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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT
BILL 2010**

SUPPLEMENTARY EXPLANATORY MEMORANDUM

Amendments and New Clauses to be Moved on Behalf of the Government

(Circulated by authority of the Minister for Agriculture, Fisheries and Forestry,
the Hon. Tony Burke MP)

AMENDMENTS TO AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT BILL 2010

GENERAL OUTLINE

Government amendments to the Agricultural and Veterinary Chemicals Code Amendment Bill 2010 (the Bill) consist of three measures which will amend the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code). The measures seek to improve the efficiency and effectiveness of the handling of approval and registration applications by the Australian Pesticides and Veterinary Medicines Authority (APVMA), without jeopardising human health or the environment.

The amendments:

- allow applicants to follow a simplified application process to effectively notify the APVMA of a limited range of defined, very low risk, minor variations to approvals or registrations instead of going through the existing technical assessment process;
- remove the requirement for applicants or interested persons affected by notices given by the APVMA to notify the APVMA in writing of the authorising of an approved person, if such an authorisation is made; and
- limit and clarify the APVMA's role in assessing chemical product labels to considerations linked to the safe and effective use of the product, enabling applicants to make changes to labels that do not affect the safe and effective use of a product without the APVMA's approval.

Amendments to the current Bill deliver several measures that address agricultural and veterinary (agvet) chemical industry concerns and bring benefits to both applicants and the APVMA as the regulator.

Notification of minor product variations

These amendments provide for a simplified application process for very low risk variations of the particulars of registered agvet products.

The kinds of variations for which the simpler application process would be permitted are variations that do not change the risk assessment in relation to the efficacy or safety of the chemical product concerned. Examples of product changes that may be eligible for notification include: the substitution of acceptable alternative non-active constituents in a chemical product, for example dyes used for aesthetic purposes; the site of manufacture; or pack size.

Under the simplified application process for variations to agvet product particulars, the APVMA will develop a legislative instrument which outlines relevant particulars which would be able to be varied by notification application. Applicants would:

- refer to this legislative instrument and any guidance provided by the APVMA;
- determine for themselves whether the proposed change is eligible for notification (with support from the APVMA if required);
- submit an application for the notified variation to the APVMA; and
- proceed with varying the product.

The APVMA will review notification applications to ensure applicants have correctly applied the notification provisions and confirm that the variation would not have a negative effect on efficacy or safety and is suitable for notification. Once satisfied, the APVMA would make the necessary change to its database(s) and advise the registrant of the acceptance and recording of the notification. The APVMA will also undertake compliance monitoring and enforcement activities in relation to products varied through notification.

This measure is expected to improve the timeliness of very low risk, minor changes to particulars of agvet chemicals and chemical label approvals and registrations while maintaining full assessment of all other changes. Implementation of this reform will improve the efficient and effective use of the APVMA's expert assessment resources by allowing them to concentrate on those applications that require technical assessment as well as allowing registrants to readily make minor changes to improve their products.

Removing requirement to notify the authorisation of an approved person

This amendment provides for the removal of an existing unnecessary regulatory burden on both agvet industry stakeholders and the APVMA and clarifies an APVMA obligation caused by the requirements of the definition of 'approved person'. Currently, applicants or interested persons affected by notices given by the APVMA are obliged to notify the APVMA in writing if they authorise a person to act or receive notices on their behalf and APVMA must verify that each person it corresponds with is an approved person. This obligation exists for applicants or persons affected by notices that do not reside in or are not incorporated in Australia.

Due to the lack of clarity of this requirement, notification has become standard practice for all approved persons authorised to act on an applicant's behalf. The amendment allows for the APVMA not to have to verify each person it corresponds with is an approved person but does not remove the requirement for registrants to authorise an Australian approved person who is liable for the products of the overseas applicants.

Limiting and clarifying the APVMA's label assessment role

These amendments seek to limit the APVMA's regulation of agvet chemical labels to matters related to 'adequate instructions' for the safe handling and safe and effective use of a product. This will allow APVMA assessors to focus on core activities by removing the APVMA as the responsible party for aspects of labelling not related to instructions for safe and effective use. The changes will also allow registrants to have greater flexibility to make changes to labels that are not related to adequate instructions which should not require APVMA review or approval.

Under current legislation the APVMA is obliged to assess all labelling elements, including the size, type and all elements of a label. This is inappropriate and unnecessary – labels include other content that is unrelated to the APVMA's principal responsibility to review labels according to its risk assessments about the safe and effective handling and use of the product. The APVMA should not be required to

cross-check label items that are of a commercial nature or are already under the authority of another regulator, as this may lead to confusion about regulatory responsibility and take resources away from the APVMA's core activities.

The amendments limit the APVMA's responsibility to ensuring that labels conform to the definition of 'adequate' instructions for safety and efficacy. The applicant remains responsible for other label elements (including other statutory requirements) such as size, type, dangerous goods, warranty and contact information. The APVMA will not expect registrants to apply for approval of changes to labels where those changes don't detract from the particulars required to be displayed on the label.

The amendments do not require consequential amendments to other Acts.

FINANCIAL IMPACT STATEMENT

The amendments have been assessed as having no significant financial impact on the Australian Government and affected parties.

REGULATION IMPACT STATEMENT

1. Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) performs a vital role in protecting human health, the environment, workers, animals, crops and Australia's trade reputation from the potentially harmful effects of agricultural and veterinary (agvet) chemicals. The APVMA assesses, registers and reviews agvet chemicals - which are used in a wide range of situations, such as on farms, in gardens, for pets, and around households - to ensure their safety.

The APVMA administers and manages the National Registration Scheme for Agricultural and Veterinary Chemicals, which sets out the regulatory framework for managing agvet chemicals in Australia up to the point of retail sale. The Department of Agriculture, Fisheries and Forestry (DAFF) with the APVMA, administer the scheme's legislation in partnership with state and territory governments and with the involvement of other Australian Government agencies and regulators.

While the APVMA is known as an agency that carries out reputable scientific and technical regulatory functions, there is still room for improvements to the efficiency and effectiveness of the processes in which agvet chemicals are regulated. The purpose of this Regulation Impact Statement (RIS) is to assess the likely impacts - of introducing a notification scheme for very minor and nil-risk product changes, streamlining the administrative requirement for the definition of 'approved person', and labelling reforms - including the impact on the regulator, government agencies and applicants.

The reforms will link to and complement other agvet chemical reforms being considered in 2010 and 2011. This includes the Better Regulation Ministerial Partnership between the Hon. Lindsay Tanner MP, Minister for Finance and Deregulation, and the Hon. Tony Burke MP, Minister for Agriculture, Fisheries and

Forestry; the Council of Australian Governments (COAG) early harvest reforms; and the development of COAG's single national framework for agvet chemicals.

2. Problems

All requests for variations to registration and approvals for agvet chemicals must currently be done using the one regulatory tool involving the submission, assessment and granting of applications. The framework does not have the flexibility to allow for a notification of a very minor change to an existing product that does not alter the quality or the risk profile of the product; where no scientific assessment is required; and where there is no creation of risk to efficacy, safety, the environment or trade. Registrants making such changes should be able to notify the APVMA, without undergoing assessment, and proceed to marketing the slightly varied product.

The APVMA is currently subject to an administrative process, which has been identified as an unnecessary regulatory burden. The legislation requires that the APVMA can only deal with an 'approved person' for its correspondence on applications and that an approved person has to be nominated in writing to the APVMA if they are authorised to act on another person's behalf. It is an unnecessary administrative burden for the APVMA to check on an ongoing basis, whether it can correspond with a particular person. The APVMA should be able to accept as being true, information that is provided on company letterhead. Other administrative reforms will be delivered via the partnership initiative.

The APVMA is currently required to review and approve all labelling items, including a label's size, type, colour and format. However, its role should be to assess and approve only the matters that relate to its risk assessment about the safe and effective use of the product, ensuring that the label contains adequate instructions for handling and use. This would reduce the regulatory burden on the APVMA, by clarifying its key responsibilities and provide greater flexibility to registrants to make changes to labels that are not of a technical nature or are outside the APVMA's scope of regulation. It would also improve the timeliness of applicants being able to put their product on the market or to make changes to its existing labels in the market.

3. Objectives

The overall objective of the proposed reforms is to enable a number of straightforward changes to agvet chemical regulation to be implemented, which would result in reduced administrative burden on applicants and the APVMA and streamlines registration processes. The reforms aim to increase the efficiency and effectiveness of the APVMA and reduce the regulatory burden on business.

4. Options

Proposed reform 1 would enable registrants to effectively notify the APVMA of specified changes, which are very minor, very low risk and where no technical assessment is required. This would allow certain applications to progress via 'notification' instead of having to undergo a full technical evaluation. Examples of items that may be eligible to be changed through a notification process include changes to:

- Concentration or substitution of non-active constituents in a product, for example dyes and colours used for aesthetic purposes;
- Site of manufacture of a product;
- Product shelf life; and
- Pack size.

The APVMA will develop a list of items that may be changed by notification.

An illustrative example of the notification process is provided below.

The APVMA would prepare guidance information for registrants (intending to notify) to determine if a change is eligible for notification, compared to those that need APVMA (technical) assessment. The registrant would prepare all necessary documentation in relation to notification, as outlined on the following page, submit the documentation and proceed with varying their product.

The APVMA would check whether a change was eligible for notification, and if so, make changes to its file records and advise the applicant of the acceptance of the change.

If a change is not suitable for notification, the APVMA would disallow the notification, for example if a change has been made that is not eligible (such as a major high-risk change). The APVMA would undertake compliance enforcement. Penalty provisions would apply to breaches.

Proposed notification scheme – summary

1. Registrant is making very minor changes, with nil risk, that do not require technical assessment.
 - There is no significant change to product chemistry, no risk to product quality, stability, efficacy, safety, the environment or trade, e.g. altering the colour of a product to increase its marketability.
 - The change is to an item the APVMA has included in its list of eligible changes.
2. Registrant refers to the APVMA's guidance materials, obtained via the website or through contacting the APVMA, this includes:
 - A flowchart, so potential applicants can see the difference between the streams of 'notification' and 'assessment';
 - A checklist so that applicants can identify whether the proposed change is eligible for notification. This includes the list of items, which are eligible for change by notification;
 - A template, with the items which an applicant must submit to the APVMA;
 - A declaration form, which an applicant would sign, to declare the changes comply with APVMA guidance information;
 - A cover sheet, for submitting their notification to the APVMA;
 - Phone contact details for the APVMA, should an applicant wish to discuss or ask questions about the notification scheme, prior to going ahead with their change; and
 - Details on the APVMA's compliance enforcement provisions, which would be in place to check that an applicant has carried out notification and implemented the notified change correctly.

Registrants should be able to determine from the above materials, what types of changes are eligible for notification and if so, how to proceed, e.g. make the change and market their product.
3. Registrant completes the checklist, cover sheet and notification template.
4. Registrant provides notification documents to APVMA and proceeds with changing their product.
5. APVMA ensures that the registrant has correctly applied the notification provisions, and that the change is indeed suitable for notification, and if so would make the necessary change to its file and advise the registrant of the acceptance of the notification. APVMA undertakes compliance monitoring and enforcement after.

The APVMA would continue to apply the current technical assessment process to other applications (with changes to chemistry and a degree of risk) that still require the APVMA staff to undertake assessment.

Status quo: Without this reform, there would continue to be the 90 day legislated timeframe for registrants with very minor and nil-risk changes, which currently cannot circumvent the APVMA's preliminary assessment (to check the completeness of an application, such as whether all the relevant data and information has been supplied) and full assessment processes (to evaluate the application, such as whether the change affects the risk profile of the product and associated administrative and documentation processes).

Only two options (notification vs. technical evaluation) have been considered, as there are no other alternatives to regulating these types of product changes.

Proposed reform 2 would reduce an administrative burden, by removing the current requirement for registrants to notify the APVMA of an 'approved person' in writing and for the APVMA to verify each person it corresponds with is an 'approved person'. This removes an unnecessary burden on applicants and the APVMA which can be achieved without compromising the integrity of the regulatory scheme.

This reform is administrative in nature relating solely to how correspondence and record-keeping occurs. There is no impact on the progress of certain applications over others (no assignment of priority for processing) or an impact on the actual scientific assessment or regulation outcome.

An 'approved person' is someone who is authorised and able to act on behalf of a company dealing with the APVMA. The APVMA needs to be clear about whom it should deal with in relation to an application, any requirements relating to that application, whom it should issue the notice of registration or approval and whom it should deal with in relation to post-registration activities such as reconsiderations, cancellations or suspensions of registrations or approval. In relation to an application, the approved person is responsible for:

- signing the application form
- giving consent to the APVMA to alter the application form
- giving extra information or varying information previously given to the APVMA
- giving the APVMA written notice to withdraw the application.

The approved person is an individual or body corporate, in Australia, who is responsible for the application. If the approved person is an individual, they must reside in Australia. If the approved person is a body corporate, it must be incorporated in Australia. In many cases, the applicant and the approved person are the same. However, the applicant can appoint a third party (an individual or body corporate outside their company) to act as the approved person for the purposes of the application. The applicant may also wish to appoint the same or a different approved person in relation to post-registration matters.

When an Australian applicant or registrant elects to appoint a different approved person a letter of authority is required. If a different approved person is appointed for any one or more of the activities specific written approval for each different person

must be supplied. When an overseas applicant or registrant appoints an Australian approved person a letter of authority is required. In the case of overseas applicants the APVMA will always deal with the Australian approved person in relation to all application matters. This reform does not seek to alter the post-registration activities such as auditing or compliance activities.

Status quo: Without this reform, there would continue to be an unnecessary administrative burden on the APVMA and registrants. The APVMA would be required to cross-check all correspondence with registrants, for example, to determine whether a person has the authority to write to the APVMA or reply to an APVMA request on behalf of an agvet chemical company. Conversely the company is required to nominate new individuals when the company's circumstances change or when there is staff turnover. This diverts the APVMA's attention from its core functions and is not necessary where there is surety about the applicant's bona fides due to the existing legal and business registration frameworks.

Removing the definition: the option of removing the definition of 'approved person' would have the effect of opening the APVMA to applications from non-residents.

While maintaining the need for an 'approved person' to be Australian could be considered to be anticompetitive, removing the requirement would unacceptably jeopardise the APVMA's goal of protecting human health, the environment, workers, animals, crops and Australia's trade reputation. There needs to be a legal entity in Australia that is responsible for each chemical. This is currently achieved by a requirement that applications must be signed by an approved person.

The APVMA requires legal and enforcement provisions to be retained for approved persons, so there is efficiency and timeliness in regulatory and administrative dealings with chemicals supplied from overseas. At times, the APVMA needs to take swift protective regulatory action to address risks to health that may arise. An example would be where a chemical in the marketplace is found to contain toxic contaminants and urgent recall is required before the chemical seriously affects someone's health.

While Australia has reciprocal arrangements with some countries to exchange data and information on agvet chemical related issues, this does not apply to all countries (including some major chemical suppliers) and it does not extend to compliance activities. It is likely that seeking legal redress in many countries through these reciprocal arrangements would be so difficult and lengthy as to be unworkable for the APVMA. Therefore, if the approved person definition was removed, a measure would need to be added to cover this aspect. It is considered that such an approach would have the same effect as the current regulations in relation to non-residents and has therefore not been considered in further detail.

Three options (amending the definition, removing it and retaining it) were considered. There are no other alternatives to this reform that achieves the same outcome.

Proposed reform 3 clarifies the APVMA's regulation of labels, which is related to safe and effective use of a product and adequate instructions for handling and use and provides greater flexibility to applicants to make changes to labels that are not of a technical nature. The applicant becomes solely responsible for compliance of all label

elements with the APVMA and other legislated requirements, but has greater flexibility to make changes to labels as permitted by the APVMA or under other legislation, without requiring assessment and approval by the APVMA. Examples include a change in the label size, type, dangerous goods hazard symbols, warranty and contact information.

The applicant would still be supplying the same information for their label, but it would be clear that they have responsibility to ensure their label complies with the APVMA's conditions of label approval and other Commonwealth and state and territory legislation. This is essentially an existing legality for applicants, as the responsibility for compliance with relevant legislation rests with the applicant. The reform eliminates an unnecessary (and duplicative) administrative process for the APVMA, who do not have regulatory responsibility for labelling items outside of what relates to safe and effective use and adequate instructions. The reform also provides greater flexibility to registrants to make change to labels that are not of a technical nature.

Compliance enforcement provisions would continue to be applied. The label size, type and format will be controlled through conditions of label approval. The applicant would be responsible to ensure that marketed labels comply with the conditions of label approval. The APVMA would undertake compliance monitoring and enforcement to verify (on an audit basis) that marketed labels comply with the conditions of approval.

Status quo: Without this reform, there would continue to be regulatory burdens on the APVMA to assess all labelling elements, including those which are beyond its core area of regulatory responsibility if such changes have no impact on the product risk profile or its use. Requiring the APVMA to check all aspects of labels would mean inefficient use of staff resources for editorial and proof-reading activities; a longer time to register products or varying labels; which subsequently delays products being available on the market.

Only two options (removing non-APVMA labelling elements (and associated verification role) from the APVMA's regulation vs. retaining them) were considered as there are no other alternatives to this reform.

5. Consultation

A range of recent reports and studies for the government have helped inform the development of the proposed reforms. This includes consultation for the Departments of Agriculture, Fisheries and Forestry and Finance and Deregulation's review of the efficiency and effectiveness of the APVMA (2010), responses to the Product Safety and Integrity Committee's discussion paper on the development of the single national framework for agvet chemicals (2010), and the Productivity Commission's (PC) research report on chemicals and plastics (2008).

On balance, the proposed reforms are likely to be supported by agvet chemical stakeholders for the following reasons.

In its 10 February 2010 submission to the discussion paper on the development of the single national framework for agvet chemicals, CropLife¹ indicated support for high-quality, rigorous and scientifically based risk assessments, and a clear structure for allocating responsibilities between the registration and risk assessment functions of the APVMA. CropLife notes the regulatory response to manage agricultural chemicals should focus on those activities and products that represent the highest risk.

In its 10 February 2010 submission to the discussion paper on the development of the single national framework for agvet chemicals, ACCORD Australasia Limited (ACCORD)² suggested that minor changes to product formulation should be self assessed and readily accepted, as should label changes without the need for re-assessment by the APVMA and additional payment of fees.

In its 9 February 2010 submission to the discussion paper on the development of the single national framework for agvet chemicals, the Animal Health Alliance³ (AHA) indicated that, by minimising the requirement for the (regulator) to conduct activities not strictly related to the assessment and registration of chemical products, financial resources could be freed for necessary reforms in the labelling system to be implemented.

The Chair of AHA's media article of 15 February 2010 stated that AHA has made a strong submission (to COAG's single national framework reforms) arguing for major reforms to make (the APVMA) a faster, more transparent and more efficient (regulator) so industry can get on with its job of supporting primary industries with the latest and best in medical technology. He also said that Australian farmers do not have access to some of the chemicals that overseas producers, who are competing in the same export markets, enjoy the benefits of, because the manufacturers have decided that the administrative burden involved in obtaining APVMA registration outweighs their likely economic benefit.

In its February 2010 submission to the discussion paper on the development of the single national framework for agvet chemicals, CHOICE⁴ discussed the APVMA's performance (in that it needs to) meet community expectations; avoid delays in bringing newer low risk chemicals to market; and review old chemicals.

APVMA advises that registrants often express frustration over the administration of the approved person requirement, as they see it as an unnecessary addition step in an already protracted assessment process. In addition to adding time, it adds administrative burden to both registrants and the APVMA, the cost which is borne by the industry. Removing this requirement is consistent with general calls from stakeholders to simplify the APVMA's administration and we anticipate acceptance of this reform. Some registrants, who currently rely on this provision to manage which of their employees deal with the APVMA, may not welcome the change.

¹ represents the developers, registrants, manufacturers and formulators of plant science solutions for use in agriculture and the management of pests in other settings

² association for the Australasian Consumer, Cosmetic, Hygiene and Specialty Products Industry

³ represents interests of registrants, manufacturers and formulators of animal health products

⁴ consumer advocacy group, protecting and assisting consumers in changes to laws and industry practices

In early 2010 key agvet chemical stakeholders, outlined in Attachment 1, were consulted about the efficiency and effectiveness of the regulator.

In relation to labelling, the consultation identified a number of improvements to the APVMA's regulatory role and operations, including:

- full cost-recovery from industry for the undertaking of design assessment and proof reading;
- removal from APVMA's responsibilities, the requirement to check final printed design of labels;
- exploration of the acquisition of software to assist in the review of subsequent versions of labels (including final printed labels) so that full read-through is only undertaken once;
- consideration of industry self-regulation of presentation of labels using regulated instructions for use. Under this model, APVMA would have a role to investigate complaints or issues in labels when they are identified; and
- consideration of the employment of low-cost contract staff to undertake label checking.

The PC's report found that suppliers should not be required to apply to APVMA for approval of changes to aspects of the product label that are outside of the APVMA's scope of regulation, and that the APVMA should not be required to approve information on labels that are the subject of another regulatory regime.

The PC further noted that other labelling schemes (e.g. hazardous workplace chemicals, poisons, cosmetics and dangerous goods) do not require label approval; it is the legal responsibility of suppliers of these chemicals or products to ensure their labels comply with labelling requirements under state and territory legislation.

6. Impact analysis

Proposed reform 1 would improve the timeliness of recording changes to agvet chemicals which are effectively minor, low risk, and where no technical assessment is required. Full assessment of changes to new agvet chemical applications and to those that entail some degree of risk, will be maintained.

It will ensure the efficient and effective use of the regulator's resources, freeing-up resources which can be reallocated to where the most effort is needed. It will improve the speed with which agvet chemical users can access and use products. It provides flexibility in the regulatory framework without compromising efficacy or safety, given that compliance monitoring and enforcement provisions apply.

The benefit to the Australian Government is reduced scientific resourcing pressures on the APVMA. While the reform reduces the initial administration and scientific assessment functions, there will be some increased compliance monitoring and enforcement activities. While the proposed reform will decrease the burden on industry, it is cost neutral from the APVMA's perspective. It will streamline the initial assessment stage, however guidance materials will need to be prepared and published and compliance functions established.

In 2008-09, the APVMA received 2494 applications for assessment, with 622 for minor variations to non-technical variations to a product or a label. On this basis, approximately 25 per cent of registrations could be suitable for notification, due to proposed reforms 1 (notification) and 3 (labelling).

Initially, the APVMA would focus on those applications where guidance material has already been developed and piloted. In 2004 calendar year, under a pilot notification scheme introduced by the APVMA, of applications for minor veterinary product formulation changes received 80 per cent⁵ (88 out of 110 applications) were deemed eligible for notification.

The additional compliance cost to applicants of determining whether a change may be suitable for notification is likely to be low.

There are unlikely to be negative or adverse impacts on control of use activities by state and territory governments.

The proposed reform is complementary to COAG's early harvest reform 10, which is developing faster and less costly arrangements for lower-risk agvet chemical products.

The APVMA has been consulted, and supports this reform. Implementation issues for the APVMA include modification to its processes and systems, including the electronic application and registration system; staff training; and preparation of a range of guidance information for applicants.

Proposed reform 2 would reduce an administrative burden, by removing the requirement for registrants to notify the APVMA on an ongoing basis of an 'approved person' in writing and for the APVMA to verify an 'approved person'. The legislation requires that applications be signed by the applicant or registrant or an appropriate delegate of the applying company (the 'approved person') who can be an employee or third-party delegate. The existing legislative frameworks provide for compliance enforcement which audits and verifies if a person can act on behalf of an agvet company.

Both the applicants and their approved person(s) can benefit from this reform. Although the APVMA would continue to record the details of the person who initially submitted the application, they would no longer need to notify the APVMA of their approved person or a change in the designated approved person, on an ongoing basis.

The legislation requires that an overseas applicant must appoint an Australian person or body corporate when submitting an application, who the APVMA can correspond with in relation to all application matters. However, this is not unlike other Australian Government regulator or program requirements, where it is important to have accurate details about an applicant.

The benefit of the reform is to reduce a regulatory burden and unnecessary administrative work for the APVMA. This would outweigh the costs of continuing to

⁵ This pilot was only for veterinary product changes however was broader than the proposed reform; in that it included both the very minor and nil-risk changes, and, minor product formulation changes that were low risk.

apply the current 'approved person' requirements in correspondence between the APVMA and the applicant. The reform is not likely to have a negative effect on the administration of overseas applications as compared to domestic applications, since the effect overall is to streamline an administrative process which would enable APVMA staff to refocus effort on review and assessment of applications.

There is no impact on competition – as due to the administrative nature of this change – it does not seek to reduce or restrict the number or range of businesses that could seek to apply or register with the APVMA, or set different standards for agvet chemical registrations, or alter the competitiveness of applications.

The benefit to registrants, employees or delegates, is that they would no longer have to complete paperwork related to this requirement. The benefit to the Australian Government is reduced resourcing pressures on the APVMA, by decreasing costs and reducing staff effort on unnecessary administrative processes. Approximately 90 per cent of the APVMA's applicants are individuals or companies that reside in Australia. There are no increased costs expected as a result of the reform.

The administrative saving for the APVMA arise where it has ongoing and multiple contacts with an approved person but has to verify each interaction is with an 'approved person'. It is estimated that this reform could reduce the administrative processing associated with verifying the applicants status with paper-based applications by 50 per cent as applicants often use third party specialists to assist in managing applications, who would still need to be approved by a the APVMA through a validation mechanism.

This reform also complements the APVMA's web-based registration process, where it is easier and quicker for the APVMA to verify that it is corresponding with an approved person.

There are unlikely to be negative or adverse impacts on state and territory governments.

The APVMA has been consulted, and supports this reform. Implementation issues for the APVMA include modification to its processes and systems (including the electronic application and registration system), by narrowing its responsibilities to approved third parties.

Proposed reform 3 would enable assessors to focus on core activities; removing the APVMA as the responsible party for labelling items not related to safe and effective use of a product and adequate instructions for handling and use; and improving the timeliness of applicants being able to put their product on the market.

It builds on COAG's Early Harvest Reform 8, by clarifying labelling requirements in legislation. The APVMA would retain its compliance role, such as provisions to check that a label contains the relevant information and instructions on safety and handling and that it has approved and otherwise complies with the conditions of label approval.

The reform would increase the speed of label changes and approval, resulting in applicants being able to put their products on the market quicker. The reform expands and builds on current mechanisms (via permit) that allow applicants to self-assess certain label changes.

The cost saving to industry is the current \$560 fee associated with an application to vary a label and reduced or eliminated costs to an applicant who might normally have to 'hold' their product and not undertake marketing and distribution until approval had been granted.

However, some applicants and industry representatives may be concerned if the onus is solely on the applicant to take responsibility for non-APVMA label requirements and for ensuring compliance with conditions of label approval. In essence, the applicant would still be supplying the same information for their label, so is not likely to be a major impact on them. The APVMA would also provide guidance on how to comply with conditions of label approval.

The benefit to the Australian Government is reduced scientific resourcing pressures on the APVMA. It decreases costs and staff effort on a demanding administrative process of cross-checking compliance with other legal requirements. Further, the APVMA Code of Practice Labelling already recognises that it is not primarily responsible for the non-technical items that fall within other legislation, and if a label is non-compliant in these areas the APVMA would need to reject an application. Compliance resourcing would be required, which can be managed by a reallocation of resources through the three proposed reforms.

In 2008-09, the APVMA received 2494 applications for assessment, with 622 for minor variations to non-technical variations to a product or a label. On this basis, approximately 25 per cent of registrations could be suitable for notification, due to proposed reforms 1 (notification) and 3 (labelling). By removing the requirement for the APVMA to check non-APVMA aspect of labelling, it will reduce approximately 15 to 20 per cent of the administrative processing required to approve the final printed label.

Applicants will need to conduct their own checking of size, type and format of the label for whether it complies with the APVMA's conditions of label approval. Applicants will need to understand Commonwealth and state and territory legislation, for what labelling elements they must comply with, if the APVMA no longer is checking for compliance on their behalf.

Other Australian Government regulators' and state and territory agencies may find an increase in the amount of enquiries directly from agvet chemical applicants, who wish to cross-check compliance of their labels with the relevant regulations. However, these agencies do have carriage of the relevant legislation and are the most appropriate contact point to field enquiries.

This reform responds to report findings which suggest that the APVMA should not have to check compliance with other legislative or regulatory labelling requirements on an applicant's behalf. The proposed reform builds upon COAG's early harvest

reform 8, which is to enable label amendments in specified circumstances without application to the APVMA.

The APVMA has been consulted, and supports this reform. Implementation issues for the APVMA include modification of its processes; by removing the APVMA as the responsible party for labelling items that are not related to safe and effective use of a product and adequate instructions for handling and use, along with removing the APVMA as the responsible party for ensuring that size, font, colour and format of a label complies with conditions the APVMA has set. The APVMA will also prepare guidance information for applicants, who will take full responsibility for the remainder of the labelling items.

7. Conclusion and Recommended Option

The three reforms seek to positively affect the APVMA, applicants and agvet chemical stakeholders by reducing regulatory burdens. The establishment of a notification scheme does not impact on the safety of agvet chemicals; as notification would apply to very minor and nil-risk changes, while being supported by audit and compliance enforcement provisions. The removal of the definition of an approved person to Australia applicants will not have an adverse impact due to the existing legal frameworks and the APVMA's existing compliance enforcement provisions. The labelling requirements that would become solely the applicant's responsibility are not overly onerous since they are underpinned by existing legal obligations. Overall, these reforms are expected to have a nil adverse impact, or at worst the potentially minor impacts can be ameliorated.

8. Implementation and Review

Parts 4 and 6 of this RIS outline the steps the APVMA will undertake to implement the reforms. Implementation would begin the day after the Amendment Bill receives Royal Assent, with transitional provisions. In some cases, legislative instruments will need to be revised or prepared. DAFF and the APVMA will monitor the impacts of the reforms, via feedback provided by applicants and other agvet chemical stakeholders and through including the reforms as a standing item for discussion at regular executive meetings of DAFF and the APVMA over the succeeding 12 months.

Key agvet chemical stakeholders consulted in the efficiency and effectiveness review of the APVMA (2010)

- APVMA
- Department of Health and Ageing
- Department of the Environment, Water, Heritage and the Arts
- Queensland Department of Employment, Economic Development and Innovation
- Victoria Department of Primary Industries
- Northern Territory Department of Resources
- Animal Health Alliance
- CropLife
- National Farmers Federation
- Victorian Farmers Federation
- Veterinary Manufacturers & Distributors Association
- WWF – Australia
- Australian Consumers Association
- National Toxics Network
- Aerial Agricultural Association of Australia
- Cotton Australia

NOTES ON AMENDMENTS

Amendment (1)

This amendment inserts items 2A and 2B to Schedule 1 of the Bill to amend section 3 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code). The items give effect to the approved person measure by removing the requirement to notify in writing from the definition of *approved person* in section 3 of the Agvet Code.

Amendment (2)

This amendment inserts item 4A to Schedule 1 of the Bill to include information stored or recorded by means of a computer in a definition of the term *file* in section 3 of the Agvet Code. This will allow the APVMA to keep electronic files of label approval information, as hard copy files of approved labels will no longer be required (see amendment 6).

Amendment (3)

Item 5A amends part of the definition of *relevant particulars* in section 3 of the Agvet Code to reflect the change to APVMA's role in label approval to only determining adequate instructions for safe and effective use, as provided in subsection 21(2).

Amendment (4)

Item 5B also amends part of the definition of *relevant particulars* as a consequence of adding the new Division 2A procedure for approving minor variations to certain relevant particulars.

Amendment (5)

Item 6A inserts an explanation of the new Division 2A into subsection 9(2) of the Agvet Code which deals with the process for notifying minor variations to certain relevant particulars as listed in a legislative instrument.

Amendment (6)

This amendment inserts items 6B and 6C to Schedule 1 of the Bill to describe a new procedure for effecting the approval of labels for containers of chemical products and makes a consequential change.

Item 6B amends subsection 21(1) of the Agvet Code to change a reference to section 23A which deals with the conditions of approval for labels.

Item 6C repeals the current label approval process and replaces it with a new subsection 21(2). Paragraphs 21(2)(a) and (b) require the APVMA to determine the relevant particulars appropriate for a label and give a distinguishing number to the label. The amendment removes reference to the APVMA determining label size and type when approving labels for containers for a chemical product. The APVMA will no longer keep a copy of the label itself on the relevant APVMA file.

Paragraph 21(2)(c) requires the APVMA to record the relevant particulars appropriate for the label and the distinguishing number in the APVMA file, along with the adequate instructions for safe and effective use of the product and any particulars that are to be contained on the label.

Paragraph 21(2)(d) also requires the APVMA to record any conditions imposed on the label approval by the APVMA under new section 23A.

Outside of the relevant particulars described above, the APVMA will no longer determine the details of the label generally and will no longer determine the size and type of a label. Instead, the size and type of a label may be regulated through conditions for approval for labels (see amendment 8). For example, a condition of approval may stipulate that labels must be formatted in a particular way and that any prescribed particulars must be legible and displayed prominently.

Amendment (7)

This amendment, along with amendment 8, provides for a separate section of the Agvet Code (section 23A) to deal with the conditions of approval for labels, distinct from a section (existing section 23) to deal with approval conditions for active constituents for chemical products and registration of chemical products.

Amendment 7 inserts items 6D and 6E to remove references to label approval conditions from Agvet Code subsections 23(1) and 23(3), leaving those subsections to deal only with approval conditions for chemical product active constituent approvals or registrations.

Amendment (8)

Amendment 8 provides for a new section to deal with the conditions of approval for labels. Item 6F inserts the new section 23A to the Agvet Code which describes that approval of a chemical container label is subject to conditions prescribed by the regulations and any conditions the APVMA decides to impose on an approval. This means there will be two types of conditions of approval: mandatory statutory conditions that apply in all cases of a particular kind; and the case-by-case conditions of approval that the APVMA thinks appropriate.

Conditions prescribed in regulations may apply to labels for particular products, to a class of products, or to labels for all chemical products. Conditions prescribed in regulations may apply whether or not the conditions are prescribed at the time the label is approved. For the APVMA-approved conditions, approval may be granted for a particular time period not exceeding a year, with the possibility to extend the period, one year at a time. The subsection mirrors provisions for conditions of approval for active constituents for chemical products and registration of chemical products in section 23, and allows for greater clarity for label approval conditions, distinct from other conditions of approval.

Amendment (9)

Item 6G inserts a new Division 2A of Part 2 of the Agvet Code to make provision for the notification of minor, very low risk variations to agvet chemical product approvals or registrations through a simplified application process rather than have a variation approved through the APVMA's existing technical assessment and registration process under Division 3. Variations will be made by notification for a limited set of relevant particulars (see the definitions in section 3 of the Agvet Code and amendment 4) identified in a legislative instrument made by the APVMA. A legislative instrument made by the APVMA is the most appropriate mechanism to identify low-risk

categories of variations as such an instrument can be varied at short notice and APVMA has the technical expertise to know what variations are low-risk. The legislative instrument will be disallowable.

Subsection 26A(1) indicates the section applies when an interested person wishes to make minor, very low risk variations to a relevant particular of an approval or registration when the relevant particular is of a kind listed in a legislative instrument made for the purposes of this section.

It is expected that the relevant particulars listed for variation by notification in the legislative instrument will be those where change to the particular involves no significant change to product chemistry, no risk to product quality, stability, efficacy, safety, the environment or trade. Particulars which may be varied by notification could include the site of manufacture or a non-active ingredient such as product colour.

Subsection 26A(2) adapts section 28 from the Division 3 variation process and places conditions on submitting an application, including that the application must be signed by an approved person, be accompanied by the prescribed fee and be lodged with the APVMA.

Subsection 26A(3) adapts paragraphs 29(1)(e) and 29(1)(f) from the Division 3 variation process to oblige the APVMA to vary a particular if it is satisfied the use of the varied product according to the instructions for use: would be effective; and would not be an undue hazard to the safety of those handling the product or using anything containing the product's residues; would not be likely to have an effect harmful to humans; not be likely to have an unintended harmful effect on animals, plants, things or the environment; and not unduly prejudice international trade or commerce.

If the APVMA is satisfied for the purposes of subsection 26A(3), subsection 26A(4) requires the APVMA to vary the relevant particulars and record the details in the APVMA file and give written notice of the variation to the interested person.

If the APVMA is not satisfied with the variation, subsection 26A(5) obliges the APVMA to notify the interested person making the notification and state the reasons, and indicate that if the person still wants to make the variation that the person must apply under the existing assessment and registration process in accordance with Division 3. This provides for a safeguard that even if variation of the particular is within the legislative instrument, a full application and assessment will still be required if the APVMA does not consider the variation meets the conditions in subsection 26A(3).

Amendment (10)

This amendment inserts item 6H to Schedule 1 of the Bill to repeal paragraph 28(1)(ba) of the Agvet Code which required applications for label approval variations to be accompanied by the proposed new label. Removing the requirement for the APVMA to approve label size and type means the APVMA no longer needs to receive copies of the label itself.

Amendment (11)

Item 6J inserts subsection 28(1A) to the Agvet Code which applies when variation applications that were expected to proceed under the Division 2A notification process have been rejected and subsequently put through the Division 3 assessment and registration process. Subsection 28(1A) requires the APVMA to offset any fee paid for the notification application against any later fee.

Amendment (12)

Item 6K changes the procedure that the APVMA must use when granting an application to vary relevant particulars of the approval of a label to remove the requirement to place a copy of the new label in the file.

This amendment is one of several amendments repealing a requirement for the APVMA to place a copy of a label in the relevant APVMA file. Removing the requirement for the APVMA to approve label size and type means the APVMA no longer needs to receive copies of the label itself.

Amendment (13)

Item 6L changes the procedure that the APVMA must use when reconsidering the approval of a label to remove the requirement to place a copy of the new label in the file. Removing the requirement for the APVMA to approve label size and type means the APVMA no longer needs to receive copies of the label itself.

Item 6M repeals and substitutes subsection 34(5A) of the Agvet Code to limit the APVMA's power to vary the conditions of approval of a label to the conditions mentioned in new subsection 23A(2). If this is not done, the APVMA would (inappropriately) be able to modify the mandatory statutory conditions set out in the regulations on a case by case basis (see amendment 8).

Amendment (14)

Item 6N substitutes a new paragraph for Agvet Code paragraph 34A(3)(a) to remove a requirement for the APVMA to place a copy of a label in the relevant APVMA file when reconsidering approval of a label when label particulars do not contain adequate instructions in relation to a matter.

Item 6P repeals subsection 34A(4) which allowed the APVMA to vary relevant particulars for label approval only if the interested person gave the APVMA the new label.

Removing the requirement for the APVMA to approve label size and type means the APVMA no longer needs to receive copies of the label itself.

Amendments (15) and (16)

Items 6Q and 6R remove the requirements at Agvet Code paragraphs 40(2)(b) and 41(4)(b) for an interested person to give the APVMA a label containing particulars proposed to be varied in accordance with a request from the APVMA, lest the label approval be suspended or cancelled.

Removing the requirement for the APVMA to approve label size and type means the APVMA no longer needs to receive copies of the label itself.

Amendment (17)

Item 6S substitutes a new paragraph for existing Agvet Code paragraph 47(5)(a) to reflect the addition of new section 23A to deal with conditions of approval for labels. The new paragraph 47(5)(a) allows label approval conditions made under section 23A to change the effect of section 47, which deals with the duration of an approval or registration.

Amendment (18)

Items 6T, 6U and 6V make amendments to several paragraphs in section 81 of the Agvet Code, which deals with controls over the supply of chemical products and active constituents for chemical products. The amendments are consequential to the change in the requirement for APVMA to approve label size and type and to file copies of the actual approved label (see amendment 6). The amendments do not change the structure of the existing section 81 offences.

Item 6T amends the requirement at Agvet Code section 81(1) for persons to supply a registered chemical product only if the label attached to the product container is identical to the approved label. As the APVMA is no longer required to approve label size and type and no longer files copies of approved labels it is no longer required to determine if a label attached to a container is identical to the approved label. The requirement is amended so that persons must only supply a chemical product if the label attached to the container states the relevant particulars required to be included on the container and does not contain information contrary to the relevant particulars. The magnitude of the penalty is not changed.

Item 6U similarly amends section 81(2) to allow a defence for the offence at section 81(1) if the person did not know or could not reasonably be expected to have known that the label attached to the container did not state the relevant particulars or contained information contrary to the relevant particulars. This is a consequential amendment to the defence currently provided for by section 81(2).

Item 6V substitutes a new paragraph for Agvet Code paragraph 81(3)(a) to indicate that the offence at section 81(1) does not apply if the label attached to the container states the relevant particulars that were required to be stated on a label at a time before the supply takes place. That is, if the container displays an earlier approved label. This is a consequential amendment that updates the current paragraph 81(3)(a) to reflect the amendment to subsection 81(1).

Amendment (19)

Item 6W repeals existing section 86 in the Agvet Code and substitutes a new section 86 which broadly requires persons not to detach or alter an existing approved label. The new section has the same effect as the old section 86, and the same defences, but the offence provision is amended to reflect the APVMA no longer being required to approve label size and type and no longer files copies of approved labels.

Subsection 86(1) provides that a person commits an offence if the person detaches or removes a label, alters, defaces, obliterates or destroys a relevant particular on a label or attaches another label which detracts from the relevant particular on a label, in relation to chemical label containing any relevant particular identical to any relevant

particular on an approved label or any matter required by an established standard for the product. The penalty of 300 units has not been changed.

Subsection 86(2) is similar to subsection 86(1) except that the prohibition is on a person causing or permitting the label offence (rather than taking the offending action themselves). This limb of the offence was previously in subsection 86(1).

Subsections 86(3) and (4) are similar to the old subsections 86(2) and (3) and provide that an offence is not committed if a person alters a relevant particular by destroying or disposing of the chemical product, or if the person has a reasonable excuse. The defendant bears an evidential burden in relation to the reasonable excuse subsection 86(4).

Amendment (20)

Items 6X and 6Y amend Agvet Code paragraphs 103(1)(a) and 103(2)(c) to reflect that the APVMA is no longer being required to approve label size and type and is no longer required to file copies of approved labels.

Amendment (21)

Item 6Z repeals section 158 of the Agvet Code which required persons making an application which related to a label for a chemical product container to give the APVMA a required number of samples of the label and of any adhesive by which the label is attached to the container. This is a consequential amendment to reflect that the APVMA is no longer being required to approve label size and type and is no longer required to file copies of approved labels.

Amendment (22)

Item 7A inserts paragraph 167(1)(baa) to allow decisions made under new section 26A (which is the new procedure for notifying variations) to refuse to vary relevant particulars of an approval or registration to be reviewed by the Administrative Appeals Tribunal.

Amendment (23)

Item 7B inserts new transition provisions into the Bill to ensure labels which were approved labels under the current Agvet Code continue to be approved labels under the amended Agvet Code and to ensure relevant particulars and conditions of approval for labels under the old law continue to apply under the new label approval regime.

Amendment (24)

Amendment 24 amends the application provisions at item 8 of the Bill by adding new paragraph 8(1)(aa) to ensure amendments to the definition of *adequate* have effect for applications to vary relevant particulars of a label approval under new section 26A of the Agvet Code made after the item commences. The change to the *adequate* definition enables the APVMA to have regard to trade concerns when taking regulatory action such as consideration of variations to label approvals.

Amendments (25) and (26)

Further amendments to item 8 of the Bill ensure that existing amendments to the definition of *adequate* have effect for reconsiderations of the approval of a label for a

chemical product under sections 34 and 34A of the Agvet Code, as amended by the Bill, that begin after the item commences.

Amendment (27)

Amendment 27 changes subitem 8(2) of the Bill to correct an existing reference from Bill subitems '3 to 7' to subitems '3, 4, 5, 6 and 7'. This change reflects better legislation drafting practice.

Amendment (28)

Amendment 28 inserts two new Bill subitems 8(2A) and 8(2B). New subitem 8(2A) applies amendments made by Bill items related to label approval to label approval applications, variations, and reconsiderations and to standards approved under section 56D made on or after the day the item commences. Effectively, the APVMA's regulatory actions in relation to labels will be undertaken under the revised label approval process. Current, but not yet complete, applications, reconsiderations and standards will proceed under the existing processes.

New Bill subitem 8(2B) applies amendments made by Bill items related to the simpler variation application process in new Division 2A to applications for variation made on or after the day the item commences. Current applications not yet finalised will proceed under the existing process.

Amendments (29) and (30)

Amendments 29 and 30 amend application provisions at subitem 8(3) of the Bill to ensure revised definitions of *approved person* and *relevant particulars* have effect for any of APVMA's approval, variation, reconsideration or standards making processes described in subitem 8(1) from the day the item commences.