instructions* relating to a number of matters as appropriate, including:

1. the circumstances in which the product should be used;
2. how the product should be used;
3. the times when the product should be used;
4. the frequency of the use of the product;
5. the withholding period after the use of the product;
6. the re-entry period after the use of the product;
7. the disposal of the product when it is no longer required;
8. the disposal of containers of the product;

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7 These matters are set out in subsection 14(3)(e) and (f) as well as 29(1)(e) of the Agvet Code.
8 The term *adequate* in respect of label instructions is defined by Section 3 of the Agvet Code.
9 These matters are set out in subsection 14(3)(g) of the Agvet Code.
(ix) the safe handling of the product and first aid in the event of an accident caused by the handling of the product;

The Agvet Code and Regulations\textsuperscript{10} also set out certain particulars that must be included on labels. This includes, amongst other things, signal headings in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The effect of these provisions is to require that the labels of agvet chemicals contain sufficient, accurate and appropriate information (adequate instructions) relating to the protection of public health, occupational health and safety (OHS), the environment, as well as adequate instruction relating to the effectiveness of the chemical and the mitigation of trade risks for persons handling the chemical (including during transport) and using the chemical in the manner intended. The nature of this content is such that expert assessment and specific approval is required so as the APVMA may determine whether those instructions are sufficient and be satisfied that the label contains adequate instructions for the safe and effective use and dealing with the product. In determining such instruction the APVMA consults with the Office of Chemical Safety and Environmental Health (public health and OHS) as well as Food Standards Australia and New Zealand (food safety) within the Department of Health and Aging; the Department of Environment, Water Heritage and the Arts (environmental protection) and other relevant expert agencies as well as utilising its own expertise (chemistry, residues). Any error in relation to such instruction could result in adverse consequences.

As such any change to the instructions and other information constituting the ‘APVMA regulatory box’ will continue to be assessed and approved by the APVMA through its consideration of applications made by the registrants of chemical products.

Further detail as to the type of information falling into this category is provided in Attachment 2.

3.2 Other Legislation Box

The labelling requirements for agvet chemicals established by the Agvet Code and Regulations interact with the requirements of other legislation and the labels of agvet chemical products must comply with the requirements of other legislation where it is relevant. In general the interface of these requirements falls into one of two categories:

- Labelling requirements of other legislation that are complementary to, or support the labelling requirements of the Agvet Codes; and

- Labelling requirements of other legislation that are not specifically related to the APVMA’s risk assessment about the safe and effective handling and use of the product.

The first category principally includes poisons legislation, particularly poisons scheduling. As noted above signal headings in accordance with the Standard for the

\textsuperscript{10} Regulations 11 and 12 of the Agvet Code Regulations set out certain information that is required on the labels of agvet chemical products.
Uniform Scheduling of Drugs and Poisons (SUSDP) are a specified particular of agvet chemical product labels. Poisons legislation also includes requirements for the size and typeface of text on labels – these requirements are set out in the SUSDP and are also reflected in the Ag Labelling Code and Vet Labelling Code. They are intended to ensure that certain label warnings and instructions are appropriately differentiated from one another, as well as ensuring their legibility.

The first category also includes the requirements of transport or dangerous goods legislation. Similarly, the requirements of the Agvet Code may also interact with environmental labelling standards or with occupational health and safety legislation. However as environmental protection and occupational health and safety are specifically areas of APVMA statutory responsibility such interactions are dealt with through the APVMA’s assessment processes and interactions with its advising agencies.

The second category can include matters such as country of origin, weights and measures and matters relating to consumer protection, such as the making of unsubstantiated claims or misrepresentations about a product.

Further detail as to the type of information constituting the ‘other legislation box’ is provided in Attachment 2.

The proposed approach for the management of labelling requirements relating to poisons scheduling, first aid and safety directions, dangerous goods classification and emergency transport advice, as well as the proposed approach for the management of claims and other label statements that are not specifically related to the APVMA’s risk assessment about the safe and effective handling and use of the product is outlined below.

3.2.1 Poisons Scheduling / First Aid and Safety Directions

In its approval of labels the APVMA specifically checks and verifies signal headings, first aid instructions and safety directions as these are integral to the adequacy of label instructions for the safe handling and use of the product.

Poisons schedule classification, as shown on labels by the signal headings, is a significant requirement and is an outcome of data submitted to the APVMA. Similarly, although safety directions and first aid instructions are published in the First Aid and Safety Directions (FAISD) Handbook, these are critical for the safe handling and use of the product and are based on data supplied to APVMA. It is not proposed to relax the requirement that either of these essential label elements be assessed and authorised by the APVMA for individual products.
The APVMA has found that in practice potential exists for some registrants to inadvertently apply the wrong scheduling classification from the SUSDP, or select the wrong safety directions from the FAISD handbook. This is more prevalent where various scheduling cut-offs exist for the relevant compounds or several iterations of safety directions exist for different formulation types (or types of presentation) of the same active constituent. The inclusion of an incorrect signal heading, or incorrect or inappropriate safety directions or first aid instructions on labels could pose a significant undue risk to persons using or handling the chemical. It is for this reason that the APVMA believes its consideration and approval of such label content is essential.

However, to improve the efficiency of implementing straightforward amendments and updates to scheduling, first aid instructions or safety directions that affect a significant number of products, a new condition of label approval underpinned by permit authorisation is proposed that would allow the changes to be made if the APVMA so directs without the need for an application to be made to the APVMA, and for individual product by product approval to be granted by the APVMA. Examples of such changes may include changes to Poisons Information Centre contact details, certain changes to prescribed safety or first aid instructions (such as the amendment of statements relating to atropine), and the rescheduling of a substance to a lower poisons schedule.

The existing labelling permits currently authorise amendments to the size and typeface of text on labels provided such amendments are in accordance with the Ag Labelling Code and Vet Labelling Code and consequently remain compliant with the parameters set out in the SUSDP. No change is proposed to this existing arrangement.

### 3.2.2 Dangerous goods classification and emergency transport advice

The Australian Dangerous Goods Code[^14] as adopted by the states and territories sets out, amongst other things, requirements for the labelling of chemicals that are classed as dangerous goods. Such labelling requirements are referred to in the APVMA’s Labelling Codes and are generally given effect through the inclusion of an ancillary panel on the label that is specifically dedicated to that purpose.

Although the label content which is mandated by the Australian Dangerous Goods Code contributes to the ‘adequate instruction’ on an agvet chemical label, particularly in terms of acute handling information that is relevant to handling during transport and storage, the APVMA has in the past based its satisfaction with respect to this content on the basis that it is specifically regulated (and enforced) by a competent authority[^15] in each jurisdiction. The APVMA has therefore not specifically assessed this content in its approval of labels as to do so would constitute a regulatory duplication. Further the nature of the information and it’s presentation is such that there is little or no potential for it to conflict or otherwise interact with the label requirements and instructions derived from the APVMA’s assessment of other aspects of occupational health and safety and the handling and management of the chemical.


At present the APVMA labelling permit, permit 6868 (discussed previously), authorises the variation of this section of the label so that registrants may vary their labels in order to comply with the Dangerous Goods Code without the need to make application to the APVMA. For the reasons outlined above it is considered that the current arrangements remain appropriate for the inclusion of dangerous goods classifications and emergency transport advice on the labels of agvet chemical products. However to clarify respective responsibilities for ensuring label compliance with the requirements of Australian Dangerous Goods Code the APVMA proposes to impose a new condition of label approval. This will ensure that all registrants are aware of their responsibilities in this regard and provide an efficient regulatory linkage to the competent authorities who carry the regulatory responsibility for that label content.

3.2.3 Claims not specifically related to the APVMA’s risk assessment

The APVMA has largely left it to registrants to comply with the requirements of other legislation that is relevant to claims not specifically related to its risk assessment about the safe and effective handling and use of the product. However as the APVMA is required to approve labels as they appear in the marketplace label amendments that are actually within the jurisdiction of other legislation have often necessitated submission of a revised label to the APVMA for approval. The fact that the APVMA approves the label in its entirety has carried with it an implication that the APVMA endorses all claims and label content, or otherwise administers (regulates) the requirements of legislation other than the Agvet Code. Because of this on occasion the APVMA has felt obliged to seek to validate claims that are not directly relevant to its risk assessment about the safe and effective handling and use of the product. The APVMA believes this is inefficient and unnecessary where alternate regulatory arrangements and frameworks exist for the regulation of such label content.

The APVMA now proposes to formalise arrangements for its deference to other legislation where that is appropriate so that the respective responsibilities are clear and label changes required or governed by legislation other than the Agvet Code, that do not have the potential to impact matters the APVMA has specifically assessed (and has statutory responsibility for), may be made without separate approval by the APVMA. Statements or graphics on labels that imply that the product may be used for a purpose or in a manner beyond that approved by the APVMA may lead to unauthorised use, with the potential to pose risk to the user, the public, animals, the environment or to Australia’s trade. As such a level of regulatory control is considered necessary through the provision of broad rules where certain content may have the potential to interact with matters the APVMA is required to assess. Examples may include graphics of animals and plants where the product has not been assessed or approved for use on those animals or plants.

The APVMA believes that the clarification of responsibilities in this way will greatly enhance the efficiency of label approval processes by providing clarity as to the label content the APVMA will assess (and for which supporting data will be required), as well as enhancing the flexibility registrants have to update label content that is not related to matters specifically within the jurisdiction of the Agvet Code to meet contemporary circumstances.
The *Trade Practices Act 1974* (Cwth) contains provisions that relate to claims and statements on labels. In particular Section 52 requires that a corporation not engage in conduct that is misleading or deceptive. Section 53 contains more specific provisions in relation to false or misleading representations, including representations relating to performance characteristics, endorsements or approvals, place of origin of goods and other matters. Agvet chemical product labels must be compliant with the provisions of this legislation as well as with corresponding state and territory laws.

Although most label claims will be verified by the APVMA through its assessment processes (for example efficacy claims), the APVMA does not propose to verify claims unrelated to its risk assessment about the safe and effective handling and use of the product, such as for example energy efficiency claims. It is the responsibility of the registrant to ensure product labels are fully compliant with the provisions of the *Trade Practices Act 1974* and associated laws.

Similarly the *Commerce (Trade Descriptions) Act 1905* prohibits goods imported into Australia from being labelled in a misleading manner including, amongst other things, information relating to the country or place at which the product was manufactured. The APVMA has not and does not intend to monitor labels for compliance with such legislative requirements, which are controlled by other regulatory arrangements.

The APVMA proposes to impose a condition of label approval to ensure that the requirements of other relevant legislation are met. The condition will clarify respective responsibilities for ensuring label compliance with the requirements of other legislation, including responsibilities for the verification of claims not directly related to the APVMA’s risk assessment about the safe and effective handling and use of the product. The condition will also ensure the APVMA has the necessary regulatory power to efficiently take appropriate regulatory action to remove labels from the market where such label content is found to be in breach of other relevant legislation, particularly where that content has potential to impact with matters that are within the APVMA’s regulatory scope.

### 3.3 Registrant Box

Many labels contain additional information that is not required by the APVMA but has been allowed to be included to assist users, to aid product marketing, to cover company liability aspects or to increase the appeal of the label. This information is not critical from the APVMA’s regulatory perspective to ensure proper use of the product but may be desirable to registrants for the purpose of product stewardship.

Provided some general rules are observed and the information does not contradict or adversely interact with information falling into the ‘APVMA regulatory box’ or the ‘other legislation box’, or otherwise impair the labels communication of adequate instructions for the safe and effective use of the product (its functional aspects), the APVMA does not believe it needs to specifically approve its inclusion or amendment. For this information the APVMA believes the ‘general rules’ can be best administered through the issue of a permit authorising the making of such changes, rather than

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16 Claims within the APVMA’s regulatory scope are those that relate to the chemical product’s capture as an agricultural or veterinary chemical product as defined by Sections 4 and 5 of the Agvet Code.
through necessitating applications for approval. The permit will allow the changes to be made but will not direct or compel the changes.

Further detail as to the type of information falling into this category is provided in Attachment 2. A proposal, which would facilitate amendments to print and background colours being included in the ‘registrant box’, is outlined below.

3.3.1 Print and background colour

The need for registrants to make application to the APVMA for the approval of changes to the print and background colour of labels has been a problematic area of APVMA regulatory control and has attracted the attention of Government in recent years\(^\text{17}\). The APVMA approves colour, font and graphics by virtue of the fact that it approves the marketed label (a label of the determined size and type) and that it is an offence for a registrant to supply a label that is not identical to the approved label unless otherwise authorised. The main risk associated with amendments to colour, font and graphics is that the critical information on the label may be difficult to read, an issue that has occurred\(^\text{18}\) and that could result in incorrect or unsafe chemical use.

The APVMA currently accepts labels submitted electronically and prints them on its own equipment to create the ‘approved label’. It is acknowledged that there is likely to be some colour variation between the label generated by the APVMA and that produced commercially and supplied to the marketplace, due to variations in printing equipment, inks and paper being used. Similarly font style and type can vary between printers. The e-label process is nevertheless well established and to move back to requiring a printed sample would be a retrograde step. It does however mean that the product label in the marketplace may not be an identical image of the APVMA approved label, even under current arrangements.

The APVMA has recently included a provision in permit 6868 that allows variations to background or print colours or graphics across a registrant’s range of registered products where the APVMA has granted approval of the variations for at least one product in the registrant’s range of registered products. It is now proposed to build on this regulatory burden reducing reform by allowing variations to background or print colours provided the label remains appropriately legible.

The Ag Labelling Code and Vet Labelling Code contained in the MORAG specify text sizing and formatting requirements for labels, which as noted previously, are derived from the SUSDP. To facilitate amendment to label colours without product by product approval the APVMA has developed a standard for label legibility and it is proposed that a new label amendment permit will allow colour changes to be made provided the label continues to comply with this standard. A copy of the proposed legibility standard is included at Attachment 3. This standard would be published in

\(^{17}\) The need to make application to the APVMA for colour related changes was raised by the Minister for Finance and Deregulation, the Hon Lindsay Tanner MP in an address to the Sydney Institute in February 2008 titled ‘Relieving the burden on business – Labor’s deregulation agenda’. The speech is available from http://www.financeminister.gov.au/speeches/2008/sp_20080226.html.

\(^{18}\) The APVMA has historically received reports of labels which due to printing variations (either intentional or unintentional) are difficult to read, particularly due to poor contrast between text and background.
the MORAG and subsequently incorporated into the Labelling Codes at the next update.

Following the progression of this reform, it is expected that the label used in the marketplace may look quite different to the officially approved version held by the APVMA, certainly much more than differences arising from the printing process. It is acknowledged that this could raise enforcement and compliance concerns, particularly in relation to control-of-use, which is currently administered by the states and territories. Indeed it was such concerns that led to the amendment of Section 21 of the Agvet Code in 2003 to include the provisions requiring the APVMA to determine the size and type of the label and to place a label of the determined size and type on the relevant APVMA file (i.e. to approve the marketed label). The Explanatory Memorandum to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2002, which amended the Agvet Code at that time, states in relation to the amendment to subsection 21(2):

“New subsection 21(2) extends the requirements of the NRA, when approving a label for a container for a chemical product, to also include the determination of the size and type of the label, and the instructions for the use of the product. The NRA must place all relevant particulars (refer Definitions section 3) and record any conditions of the approval in the relevant NRA file. The introduction of these additional clauses is made at the request of the States and Territories who have requested that the NRA specifically approve the actual product label rather than the text contained therein for the purposes of strengthening their control-of-use compliance activities.”

However it is the words and instructions constituting the ‘APVMA regulatory box’ and the ‘other legislation box’ that are the critical component of the label and that underpin control of use laws. The APVMA has the authority under Section 149 of the Agvet Code to issue evidential certificates in relation to label content. Such evidential certificates should technically be adequate to resolve any compliance or judicial matters as to whether an instruction on a label (the ‘adequate instructions’) has been approved by the APVMA.

Further, it is apparent that such enforcement and compliance concerns are not reflected in the contemporary context, where there is significant appetite to harness reform opportunities that can enhance regulatory efficiency without compromising effectiveness. Indeed this is reflected in COAG’s agreement to the early harvest reform package, including this labelling reform. On this basis both the APVMA and the Department of Agriculture, Fisheries and Forestry consider it legitimate and appropriate to extend the permissible flexibility for labelling to the extent possible in the context of the existing statutory provisions.

Nevertheless the regulatory framework for the agvet chemicals is a complementary one with a shared division of responsibilities between the Commonwealth and the states and territories and the APVMA must be cognisant of these prior concerns. The APVMA therefore proposes to continue to require the provision of electronic colour versions of the label (known as Marketed Product Labels or MPL’s) when the product is first registered and wherever the APVMA approves variations to label instructions

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19 Prior to 2003 label approval was granted on the basis of a text label. Registrants then incorporated colour and artwork to that approved text.
(i.e. whenever an application is required to the APVMA). This will ensure that the APVMA record will contain a copy of the label which is similar to that used in the marketplace.

The APVMA does however appreciate that some products are not intended to be marketed but rather are intended to be registered as ‘shelf products’, often as a reference product for subsequent repack or image applications. For such products registration will continue to be granted on the basis of a black and white label\(^20\) as is currently allowed, or a text label\(^21\). However where registration is granted on the basis of a text label the applicant will be required to make a declaration in the covering letter for the application that the product is not intended to be marketed and is intended as a ‘shelf registration’. It will be a condition of approval of such a label that it may not be affixed to a container of a chemical product that is supplied in the marketplace. Without this condition it is anticipated that some registrants may seek to have all label approvals granted on the basis of a text label and it is anticipated that this would not be acceptable to the relevant state and territory departments who administer control-of-use (see above). Should circumstances later change and the registrant wish to market the product with a full colour label (an MPL) an application will be required to the APVMA for the approval of that label.

Copies of labels altered as a result of the changes to be allowed by the new permit and conditions would not normally be required to be submitted. In certain circumstances, however, the APVMA may require the provision of labels under a proposed new condition of label approval intended primarily to assist bring registrants found to experience difficulty in producing compliant labels into compliance (see Section 6 “Assuring Compliance” for further details). The new condition will provide an efficient regulatory link between the making of a request for a label and the ongoing label approval, facilitating the efficient administration of these reforms.

As noted in section 2 above, the existing labelling permits (see Table 1) already allow a large degree of flexibility with product labelling. This proposal will further increase this flexibility by covering a wider range of label information that is not critical for safe and proper handling and use of the product. To facilitate this greater flexibility whilst retaining sufficient regulatory oversight and control, as well as stakeholder confidence in the labelling framework, the APVMA proposes to apply a new condition of label approval linking the specified label amendments that are authorised without application being made to the APVMA, with the label approval. This condition will provide an efficient mechanism for the administration of the reforms and the management of labels found to have been varied beyond the scope of the prescribed authorisation.

It is important to note that the current labelling permits only relate to changes to labels. The proposal presented in this paper offers the additional utility of better defining the scope of the APVMA’s consideration with respect to labelling to only

\(^{20}\) A ‘black and white label’ is a label that contains no colour (it is black text on a white background) but otherwise complies with the character (font) style and size requirements set out in the SUSDP and Ag or Vet Labelling Codes. It is essentially a Marketed Product Label (MPL) without colour.

\(^{21}\) A ‘text label’ is a label that contains all instructions and text required by the APVMA but is not presented in a format suitable for direct application to a container, generally because it does not fully comply with the character (font) style and size requirements set out in the SUSDP and Ag or Vet Labelling Codes.
that information which is relevant to it’s risk assessment during the initial application for product registration. It is anticipated that a number of difficulties that have been encountered historically will be more efficiently navigated through the APVMA determining that certain information fits the ‘registrant box’ or ‘other legislation box’ classification and prescribing broad rules through the proposed new permit facilitating the amendment of that information without application to the APVMA. In addition the further clarity in terms of the matters that the APVMA does and does not specifically assess and approve will enhance the efficiency with which applications are prepared and assessed, particularly for matters that are dealt with by other legislation and for which responsibility for compliance rests almost entirely with the registrant.

4. IMPLEMENTATION

The proposed reform can be implemented without change to the Agvet Code or the Regulations. Although Sections 21 and 81 of the Agvet Code have the overall effect of requiring the APVMA to authorise all label amendments, some scope for flexibility exists. Specifically Subsection 21(1) of the Agvet Code provides that the APVMA may approve labels subject to conditions (as mentioned in Section 23\textsuperscript{22}) and Subsection 21(2)(a) provides that approval of a label takes place by “determining (if appropriate) the size and type of the label” [emphasis added]. Further as noted previously, Section 81 (Subsection 81(1)(b)) of the Agvet Code does allow the supply of a registered chemical product with a label differing from that approved by the APVMA if such supply is so authorised by a permit.

For the reasons outlined above the APVMA believes that in certain circumstances it may not be appropriate for it to specifically determine the size and type of the label, particularly where this creates regulatory inefficiency and acceptable regulatory outcomes can be achieved, and if necessary enforced, through the imposition of appropriate rules via conditions of label approval and a permit.

Details of the proposed conditions and labelling permit, which establish the framework to facilitate the reforms proposed in this paper and prescribe the circumstances where it is not considered necessary or appropriate for the APVMA to specifically determine the size and type of the label, are outlined below.

4.1 Conditions

As noted above Subsection 21(1) of the Agvet Code provides that the APVMA may approve labels subject to conditions as mentioned in Section 23. Subsection 23(1) provides, amongst other things, that the conditions of the approval of a label for containers for a chemical product are the conditions that the APVMA thinks appropriate.

In order to facilitate the aforementioned regulatory reforms the APVMA believes the following new standard conditions are necessary and appropriate for label approvals. These proposed conditions are considered necessary to clarify responsibilities for compliance with matters not specifically related to the APVMA’s risk assessment about the safe and effective handling and use of the product, as well as to provide a

\textsuperscript{22} Section 23 of the Agvet Code deals with conditions of approval or registration
framework within which the APVMA may remain satisfied that approved labels will continue to meet appropriate standards and be able to efficiently take appropriate and timely regulatory action should that not be the case. As is currently the case, a breach of a condition of label approval may result in the label approval being cancelled or suspended.  

4.1.1 Proposed new standard conditions of label approval

“Label must meet the requirements of other legislation”

The approved label affixed to containers must contain information required by relevant Commonwealth, State and Territory legislation relating to:

- Transport of Dangerous Goods - specifically the labelling requirements of the latest edition of the *Australian Dangerous Goods Code* as adopted by the states and territories; and
- Weights and Measures – specifically the labelling requirements of the *National Measurement Act 1960* and *National Trade Measurement Regulations 2009* (Note: effective from 1 July 2010); and
- Labelling of imported goods – specifically the labelling requirements of the *Commerce (Trade Descriptions) Act 1905*.

“Label must not make false or misleading claims”

The approved label affixed to containers must comply with the requirements of the *Trade Practices Act 1974*, which amongst other things prohibits the making of false or misleading representations.

As is discussed in Section 3.2.2 and 3.2.3 these conditions are intended to clarify the respective responsibilities for ensuring label compliance with the requirements of other legislation, whilst also ensuring the APVMA has the necessary regulatory power to take appropriate regulatory action to remove labels from the market where such label content is found to be in breach of other relevant legislation, particularly where such breaches have potential to impact with matters that specifically relate to the APVMA’s risk assessment about the safe and effective handling and use of the product.

The supply of labels altered to comply with such relevant legislation will be authorised by the proposed APVMA Labelling Flexibility Permit (see below).

“Label may be altered in accordance with prescribed parameters”

The approved label may be altered as permitted by the APVMA Labelling Flexibility Permit without affecting the approval status. It is a condition of the approval that variations only be made as expressly authorised by the APVMA Labelling Flexibility Permit.

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23 Section 36 of the Agvet Code deals with suspension or cancellation of approval or registration for breach of condition.
As is discussed in Section 3.3.1 the reforms proposed in this paper will further increase the flexibility available to registrants to make label amendments without the need to make application to the APVMA for the approval of those amendments. The intent of this condition is to provide a clear linkage between the label amendments that are authorised to be made without application to the APVMA and the ongoing approval of the label. This condition will allow the APVMA to efficiently deal with any labels found in the marketplace that have been amended beyond the scope of the prescribed authorisation. Although the supply of such labels would constitute an offence under Section 81 of the Agvet Code (‘supply of a registered chemical product with an unapproved label’), if not for this condition the only mechanism through which the APVMA could affect the ongoing approval of such labels would be through the conduct of a reconsideration under Division 4 of the Agvet Code. This would be inefficient and cumbersome for both the APVMA and the affected registrants.

“Label to be amended as instructed by the APVMA”

It is a condition of approval of this label that it is updated to comply with the Standard for the Uniform Scheduling of Drugs and Poisons or the Handbook of First Aid Instructions and Safety Directions if instructed to do so in writing by the APVMA and within the time period set out in that instruction.

As is discussed in Section 3.2.1 this condition will ensure that the APVMA has the power to direct that straightforward amendments and updates to scheduling, first aid instructions or safety directions be made within a reasonable period. The condition will improve the efficiency with which such updates can be effected as under existing arrangements in order for such changes to be required the APVMA may only otherwise affect the label approval of existing labels (bearing outdated instructions) by the conduct of a reconsideration under Division 4 of the Agvet Code. Although a similar power to that provided by the proposed condition is provided by Section 34A of the Agvet Code there is not always a need to reconsider the label to ascertain the need for an amendment to update such instructions. Further, the condition facilitates updates in response to such a request being made without need for an application and for individual product by product approval to be granted by the APVMA.

The supply of labels altered to comply with such a request will be authorised by the proposed APVMA Labelling Flexibility Permit (see below).

“Registrant to supply samples of labels if requested”

The registrant must, within 5 business days, or shorter or longer period as the APVMA allows, of a formal request from the APVMA, provide to the APVMA a sample of any labels currently being affixed to containers of the chemical product in the form the APVMA requires.

This proposed condition provides an efficient regulatory link between the making of a request and the ongoing label approval, particularly where a registrant is found to be having difficulty in producing compliant labels (see discussion in Section 3.3.1). The proposed reforms offer significant freedoms for the registrants of chemical products and it is essential that the APVMA be able to obtain copies of labels used in the marketplace in a timely fashion should intelligence reports suggest there may be an
issue with a label, particularly one which compromises the safe use and/or handling of the product, so that it may identify whether regulatory action is necessary. The APVMA would generally require copies of labels in either hard copy or electronic formats.

4.1.2. Proposed new condition of approval for text labels

In addition to the above standard conditions of label approval the APVMA also proposes to apply the condition shown below when granting the approval of a text version label for which the applicant has declared that the chemical product is not intended to be marketed bearing that label and rather is intended as a ‘shelf registration’ (see discussion in Section 3.3.1).

“Use of text label in the marketplace”

It is a condition of label approval that the label not be affixed to the container of a chemical product that is supplied or intended for supply to the marketplace.

As discussed in Section 3.3.1 the APVMA intends to continue to require the provision of Marketed Product Labels when a product is first registered and whenever the APVMA approves variations to label instructions. Although the reforms proposed in this paper allow significant label variations to be made post approval this process is considered to remain relevant as it ensures that the APVMA record will contain label that is similar to that used in the marketplace. Without this condition some registrants may be tempted to seek such approval on the basis of a text label for products they intend to market and it is anticipated that this would not be acceptable to the relevant state and territory departments who administer control-of-use. As previously noted it was these agencies that raised issue with the text label process that existed prior to 2003.

4.1.3 Application of Conditions

The APVMA may only vary the conditions of an existing registration or label approval of its own accord where the conduct of a reconsideration under Division 4 of the Agvet Code demonstrates that it can no longer be satisfied of the relevant statutory criteria without making such a variation (see Section 34 of the Agvet Code). In respect of the conditions of label approval such a variation may only be made if the reconsideration finds that without such a variation the label would not comply with the prescribed requirements (see Subsection 14(3)(d) of the Agvet Code) or would not contain adequate instruction (see Subsection 14(3)(e) of the Agvet Code).

Generally when the APVMA is considering the broad imposition of a new condition it would conduct a global review of all currently registered products and approved labels – this is what occurred when the Ag Quality Assurance (QA) condition of registration was applied to all registered Agricultural Chemical Products. However, this reform presents a different circumstance as the APVMA’s satisfaction of the relevant statutory criteria with respect to existing label approvals remains unchanged and the proposed new conditions specifically relate to the facilitation of a greater level of freedom and flexibility with label approval – something the chemical industry have sought for some time.
Because the APVMA’s satisfaction of existing approved labels is not impacted by the proposed reforms it is not considered necessary that the above conditions be applied retrospectively. They would however be applied to all new label approvals so as to enhance the efficiency with which those future label approvals may be administered and managed.

Registrants wishing for the proposed new conditions (other than the text label condition) to be applied to existing approved labels so that they may access the additional permissible label alterations and flexibility that will be authorised by the new ‘Labelling Flexibility Permit’ (see Section 4.2 below) to aid their stewardship of those labels, may make a Category 13 application (no fee) to the APVMA for that purpose\(^\text{24}\). As noted previously the proposed reforms offer significant freedoms with respect to labelling and the proposed conditions are considered necessary in order for this latitude to be administered with regulatory efficiency. Should the proposal proceed the APVMA intends to produce a special application form for this purpose that will allow registrants with multiple products and multiple approved labels to make a global request for the conditions to be applied.

### 4.2 Permit

As previously discussed the APVMA has to date issued three permits that allow for specified amendments to be made to labels without the need for an application to be made to the APVMA for their approval, permits 6868, 9284 and 9523. The APVMA acknowledges that since their initial issue these permits (particularly permit 6868) have to an extent become cumbersome to use and that on occasion it has been difficult for registrants to simply determine with certainty whether a planned label amendment is covered by one of those permits. In progressing this reform, should it be accepted, the APVMA proposes to consolidate these permits into one ‘Labelling Flexibility Permit’ and to widen the scope of changes that may be made to authorise the amendments proposed under the “registrant box”.

A draft of the proposed permit is included as Attachment 4. The principal additional label variations that would be authorised by the proposed permit are set out in Attachment 2 and include:

- Variation to the background or print colour of the label provided legibility is maintained;
- Changes to the size and/or shape of a label provided the placement of key information is not altered and legibility is maintained;
- Addition or changes of graphics or pictures on labels provided they do not infer that the crops, animals or situations of use or the target pests which are inconsistent with the approved use patterns of the product;
- A broader range of amendments to label wording than are currently allowed, including (but not limited to) claims that do not come within the APVMA’s jurisdiction, package opening instructions, optional product availability statements and references to websites and help lines.

\(^{24}\) Applicants may also otherwise request that the conditions be applied to existing label approvals as part of any other variation application for the relevant product that is under the APVMA’s consideration.
The permit would also consolidate changes to logos and promotional material allowed under permit 9284 and changes to net contents and pack sizes allowed under permit 9523 into a single permit.

As indicated in section 4.1.3 above access to these broader range of authorised label amendments will be dependant on the label approval of the label being varied being subject to the proposed new conditions (other than the text label condition) that are described in section 4.1.1 above.

5. REGULATORY IMPACT

The proposed changes constitute a reduction in regulatory burden and as such no registrant will be adversely affected by the adoption of the new conditions of label approval or by the consolidation and extension of the existing labelling permits.

Although new conditions will necessarily be imposed on all new label approvals so that the reforms may ultimately be administered in an efficient and effective manner and with the appropriate regulatory control, all currently approved labels are already in compliance by virtue of the fact that they are approved. As such there will be no increased burden for registrants seeking to have new labels approved. There will also be no increased burden for registrants electing to have the new conditions applied to existing label approvals. For registrants not electing to apply to have the new conditions applied to existing label approvals the status quo will remain and they will continue to be able to make amendments to those labels consistent with that currently allowed under permits 6868, 9284 and 9523.

With the proposed conditions in place the APVMA believes that the proposed reforms will not compromise the effectiveness of labels in terms of communicating adequate instructions to persons using agvet products or handling the containers, or as a regulatory tool for control-of-use enforcement. As such the proposed reforms will not compromise environmental protection, public health, the protection of users of agvet chemicals, product efficacy, or trade (regulatory outcomes of the Agvet Code).

Because the reforms are burden-reducing and are not expected to unduly impact regulatory outcomes a detailed regulatory impact assessment is not planned at this stage.

6. ASSURING COMPLIANCE

As noted in section 3.3.1 copies of labels altered as a result of the changes to be allowed by the new permit and conditions would not normally be required to be submitted to the APVMA. However in order for the proposed arrangements to be administered effectively, the APVMA believes that a specific compliance program will be required to accompany the schemes implementation. The conditions proposed above will be integral to underpin compliance and enforcement activities.

Note: For administrative efficiency the conditions will be imposed mandatorily to all new label approvals from the date of implementation. There will be no ability for registrants to elect to not have the conditions applied.
To monitor the quality of labels in the marketplace and their compliance with the above conditions of label approval the APVMA intends to conduct random audits of labels in addition to its routine monitoring of the marketplace. Such audits may also be targeted where certain registrants are found to be having difficulty in complying with the conditions of label approval. Under this process the APVMA will require registrants to supply copies of certain labels, which it will check for compliance.

The APVMA’s ability to obtain labels for the conduct of a compliance audit in an efficient manner is facilitated by the above conditions.

The identification of labels that are non-compliant with the conditions of label approval or that do not otherwise conform to the parameters prescribed by the ‘Labelling Flexibility Permit’ may result in the suspension or cancellation of label approval until they are amended to be compliant. There will be no phase out period for non-compliant labels and non-compliant labels may be required to be recalled from the marketplace or replaced with compliant labels at the registrants cost.

7. CONSULTATION

The APVMA is seeking to consult with key stakeholders to ensure the proposed framework offers genuine benefit in terms of improving the regulatory efficiency of labelling regulation, is readily understood and is straight-forward in terms of achieving compliance.
‘REGULATORY BOX’ APVMA LABELLING REFORM PROPOSAL

Regrettant Box

- Any other matters that registrant places on label for commercial reasons
  eg. Logo
  Warranty

Other Legislation Box

- Matters that other legislation requires to appear on label but which are not controlled by APVMA
  eg. Poisons Scheduling
  Dangerous Goods Classification

APVMA Regulatory Box

- Instructions determined by APVMA
- Matters that Agvet legislation says must appear on label and which are determined by APVMA

Control by Permit
Control by condition
Control by application to the APVMA
# PROPOSED LABELLING HIERARCHY

## 1. APVMA REGULATORY BOX

<table>
<thead>
<tr>
<th>Item</th>
<th>Currently covered by Condition</th>
<th>Currently covered by Permit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agvet Code</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the circumstances in which the product should be used</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>how the product should be used</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the times when the product should be used</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the frequency of the use of the product</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the withholding period after the use of the product;</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the re-entry period after the use of the product</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the disposal of the product when it is no longer required</td>
<td>n/a</td>
<td>Permit 6868 for certain changes</td>
</tr>
<tr>
<td>the disposal of containers of the product;</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>the safe handling of the product and first aid in the event of an accident caused by the handling of the product;</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>any other matters prescribed by the regulations</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Regulation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the appropriate signal heading in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the name of the chemical product;</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the name of each active constituent of the product</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the proportion of each active constituent of the product</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the name of each other constituent classified as a poison in the Standard for the Uniform Scheduling of Drugs and Poisons</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>the proportion of any other constituent referred to in paragraph</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>provision for a batch number</td>
<td>Conditions 6 and 7(^1)</td>
<td>n/a</td>
</tr>
<tr>
<td>provision for an expiry date, if applicable</td>
<td>Conditions 2(^2) or 7(^1)</td>
<td>n/a</td>
</tr>
<tr>
<td>provision for a date of manufacture, if applicable</td>
<td>Conditions 6 and 7(^1)</td>
<td>n/a</td>
</tr>
<tr>
<td>the name and address of the person who is primarily responsible for marketing the product</td>
<td>n/a</td>
<td>Permit 6868 (for changes)</td>
</tr>
<tr>
<td>the net contents of the product;</td>
<td>n/a</td>
<td>Permit 9523 (within specified range)</td>
</tr>
<tr>
<td>the distinguishing number of the label (including any distinguishing number given to the label under paragraph 178 (2) (a) of the Code);</td>
<td>n/a</td>
<td>Permit 6868 for some specified changes</td>
</tr>
<tr>
<td>any other particulars of the product that the APVMA thinks appropriate</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

\(^1\) Standard Condition 6 requires that the label must contain a Date of Manufacture and Batch Number; Standard Condition 7 requires that the label must contain a Date of Manufacture, Batch Number and Expiry Date no greater than 2 years after the DOM.

\(^2\) Standard Condition 2 requires that the label contain an expiry date.
2. OTHER LEGISLATION BOX

<table>
<thead>
<tr>
<th>Item</th>
<th>Currently covered by Permit</th>
<th>Relevant Legislation</th>
<th>Responsible Agency (Regulator)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Matters that are complementary to, or support the labelling requirements of the Agvet Codes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signal headings as well as typeface and font sizing requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)</td>
<td>Permit 6868 (for some changes)</td>
<td>State and territory poisons legislation.</td>
<td>National Drugs and Poisons Scheduling Committee and State and Territory Departments of Health</td>
</tr>
<tr>
<td>Dangerous goods classification and emergency transport advice</td>
<td>Permit 6868 (for changes)</td>
<td>7th edition of the Australian Dangerous Goods Code given effect through supporting Act and Regulations in each jurisdiction (See also National Transport Commission (Model Legislation — Transport of Dangerous Goods by Road or Rail) Regulations 2007)</td>
<td>Relevant Authority in each state and territory</td>
</tr>
<tr>
<td><strong>Matters controlled by other legislation or mechanisms and that do not specifically relate to the APVMA’s risk assessment about the safe and effective handling and use of the product.</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claims other than those governed by the Agvet Code.</td>
<td>N/a</td>
<td>Trade Practices Act 1974 (Cwth)</td>
<td>Australian Competition and Consumer Commission</td>
</tr>
<tr>
<td>Labelling of imported goods</td>
<td>N/a</td>
<td>Commerce (Trade Descriptions) Act 1905</td>
<td>Australian Customs and Border Protection Service</td>
</tr>
<tr>
<td>Australian Made logo and statements</td>
<td>n/a</td>
<td>Authorised under license by the Australian Made Campaign Limited</td>
<td>n/a</td>
</tr>
</tbody>
</table>

3. REGISTRANT BOX

3(a). Changes currently authorised by permit

<table>
<thead>
<tr>
<th>Item</th>
<th>Currently covered by Permit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warranty /Conditions of sale</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Distributor/registrant/formulator name and contact details</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Logos such as company, DrumMuster, WormBoss</td>
<td>Permits 6868, 9284</td>
</tr>
<tr>
<td>Promotional material</td>
<td>Permit 9284</td>
</tr>
<tr>
<td>Duplicate text</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Australian-made expressions</td>
<td>Permit 6868</td>
</tr>
<tr>
<td><strong>“New” stickers</strong></td>
<td>Permit 6868</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Variations of text weight, print size, type, case, font, column breaks and text wrapping</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Mandatory changes to pesticide mode of action group letters or numerals or resistance management statements</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Addition of Poison, not to be taken or not to be used as a food container as required by the SUSDP</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Country of origin statements</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>NZ registration statements</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Deletion of obsolete names from compatibility statements</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Replacement of “environmentally friendly” with “CFC free”</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Certain specific amendments to product disposal statements</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Certain amendments to the label approval number</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Change to net contents within APVMA approved range of pack sizes</td>
<td>Permit 9523</td>
</tr>
<tr>
<td>Trademarks, patent numbers, barcodes, printers numbers</td>
<td>Permit 6868</td>
</tr>
<tr>
<td>Variation to background or print colours provided one product in range has had APVMA approval of the change</td>
<td>Permit 6868</td>
</tr>
</tbody>
</table>

### 3(b). New Proposal

The APVMA proposes not to consider the following wording and graphics on labels:

- Logos;
- Warranty/condition of sale statements;
- “Australian made” expressions and logos³;
- Country of origin statements;
- NZ registration statements;
- Trademarks, patent numbers, barcodes, printers numbers, label revision date and/or number (not the APVMA approval number);
- Inclusion of claims that do not come within the APVMA’s jurisdiction, such as energy consumption, sunburn protection factors, fertilizer claims and analysis;
- Inclusion on the approved label of the promotional material currently allowed (as an extra label) by permit 9284;
- Product compatibility statements (except specific instructions to mix products that are within the directions for use);
- References to websites relating to the product or to the company marketing the product;
- References to company provided contact, customer service or help lines and/or email addresses for assistance or for placing orders;
- Product guarantee statements;
- Copyright statements;
- Package opening instructions other than those required as part of an approved instruction or required safety direction;
- Statements limiting the availability of the product that are not required by the APVMA, for example “only available from a veterinarian” on a product that is not in Poisons Schedule 4;
- Trade mark acknowledgement statements, eg “XXX is a registered trademark of YYY Co”;
- Company slogans or mottos;

³ Note: Australian Made claims are specifically authorised under license by the Australian Made Campaign Limited.

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• Date when company was established.

The APVMA also proposes to allow the following alterations to label colour, design and layout without APVMA approval of individual labels:

• Any variation to the background or print colour of the label provided legibility is maintained;
• Variations of text weight, print size, type, case, font, column breaks and text wrapping;
• Changes to the size and/or shape of a label provided the placement of key information (as per the APVMA Regulatory Box) is not altered and legibility is maintained;
• Addition or changes of graphics or pictures on labels provided they do not infer that the crops, animals or situations of use or the target pests are changed;
• Insecticide, fungicide and herbicide resistance group symbols and warning statements that are consistent with the Agricultural Labelling Code and current CropLife requirements.
APVMA Label Legibility Standard

1. Purpose

To establish appropriate parameters for the legibility of agricultural and veterinary chemical product labels approved by the APVMA under the Agricultural and Veterinary Chemicals Code (the Agvet Code). It is critical that agricultural and veterinary chemical product labels be legible by persons handling and using the product or otherwise dealing with the containers as the label contains critical information for the appropriate method of dealing with and using the product, including reference to other information sources such as MSDS where relevant information may be obtained.

Labels not complying with this standard and which are not readily legible may pose a safety risk to persons handling or using the chemical product or otherwise dealing with the containers. It is the registrant’s responsibility to ensure that a chemical product for which they are responsible is not supplied either advertently or inadvertently with a label affixed to the container that is not readily legible.

The label approval for labels found in the market that do not conform to this standard and which are not readily legible may be suspended.

2. Objective Requirements

The label instructions required by the APVMA and any other information relevant to the handling or use of the chemical product contained on a label must be legible to the average person using their normal reading aids (e.g. glasses) if required, in good natural light conditions (320 lux). If the product is primarily for use indoors (e.g. household products) it must be legible using incandescent lighting of the type used in the average household (160 lux).

Labels for agricultural and veterinary chemical products registered under the Agvet Code must adhere to following requirements when printed for attachment to containers of the product.

2.1 Print size

The legislative arrangements for poisons scheduling include requirements for the size and typeface of text on labels. These requirements are set out in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and are reflected in the Ag Labelling Code and the Vet Labelling Code in the Manual of Requirements and Guidelines (MORAG) (as relevant to the product type). The requirements include print styles and minimum print sizes for certain words and expressions used on labels.

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1 The Agvet Code is a Schedule to the Agricultural and Veterinary Chemicals Code Act 1994.
and must be observed\(^3\). Examples are the signal headings, active constituent statements and withholding periods. Consult the relevant Labelling Code for further details.

Wording on a label for which there is no minimum type size specified in the Ag Labelling Code or the Vet Labelling Code (as appropriate) must have a minimum letter height of 1.5 mm, which equals 6 points. Letters with ascenders or descenders, such as b, f, g, h, l, t, etc are to be a minimum of 1.5 mm in height. Letters without ascenders or descenders, such as a, e, i, o, u, m, r, etc are to be a minimum of 1 mm in height.

This minimum print size should only be used where space is extremely limited. Larger print, that is 2 mm or greater, should be used unless label space is limited. Larger print sizes are more readily read by users and other persons dealing with the chemical, facilitate the clear communication of warnings and instructions and contribute to the safe handling and use of the chemical.

2.2 Print style

Typefaces chosen need to be clear and simple. Complicated or decorative fonts can be difficult to read and should be avoided.

Bodies of text should not be in all capitals or italics, unless required by the Ag Labelling Code or Vet Labelling Code (e.g. withholding period statements). Closely spaced, condensed or widely spaced lettering should be avoided. Bold text can be used for emphasis, and where required by the relevant Labelling Code. Where bold text is used registrants must ensure the type does not become so thick that it reduces white spaces within characters.

2.3 Print quality

Printing must be clear and crisp and free from blurring or other distortion.

Printing must be sufficiently durable so as not to fade, run, smudge or otherwise lose legibility during reasonable handling and storage for at least 2 years or the stated shelf life of the product in the case of date-controlled products.

2.4 Colour

The colour of the letter print must be distinctly contrasted to the background colours. Use light coloured text on dark backgrounds and dark text on light backgrounds. Use well contrasted colours with widely differing hues and an appreciable difference in value. Avoid strongly saturated colour pairs for text and background.

\(^3\) The size and typeface requirements of the SUSDP are intended to ensure that certain label warnings and instructions are appropriately differentiated from one another, as well as ensuring their legibility. For these reasons, as well as consistency, the APVMA believes that the size and typeface requirements of the SUSDP are equally relevant to the labels of chemical products that are not subject to poisons scheduling.
There must be a luminance contrast of at least 30% between letters and background. (Australian Standard AS1428.1, particularly Appendix D, provides further details on luminance contrast)\(^4\).

Text printed directly over pictorial or multicoloured backgrounds may be difficult to read and should be avoided. A plain background, preferably white, may be used beneath the letters to improve legibility in these situations.

Colour blindness affects a significant number of people in the community, between 5 to 10% of males but only around 0.5% of females. These people usually have difficulty with the colours green, yellow, orange and red. This should be taken into account when choosing label colours for critical information. In particular avoid red print on green background or the reverse. Do not use red, green, brown, grey and purple next to each other or on top of each other.

3. Definitions and Interpretation

In this Standard the following words have the following meanings:

**Hue** means that attribute of a colour by which it is recognised as a red, green etc and which is dependent on its dominant wavelength, and independent of intensity or lightness\(^*\).

**Luminance contrast** means the amount of light reflected from one surface or component, compared to the amount of light reflected from the background or surrounding surfaces\(^#\).

**Saturation** means the degree of intensity of a colour; relative freedom from admixture of white\(^*\).

**Value** means that quality of a colour, corresponding to tone or reflectance, which when assigned a numerical value according to its degree of lightness or brilliance can be used in combination with hue and chroma to identify the colour uniquely\(^*\).

*Source: *Shorter Oxford English Dictionary

# Source: Standards Australia AS 1428.1 Design for access and mobility.

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\(^4\) This Australian Standard relates principally to painted surfaces. However the concept of luminance contrast is considered to be applicable to any coloured surfaces irrespective of how the coloration is achieved. This Standard is the only one that the APVMA is aware of that defines the term.
Labelling Flexibility Permit

PERMIT FOR SUPPLYING A REGISTERED CHEMICAL PRODUCT WITH A LABEL WHICH IS NOT IDENTICAL TO THE APPROVED LABEL

PERMIT NUMBER XXXX

Purpose

This permit is issued so that, within defined circumstances, a registered chemical product may lawfully be supplied with a label that is not identical to the label for containers for that product which the Australian Pesticides and Veterinary Medicines Authority (APVMA) or the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has approved. But for the operation of this permit, such supply would be an offence under Sections 81 and 84 of the Agricultural and Veterinary Chemicals Code (the Agvet Code), being a Schedule to the Agricultural and Veterinary Chemicals Code Act 1994.

Scope of permit

Parts A, B and C of this permit set out those administrative label amendments that can be made under this permit. Label approval holders do not need to make application to the APVMA to vary the approved label for those things set out in Parts A, B and C.

Permit issued under s6 of the Agvet Code

This permit is issued under Section 6 of the Agvet Code. It gives permission to any person to supply, or cause or permit to be supplied, a registered chemical product in a container where the label attached to the container is not identical to a label approved by the APVMA or NRA for containers for that product in respect to those things that are authorised in Parts A, B and C only.

Note: To avoid confusion this permission does not apply where differences between the approved label and the label attached to the container extend beyond those expressly permitted by this permit.
Permit does not affect other obligations under the Agvet Code

1. Any label variations that are not expressly authorised by this permit may only be made if the APVMA has granted an application under Section 29 of the Agvet Code to vary the approved label.

2. The label must only be attached to containers for the relevant agricultural or veterinary chemical product that is registered under Part 2 or 2A of the Agvet Code of the jurisdiction in which the supply takes place.

3. Any conditions that apply to the approved label for the product must continue to be met.

General requirements

1. Any amendments to labels made under this permit must only be made with the consent of the registrant – that is the person or company in whose name the product is registered with the APVMA and in whose name the approved label for that product is held.

2. Labels amended under this permit and subsequently affixed to containers of a registered chemical product must remain suitably legible and as a minimum must comply with the standard for legibility contained in Part B.

3. The format (layout) of the labels amended under this permit, including text size requirements, must be as specified in the Ag Labelling Code or the Vet Labelling Code as relevant to the product.

4. The registrant must maintain a copy of any labels affixed to containers for a period of at least 5 years from the date of marketing and provide an example, including a version showing the differences from the approved label, at the request of the APVMA.

5. This permit does not authorise the adapting of a text label that has been approved for a shelf product registration to a printed or marketable label. In such cases an application for approval of the revised label is required.

6. The authorised variations described in paragraphs 3, 4, 5, 8, 20, 29, and 31 of Part A of this permit can only be made to labels for which the label approval has been granted subject to the following conditions:
   a. Label must meet the requirements of other legislation; and
   b. Label must not make false or misleading claims; and
   c. Label may be altered in accordance with prescribed parameters; and
   d. Label to be amended as instructed by the APVMA; and
   e. Registrant to supply samples of labels if requested.

Note: Conditions of label approval for each label approved by the APVMA are set out in the Notice of Registration of Chemical Product and Approval of Label Under the Agvet Codes, Notice of Variation of Registration of Chemical Product and Approval of Label Under the Agvet Codes, or Notice of Approval of Label Under the Agvet Codes.
**Aids to interpretation**

*Additional label* means stickers, neckties or tags attached to the container of a chemical product in conjunction with an approved label.

*Approved Label* has the meaning given in Section 3 of the Agvet Code.

*Ag Labelling Code* means the Ag Labelling Code published in Volume 5 of the APVMA Manual of Requirements and Guidelines (*MORAG*), which is available from the APVMA website.


*Claim* is defined by the Agvet Code to include any statement. For the purposes of this permit *claim* in relation to a statement on a label is defined more narrowly to mean a statement that the chemical product exhibits certain properties or has certain effects, for example efficacy against a particular disease.

*Label* is defined by the Agvet Code to include a tag, leaflet, brand stamp, mark stencil or written statement.

*Label instructions required by the APVMA* for the purposes of this permit means instructions and other label content, the amendment of which is not expressly authorised by this permit and which may only be altered with the approval of the APVMA.


*Notice of Label Approval* means Notice of Registration of Chemical Product and Approval of Label Under the Agvet Codes, Notice of Variation of Registration of Chemical Product and Approval of Label Under the Agvet Codes, or Notice of Approval of Label Under the Agvet Codes.

*Promotional material* means stickers, neckties or tags (‘additional labels’) affixed to the containers of registered chemical product advertising or highlighting that the product is new or has recently had a new use approved by the APVMA. See also explanatory note for ‘promotional material’ at Part C.

*Shelf product registration* means a registered product which the registrant has indicated is not intended to be marketed directly at the current time and for which the registration is rather held for contingency purposes or to be used as a reference product for the registration of other products that are ‘similar’, ‘closely similar’ or ‘the same’ as defined in Schedule 6 of the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

*Text label* means a label that contains all the label instructions required by the APVMA and other relevant information but is not presented in a format suitable for direct application to a container.

*Vet Labelling Code* means the Vet Labelling Code published in Volume 5 of the APVMA Manual of Requirements and Guidelines (*MORAG*), which is available from the APVMA website.
Parts

Part A sets out the specific label amendments authorised by this permit.

Part B is a label legibility standard that applies when making the amendments authorised by Part A.

Part C sets out the type and nature of additional labels authorised by this permit.

Commencement/expiry

This permit commences on xxxxx and remains in force until it is cancelled.

..................................
Delegated Officer
Dated:
PART A

AUTHORISED LABEL AMENDMENTS

Contents

1. Format and layout
2. Graphics and colours
3. Label wording and content
   3.1 General
      - Promotional material
      - Label approval number (LAN)
      - Contact details
      - Net Contents
   3.2 Instructions and Standard Statements
      - Amendments in compliance with certain other legislation and controls
      - Signal Headings, First Aid and Safety Directions
      - Resistance management
      - Disposal Instructions
      - Packaging specific statements
   3.3 Product Stewardship and other registrant desired information
      - General
      - Claims beyond the scope of APVMA consideration
      - Compatibility statements
      - New Zealand (NZ) specific statements

This permit authorises the supply of labels that have been amended only as described below.

1. Format and layout

This permit allows the following variations to label format and layout:

1. Addition and/or deletion of duplicate blocks of text or panels of the approved label on the same label part provided the label complies with any parameters described in the latest edition of the Ag Labelling Code or Vet Labelling Code, as appropriate to the product;

2. Changes to column breaks and/or text wrapping arising from variations authorised by this permit provided the label complies with any parameters described in the latest edition of the Ag Labelling Code or Vet Labelling Code, as appropriate to the product;
3. Changes to the shape or dimensions of the label provided the label is appropriate for the container to which it is affixed and complies with any parameters described in the latest edition of the *Ag Labelling Code* or *Vet Labelling Code*, as appropriate to the product.

2. **Graphics and colours**

This permit allows the following variations to label graphics and colours:

4. Changes to the text weight, print size, type, case or font, and the colour of the printing of words on the label and the background colours of the label provided:
   i. All text included on the label complies with any requirements, including case, font and sizing requirements, specified in the *Ag Labelling Code* or the *Vet Labelling Code* as relevant to the product; and
   ii. The words contained on the label are appropriately legible and as a minimum the label complies with the APVMA Label Legibility Standard at Part B of this permit.

5. The addition of, or changes to, logos (e.g. drumMuster logo, company logo), graphics or pictures on labels provided they:
   i. Do not infer situations of use (such as crops or animals) or purposes of use (such as pests and diseases) that are inconsistent with that for which the product is registered;
   ii. Are not misleading in respect of the use, safety, environmental impact or efficacy of the product;
   iii. Do not take up excessive amount of label space or obscure label instructions required by the APVMA; and
   iv. Are in accordance with any parameters described in the latest edition of the *Ag Labelling Code* or the *Vet Labelling Code*, as appropriate to the product.

6. The removal of any such logos, graphics or pictures from labels provided they do not affect the communication of label instructions required by the APVMA.

**Note:** Variations made to graphics and colour must not have the effect of altering the product name.

3. **Label wording and content**

This permit allows the following variations to label wording and content:

3.1 **General**

**Promotional material**

7. Addition or removal of promotional material or additional labels as authorised by Part C of this permit.

8. Addition or removal of a promotional message on the label that would otherwise be authorised for inclusion as a sticker by Part C of this permit, provided:
i. Such an inclusion complies with all requirements set out in Part C for the inclusion of an additional label component. To avoid confusion for the purposes of this provision such an inclusion is considered to be the same as a sticker that comprises an additional label component as described in Part C; and

ii. The inclusion does not obstruct or otherwise interfere with any label instructions required by the APVMA; and

iii. The format of the label remains compliant with any parameters described in the latest edition of the Ag Labelling Code or the Vet Labelling Code, as appropriate to the product.

Label approval number (LAN)

9. Replacement of NRA with APVMA in the prefix to the LAN.

10. The inclusion of a pack size identifier in the LAN where a pack size identifier was not previously included in the LAN, provided:
   i. The pack size identifier is compliant with any parameters described in the latest edition of the APVMA Label Approval Process; and
   ii. The pack size identifier being included corresponds with the approved pack size specified in the Notice of Label Approval for the label being so amended; and
   iii. There is no change to the ‘product number’ or ‘version control’ components of the LAN (see note below).

11. Repositioning a LAN that the APVMA has stamped or otherwise placed on the approved label, so that the LAN follows the words ‘APVMA Approval No.’ or ‘APVMA’ as applicable.

12. Repositioning the block ‘APVMA Approval No: [LAN]’ to another position on the label.

   Note: Information relating to label approval numbers (LAN) can be obtained in the APVMA Label Approval Process published in Volume 5 of MORAG.

Contact details

13. Changes to update (but not deletion of) the company name and contact details (including website details) in respect of the distributor, the registrant or a manufacturer except in circumstances where:
   i. The name and contact details to be amended are those of the registrant and a corresponding notification of the change has not been made to the APVMA by submitting the form ‘Change to Registration Records’; or
   ii. The name and contact details to be amended are those of a manufacturer and an appropriate notification of the change has not been made to, and if required, approved by the APVMA. A variation to the site of manufacture or formulation for a product requires an application to be made to the APVMA.

   Notes: (a) The form ‘Change to Registration Records’ is available from the APVMA website at http://www.apvma.gov.au/forms/docs/KP22_3F04.doc; (b) Information on procedures and requirements for making an application to vary the site of manufacture or
formulation of a product can be found in the APVMA’s MORAG; (c) It is a requirement that the name and contact details of the person primarily responsible for marketing the product be included on the product label.

Net Contents

14. Addition or variation (but not removal) of a net contents statement of an approved label where the net content to be stated on the varied label is:

i. Within the range of pack sizes specified in the Notice of Label Approval, for the label being so amended – this is also reflected in the ‘pack size identifier’ component of the APVMA Label Approval Number (LAN) for the label; and

ii. Appropriate to the actual net content of the container to which the label is to be affixed.

Notes: (a) Information relating to label approval numbers (LAN) and labels for a range of pack sizes can be obtained in the APVMA Label Approval Process published in Volume 5 of the MORAG; (b) The variation to a net contents statement authorised by this permit may only be within the range specified in the ‘pack size identifier’ component of the Label Approval Number (LAN). For example if the pack size identifier is 1-10L the Net Contents statement on the label may only be varied within the range of 1L to 10L; (c) The containers to which labels are affixed must comply with any relevant conditions of registration of the product.

3.2 Instructions and Standard Statements

Amendments in compliance with certain other legislation and controls

15. In accordance with the relevant controlling legislation and any parameters described in the latest edition of the Ag Labelling Code or the Vet Labelling Code as appropriate to the product the addition, deletion or amendment of:

i. Dangerous goods and emergency transport advice as required by the most recent addition of the Australian Dangerous Goods Code; or

ii. Weights and measures descriptors (e.g. National Measurement Act 1960); or

iii. Country of origin statements (e.g. Commerce (Trade Descriptions) Act 1960).

Signal Headings, First Aid and Safety Directions

16. Where appropriate and necessary to comply with the provisions of the Standard for the Uniform Scheduling of Drugs and Poisons for containers of Schedule 5 poisons the addition of the expressions:

i. POISON, NOT TO BE TAKEN; or

ii. NOT TO BE USED AS A FOOD CONTAINER

17. Amendment to the signal headings to comply with the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), or changes to the safety directions or first aid instructions to comply with the First Aid and Safety Direction (FAISD) Handbook, but only where such amendments are directed or otherwise authorised in writing by the APVMA.
Resistance management

18. Changes to the pesticide mode of action group letters or numerals and pesticide resistance management statements for resistance management strategies, that are consistent with any parameters specified in the latest edition of the *Ag Labelling Code* (agricultural chemical products only).

Disposal Instructions

19. Amendment of disposal instructions to include either of the following statements as appropriate to the product:

i. For products that are used undiluted or are not applied via a spray tank:

   This container can be recycled if it is clean, dry, free of visible residues and has the *drumMUSTER* logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate or any undiluted chemical according to State legislative requirements. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any *drumMUSTER* collection or similar container management program site. The cap should not be replaced but may be taken separately.

or

ii. For products that are applied via a spray tank:

   This container can be recycled if it is clean, dry, free of visible residues and has the *drumMuster* logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any *drumMUSTER* collection or similar container management program site. The cap should not be replaced but may be taken separately.

or

iii. For product containers that will not be recycled (may also be included with either of the above disposal instructions):

   If not recycling, break, crush or puncture and bury empty packaging in a local authority landfill. If no landfill is available, bury the packaging below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

Packaging specific statements

20. Addition, deletion or amendment to the instructions for the opening of packages or containers provided those instructions:

i. Are appropriate to the packaging in which the product is supplied; and

ii. Do not conflict with any required safety directions or other instructions required by the APVMA relevant to the dealing with the packaging of the product.
3.3 Product Stewardship and other registrant desired information

General

21. Correction of typographical or print errors.

22. Addition, removal or amendment of warranty, liability, guarantee or conditions of sale statements (including statements intended to limit the availability of a product that have not been required by the APVMA) provided such statements do not:
   i. Conflict with label instructions required by the APVMA; or
   ii. Infer or imply to be requirements of the APVMA; or
   iii. Infer or imply to be statements that are underpinned by APVMA endorsement.

23. Addition, removal or amendment of references to websites relating to the product or to the company marketing the product.

24. Addition, removal or amendment of company-provided customer service contacts, including help lines and email addresses as well as contact details for assistance in placing orders.
   
   Note: A specific requirement for company contact details remains – see paragraph 13 above for details of authorised amendments to company contact details.

25. Addition, removal or amendment of barcode or printer’s number, label revision date or number, but not including the APVMA Label Approval Number (LAN).
   
   Note: See paragraphs 9-12 above for details of authorised amendments to the LAN.

26. Addition, removal or amendment of trademarks or trademark symbols (® or ™) including trademark acknowledgement statements, copyright statements, and patent numbers.

27. Addition, removal or amendment of company slogans or mottos, including that relating to the date when the company was established, where such slogans or mottos may not be taken to imply a claim about the chemical product that is inconsistent with its approved uses.

28. Addition, deletion or amendment of Australian-made expressions or graphics that may imply Australian ownership or content provided the inclusion of such information does not interfere with label instructions required by the APVMA.
   
   Note: The Australian Made logo and statements are authorised under license by the Australia Made Campaign Limited.

Claims beyond the scope of APVMA consideration

29. Addition, removal or amendment of label claims that are outside the scope of APVMA consideration but that are otherwise compliant with the requirements of the Trade Practices Act 1974 and other relevant legislation. To avoid confusion “claims outside the scope of APVMA consideration” are those that do not relate to whether the chemical product is an agricultural chemical product or a veterinary chemical product as defined by Sections 4 and 5 of the Agvet Code. Examples of such claims include energy efficiency claims, sunburn protection factor claims on personal insect repellents, fertilizer claims, ‘CFC free’ or ‘environmentally
friendly’ claims, ‘natural’ claims or claims related to organic certification or use in agricultural production systems certified as organic.

Note: It is an offence under Section 84 of the Agvet Code for a person to make any claim, or cause or permit any claim to be made in respect of a registered chemical product or a listed chemical product that is inconsistent with any of the instructions on the approved label except where such claims are exempted from the operation of Section 84 by the APVMA. To avoid confusion paragraph 29 exempts the making of claims outside the scope of APVMA consideration from the operation of that section. It is the registrant’s responsibility to ensure that any such claims added, removed or amended under this permit are in fact outside the scope of APVMA consideration. If unsure, registrants who intend to make such variations should first check with the APVMA. A lack of awareness as to whether a claim was within or outside the APVMA’s consideration would not constitute a reasonable excuse, particularly where there is no evidence of any verification being sought from the APVMA.

Compatibility statements

30. Deletion of obsolete product names from general compatibility statements.

31. Addition, deletion or amendment of references to other products or active constituents with which the product is chemically compatible in the dedicated general compatibility statement, provided:
   i. The label being so amended is that of an agricultural chemical product; and
   ii. The registrant of the product has determined by its own enquiries or scientific testing that the statement of compatibility is correct; and
   iii. The reference to compatibility with other products does not constitute or cannot be taken to imply an instruction to mix certain constituents or products; and
   iv. No additional claims are made with respect to any products or constituents added to the compatibility statement.

Notes: (a) Paragraph 31 is only applicable to the labels of agricultural chemical products and does not authorise the amendment of labels for veterinary chemical products which do not have a similar general compatibility section; (b) To avoid confusion the amendment of compatibility statements authorised by paragraph 31 does not extend to specific instructions to mix or combine products that form part of the directions for use approved by the APVMA; (c) A claim that the combination other products or constituents with the product will enhance its properties or attributes (e.g. efficacy) is within the scope of APVMA consideration and must be approved through the APVMA’s assessment processes.

New Zealand (NZ) specific statements

32. Addition and/or deletion of New Zealand classification or approval details and relevant New Zealand contact details as specified and required by the Agricultural Chemicals and Veterinary Medicines (ACVM) group of the New Zealand Food Safety Authority (NZFSA) provided such information:
   i. Appears only on an ancillary label panel or in a New Zealand section or box that is prefixed by words such as ‘In New Zealand’ or alike to clearly identify that content as applying only in New Zealand; and
ii. Is consistent with and does not extend or contradict a claim or instruction approved by the APVMA for the use of the product in Australia.

Notes: (a) To avoid confusion the amendment of information in the New Zealand panel, section or box authorised by paragraph 32 only relates to information that is necessary for the product to be marketed in New Zealand for the same use patterns as the product is registered for in Australia. Paragraph 32 does not authorise the addition of references to use patterns (claims) that are not included on the approved Australian label for the product. Similarly all other instructions, recommendations and warnings (including withholding periods where relevant) must be consistent with the instructions approved by the APVMA for the product. Inconsistencies in such information has the potential to cause confusion amongst users and contributes to the misuse of chemical products; (b) Registrants wishing to include content in the New Zealand section beyond that permitted by this permit may make an application to the APVMA. Information on procedures and requirements for making an application can be found in the APVMA’s MORAG.
PART B

Legibility of Labels

Labels varied in accordance with the authorised parameters set out in Part A and subsequently affixed to containers of a registered chemical product must remain suitably legible and as a minimum must comply with the following standard for legibility.

APVMA Label Legibility Standard

The APVMA Label legibility Standards has been separately included as Attachment 3 to the Labelling Reform Proposal Paper and has not been reproduced here.
PART C

REQUIREMENTS FOR SUPPLY OF A CHEMICAL PRODUCT WITH AN ADDITIONAL LABEL COMPONENT (STICKERS, NECKTIES AND TAGS)

Stickers, neckties and tags constitute a label for the purposes of the Agvet Code when affixed to the container of a registered chemical product. For the purposes of this Permit they are defined as an additional label.

This permit allows any person to supply or cause or permit to be supplied, a registered chemical product with an additional label that is not identical to the approved label, if the additional label conforms to all of the following requirements:

(a) The additional label may only be a sticker, leaflet, tag or the like which is attached to the container for the chemical product that has been placed on the container by, or at the request of, the person that holds the registration of that product;

(b) The additional label contains only promotional material (see Explanatory Notes below) that makes no express or implied claims about the performance of the product that are additional or contrary to the claims on the approved label and does not contain any additional instructions about the use of the product.

(c) Any statements contained on the additional label are appropriately justified and supported as required by the *Trade Practices Act 1974* and other relevant legislation and are not contrary to or inconsistent with other information included on the approved label.

(d) The container to which the additional label is attached also has attached to it an approved label being:

   i. a label approved under Part 2 of the Agvet Codes in the case of a registered chemical product;

   ii. a label consistent with the relevant standard established under Part 2A of the Agvet Codes in the case of a registered listed chemical product; or

   iii. an approved label varied in a manner authorised or permitted by the APVMA; and

(e) The additional label does not obstruct any text of the approved label.

**Explanatory notes:**

1. **Promotional Material**

Examples of promotional material include indication that a product or formulation is new; that a new use has recently been approved (by registration) by the APVMA such as “now approved for use on canola”; drawing attention to programs such as “WormBoss” or “drumMUSTER”; highlighting a promotional give-away or advertisement for a competition.
Promotional material indicating that a product, formulation or use pattern is ‘new’ should only be used on a label for a maximum period of 6 months and then removed. Use of such material for an extended period could be construed as misleading.

‘Promotional material’ may also include information alerting the reader to label changes resulting from APVMA review outcomes that have formally changed the use of the product or other label instructions such as new withholding periods.

For veterinary products, due to the requirements of Good Manufacturing Practice (GMP), any additional label carrying label changes indicating a new approved use must be affixed in a GMP licensed premises.

2. Promotional, Display and Shipper Packs

Promotional, display and shipper packs are defined as outer packaging containing one or more registered products used to promote, display or protect the products or the special deal for the purchaser in the form of a price discount, a free bonus pack or a gift. Registrants should note that clarity on the use of promotional, display and shipper packs is provided in the APVMA Operational Notice, Promotional, Display and Shipper Packs, dated October 2003.