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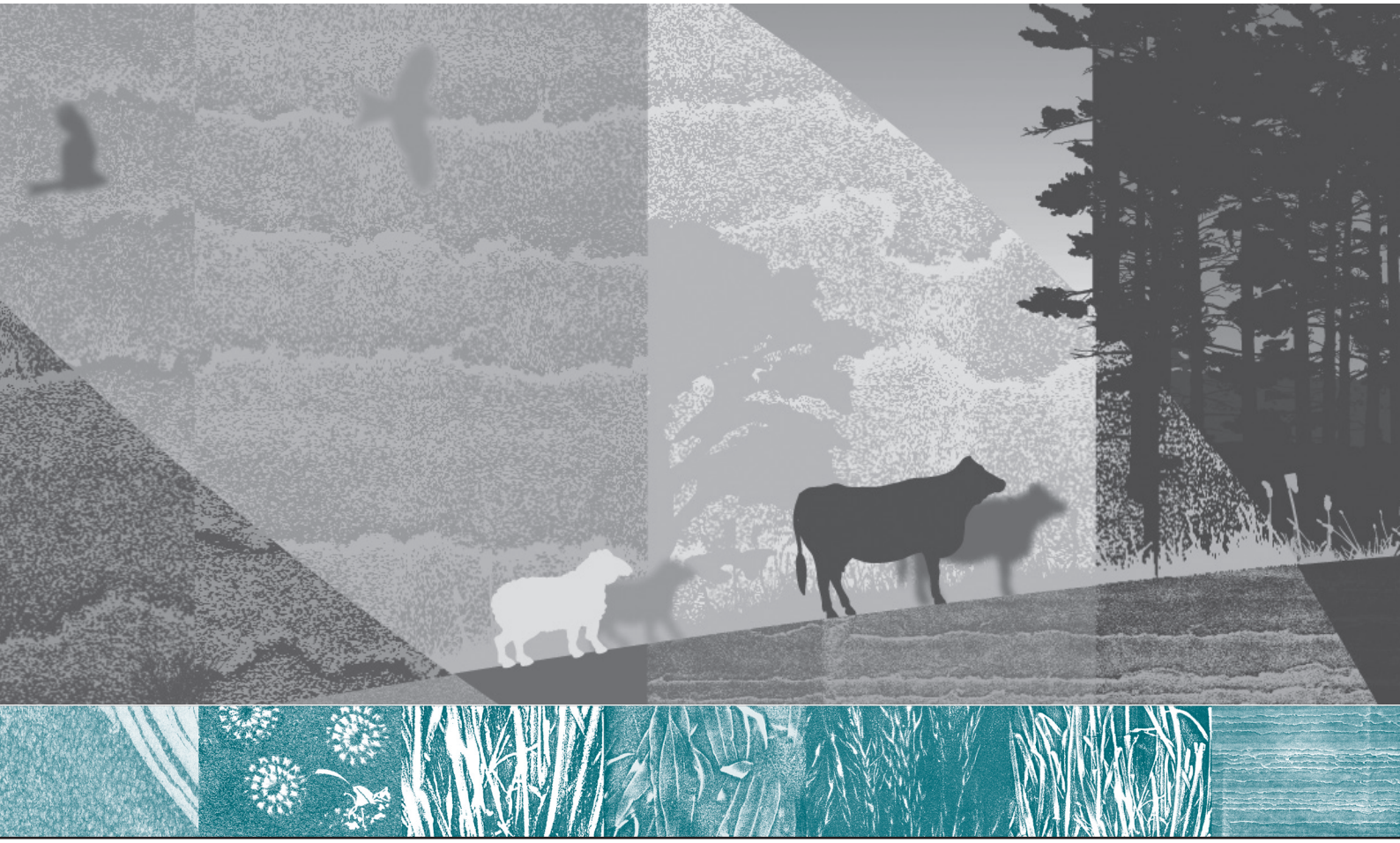

PRELIMINARY REGULATORY IMPACT STATEMENT
FOR THE APVMA OPERATING PRINCIPLES IN RELATION TO SPRAY DRIFT RISK

20 FEBRUARY 2008

Preliminary Regulatory Impact Statement for the APVMA operating principles in relation to spray drift risk

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This document is published by the APVMA. In referencing this document, the APVMA should be cited as both author and publisher.

For more information on the APVMA go to <http://www.apvma.gov.au>

Important information

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has prepared this Preliminary Regulatory Impact Statement (RIS) to accompany the fourth draft of its *APVMA operating principles in relation to spray drift risk*, a document describing the APVMA's approach to spray drift risk assessment and risk management.

The current version of each document will be the last offered for public comment before proceeding to implementation. Both documents should be considered together in preparing submissions. The period for submitting written submissions concerning this RIS and the *APVMA operating principles in relation to spray drift risk* will end on Friday, 21 March 2008.

Your written comments should be addressed to:

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Please have your response to the APVMA by close of business on **Friday, 21 March 2008**.

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Abbreviations and acronyms

ADI	Acceptable Daily Intake
AGDISP	computer-based spray drift model
AgDRIFT	computer-based spray drift model
agvet	agricultural and veterinary
Agvet Code	*Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
BCC	Business Cost Calculator
CALPUFF	atmospheric predictive modelling application
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department of Agriculture, Fisheries and Forestry
DEWHA	Department of Environment, Water, Heritage and the Arts
DoHA	Department of Health and Ageing
ISO	International Organisation for Standardisation
MRL	Maximum Residue Limit
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRS	National Registration Scheme
OBPR	Office of Best Practice Regulation
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
PMRA	Canadian Pest Management Regulatory Agency
PSD	United Kingdom Pesticides Safety Directorate
RCP	Restricted Chemical Product
RIS	Regulatory Impact Statement
TAPM	atmospheric predictive modelling application
FAO	Food and Agriculture Organisation
ULV	ultra-low volume
US EPA	US Environmental Protection Agency

1 Introduction

The APVMA published a discussion paper on 1 July 2003 (*Operating principles and proposed registration requirements in relation to spray drift risk*) in which it described its approach to spray drift risk assessment and risk management. Since then, two more draft versions have been published, and a fourth and final draft is provided with this document. This present document is identified as a Preliminary Regulatory Impact Statement (RIS), but it would be more accurate to describe it as 'RIS-like'. The following paragraphs explain this distinction.

Because the early drafts of the spray drift discussion paper included proposed requirements for applicants and registrants to provide preliminary spray drift risk assessments and proposed label statements and because there were uncertainties about how much additional scientific data might be required to complete those risk assessments, the agricultural chemical industry had the reasonable expectation that the APVMA's new requirements would impose additional compliance costs. As a result, chemical industry representatives have considered the APVMA's proposals to be a form of new regulation and have expected that a RIS would be provided for comment prior to implementation of the proposals. Such a RIS would need to be prepared in consultation with the Office of Best Practice Regulation (OBPR).

During the previous 12 months, the APVMA has re-examined its proposals in relation to requiring industry to provide preliminary risk assessments with applications for new products or uses and for chemical reviews. The APVMA decided that it would be more efficient if it abandoned that requirement and instead retained responsibility within the APVMA (including financial responsibility) for all spray drift risk assessments.

This significant change in the APVMA's position along with the expectation that no new studies will be needed to complete risk assessments means that no new regulatory burdens and associated costs will be placed on industry. That change is reflected in the current draft of the spray drift discussion paper's title in which the words, 'and proposed registration requirements' have been deleted. The current discussion paper provides an overview of the APVMA's spray drift risk assessment and risk management methods including a number of refinements to strengthen and modernise the approach. However nothing in the discussion paper is properly described as 'new regulation'.

Nonetheless, many chemical company representatives have expected that the APVMA would provide a RIS to clearly explain the potential economic impacts on the agricultural chemical industry of its refined spray drift assessment approach. This present document is intended to serve that purpose even though it is not a formal RIS in all senses of the term. It is based on guidance from the OBPR and follows an OBPR RIS format as much as possible, but some elements are not included because they are not applicable.

One area in which misunderstandings may yet remain is in relation to chemical reviews. Under the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Codes), the APVMA has

the power to ‘reconsider’, that is carry out a chemical review, for an existing product (often including the active and the label) when it cannot be satisfied that the product can be used without unacceptable risk to human health, the environment or Australia’s international trade. A specific reason included in the Agvet Codes for initiating a review is the case where a product label does not contain adequate instructions to inform users how to use the product safely. This is the situation that now prevails for a large number of older products in relation to spray drift risk. These products require a modern (meaning current best practice) risk assessment and label upgrade to meet current standards, and therefore a chemical review is needed and justified. It should be clearly understood that a chemical review does not constitute new regulation.

Much of the discussion that follows in this document, including references to potential costs, is in relation to chemical review activities. The discussion of potential costs is included to fulfil the intent of this RIS-like document, but it needs to be emphasised that these costs are not the result of imposed new regulation. Rather, they are only the result of normal and necessary review activities and are provided as estimates so that industry will have an expectation of what might develop in relation to spray drift risk assessment efforts during the next four to five years.

2 Identification of the issue

As explained in the Section 1 ‘Introduction’, the APVMA’s spray drift risk assessment methods no longer contain elements of new regulation because the APVMA has dropped requirements for industry-supplied risk assessments and proposed label statements. However, since many in the pesticide manufacturing industry have had a long expectation that the APVMA would provide a RIS in relation to its spray drift discussion paper (*APVMA operating principles in relation to spray drift risk*) this document has been prepared to satisfy that expectation and explain what might be expected when the APVMA implements its modernisation of spray drift risk related label statements.

The Commonwealth of Australia and the states and territories work together to regulate agricultural chemicals and veterinary medicines in Australia. The Commonwealth, through the Australian Pesticides and Veterinary Medicines Authority (APVMA), assesses all products prior to registration and determines how those products may be used by putting instructions and limitations on product labels. Also, since the commencement of the National Registration Scheme, the APVMA has been involved in review of existing chemicals to ensure that they meet contemporary standards. Such reviews are undertaken on a priority basis related to an assessment of risk.

The legislation under which the APVMA derives its powers, the Agvet Codes sets out the factors that the APVMA must consider in registering an agricultural or veterinary chemical product for use. When the APVMA considers registering an agricultural chemical product, it must satisfy itself, according to scientific principles, that the product can be used to achieve its intended purpose and at the same time not be likely to harm human health, the environment or Australia’s international trade. To achieve this end, the APVMA determines instructions for use and limitations on use for each product and places them on the product’s label. The individual states and territories are responsible for user compliance with these instructions and limitations.

An important aspect of assessing risk from agricultural chemicals is consideration of the possibility of spray droplet drift onto off-target areas, meaning any areas outside the target crop. The APVMA acknowledges its responsibility to address the potentially harmful effects of off-target spray drift that can occur at times with applications of agricultural chemicals.

The problem being considered relates to one of potentially unacceptable risk to human health, the environment and international trade resulting from exposure of non-target areas to agricultural products as spray drift following application to target crops.

Off-target spray drift is a significant problem. Although the APVMA has been assessing chemical product uses for spray drift risk since its inception, mainly in relation to environmental risk and international trade risk, many older products, some of which were inherited from state registration systems (pre–1994), are acutely in need of review to upgrade label instructions to current standards. Many of those older ‘inherited’ products lack spray drift related instructions

entirely, and others that do have such instructions do not have, by modern standards, instructions adequate to control risk. Moreover, tools for assessing spray drift risk have improved substantially over time and older instructions for chemicals that have previously undergone such an assessment may now be inconsistent with current best practice approaches. Updating labels to modern standards is necessary for the APVMA to be satisfied that the products can be used safely.

There are a large number of older agricultural products registered for use in cropping situations that have not undergone a modern spray drift risk assessment and do not carry adequate spray drift-related label instructions. Such products that do not contain suitable label statements (for example, specifying appropriate buffer zones or limiting spraying conditions) can legally be applied in unsafe spraying conditions increasing the chance of off-target movement. Adverse effects may occur even though they are not noticed or not reported.

If these labels are not assessed and upgraded, continued off-target exposure may occur routinely thereby giving rise to potentially unacceptable levels of risk to human health, the environment and Australia's international trade.

It should be noted that this is not a deficiency in the current regulatory system. Rather, the issue is being addressed within the current regulatory framework. Presently, existing products are reconsidered under the chemical review powers of the APVMA on a case-by-case basis often examining a number of risks. Such an approach however would be too slow for the large number of products in need of review. Instead, these reviews will be grouped appropriately and focus only on the issue of spray drift risk assessment and risk management.

There is also a separate but important issue relating to this problem that should not be ignored. Currently, new chemicals, new uses for existing chemicals and existing chemicals already under review are assessed to the modern standards outlined for spray drift risk assessment. This imposes a stricter set of requirements (for example, the possibility of mandatory buffer zones) on these product labels potentially giving an unfair market advantage to older products that have no such risk management requirements. The APVMA will make an effort to minimise such unintended disparities as much as possible.

3 Objectives of government action

The APVMA follows a risk management approach consistent with past experience in the Authority, with current scientific understanding of spray drift risk and with current international methodologies. The APVMA continues to refine its suite of spray drift risk assessment and risk management methodologies and has described them in its discussion paper, *APVMA operating principles in relation to spray drift risk*. This summary of its methodologies describes a refinement and standardisation of existing practices and no longer contains elements of new regulation that would impose added compliance costs on industry.

The document outlining these principles has gone through several iterations with public comment sought after publication of each version. The current draft will be the last one offered for public comment before proceeding to implementation. These risk assessment and risk management principles have been developed with four aims:

- Ensure that registration and review processes deal adequately with spray drift related risks to human health, the environment and international trade.
- Create and maintain a consistent and transparent process for making registration and review decisions in relation to spray drift risk assessment and risk mitigation.
- Harmonise the APVMA's approach with the respective capacities of the states and territories to enforce spray drift risk mitigation measures.
- Promote understanding among product registrants, chemical users and the community about how the APVMA makes regulatory decisions when there are spray drift concerns.

The risk assessment and risk management approaches will apply to all agricultural chemical products (including biological control agents) labelled for use outdoors that can be applied as sprays or dusts (with exceptions noted below). Application methods include, but are not limited to, aerial application, application with ground hydraulic boom sprayers or airblast equipment and application with handheld or backpack equipment. Application sites for affected products include, but are not limited to, agricultural crops, forest areas, pastures and rangelands, rights-of-way, recreational areas and lawns.

These requirements do not apply to:

- home garden products
- animal treatments applied as sprays
- products labelled solely for indoor use
- products labelled for outdoor use(s) that are applied in a form other than spray or dust such as a granular formulation
- fumigant products that exist as a gas under pressure and temperature ranges found outdoors.

These five classes of products are excluded because the spray drift risk is very much lower due either to the limited scale of use such as with home garden products and animal treatments or because there is no spray involved such as with granular products and fumigants.

The regulatory strategies will be applied consistently to all applications for new products and variations to existing products falling within the above scope. In addition, existing products will be assessed and labels upgraded for spray drift concerns according to prioritised need.

3.1 Applications for new registrations and variations

The regulatory strategies described in this document will be applied consistently to all registration applications. These include applications for new products and variations to existing products that fall within the scope of spray drift risk.

When the outcome of an application for variation to an existing product would lead to more stringent label requirements than those of competitive products with the same active, the other product labels will be brought up to the same standard through review action or else the varied product's label will be kept equivalent to the other competing products until all can be reviewed simultaneously. The approach that is chosen will depend on an evaluation of risk for that product group and comparison to other groups already prioritised for review. In either case, like products will be reviewed as a group so that newer uses or products are not assessed in isolation and possibly disadvantaged.

3.2 Updating existing products

Registrants of existing products that fall within the scope of these risk assessment methods will be advised when those product labels must be updated to reflect approval by the APVMA for spray drift risk concerns. The APVMA plans to group product types and assess them for label updating according to prioritised need. Where existing spray drift related instructions are already on a label, the APVMA may amend those instructions as necessary under the provisions of Section 34A of the Agvet Codes. In other cases, the APVMA will place the products and their labels under formal reconsideration, but such reviews will be focussed only on spray drift related issues.

The APVMA expects that several years will be needed to work through the large number of products affected. The timing of the schedule is contingent upon the availability of key data components (human toxicity data, environmental toxicity, and stability data, etc.), and there may be delays for some older products that might lack some of those components.

The APVMA plans to prioritise product groups so that those judged as having the greater risks will be assessed and have their labels upgraded first. Lower priority groups, meaning those of lower risk, will be updated as soon as possible after that.

4 Options that may achieve the objective(s)

The APVMA is not able to entertain the option of doing nothing in relation to this issue because that option would not satisfy the APVMA's obligation to protect human health, the environment and Australia's international trade. Two other options have been considered:

1. requiring industry to provide preliminary spray drift risk assessments and proposed label statements for the APVMA to assess

   or

2. having the APVMA undertake all responsibility for risk assessment and the formulation of new label statements.

Option 1

It was originally considered that to bring all labels up to modern standards, each registrant or applicant would undertake its own preliminary risk assessments and provide them to the APVMA along with updated spray drift related statements for inclusion on labels. Such an approach could result in significant increased burdens on industry. At the same time the APVMA would be responsible for ensuring the accuracy and appropriateness of industry-prepared risk assessments and label statements.

Option 2

A second option considered is that the APVMA would complete all risk assessments and label revisions without reliance on industry assistance. Assessment costs would be borne by the APVMA as is currently the case for any other review chemical or new product.

The APVMA has chosen Option 2 for the following reasons:

- Additional compliance costs would not be placed on industry.
- Such an approach would ensure quality and consistency in risk assessment because the work would be undertaken by the APVMA or one of its external service providers, just as chemical reviews and new product assessments are currently done.
- It is expected that the overall cost to the APVMA would be lower by avoiding the need to rigorously audit company derived assessments and label statements and ensure all such assessments meet the APVMA's standard.

4.1 Does this option constitute new regulation?

Legislative basis

The APVMA has powers and indeed a duty under the Agvet Codes to review currently approved chemicals and registered products when a legitimate concern exists in relation to the safety of their use.

These powers allow the APVMA to reconsider the registration of chemical products, the approvals of active ingredients and labels, and to require relevant information to be provided by sponsor companies. Relevant trial work can be requested by the APVMA to generate results needed for the review, and additional information can be requested for delivery within specific time frames.

Outcomes of a review can include the suspension or cancellation of the approval of an active constituent, the registration of a product, or the approval of a product's label.

Proposed targeted risk assessment approach

The purpose of this current exercise is to provide adequate directions for spray drift management to agricultural product labels falling within the scope of the exercise, based on a standard and validated risk assessment process. Performing the targeted risk assessments within the current chemical review program does not constitute new regulation. This conclusion is supported through consideration of the following:

- The APVMA already assesses spray drift in relation to environmental risk (through the Australian Government Department of the Environment, Water, Heritage and the Arts—DEWHA) and international trade risk.
- For new applications, the existing spray drift assessment approach has not imposed additional costs on industry applicants because no specific spray drift deposit studies have been required.
- DEWHA uses existing spray drift data sets (such as the Ganzelmeier set), and spray drift mathematical modelling programs were introduced as they have became available.
- The APVMA previously used a simple and conservative assumption of 10% of field rate for downwind spray drift deposits for residue assessments. Other necessary data needed to complete the risk assessment (environmental toxicology studies and standard residue studies) are already supplied as a normal part of the data requirements for the application.
- In 1998 beginning with the endosulfan review, the APVMA residues assessors also began using mathematical modelling for spray drift deposits to assess trade-related spray drift risk, still at no additional cost to applicants or registrants. The use of such modelling resulted in more realistic estimates of spray drift deposits in being able to move away from the conservative 10% drift (of field rate) default approach previously used.

- In relation to existing product labels, there is no need to fully review actives or products, only product labels to ensure that adequate instructions for spray drift risk control are present.
- Chemical reviews do not fall under the category of new regulation, and the APVMA needs to undertake reviews when soundly-based concerns do not allow the APVMA to be satisfied that a particular product or products can be used safely.

5 Impact analysis—costs, benefits and risks

5.1 Who is affected by the problem and who is likely to be affected by proposed solutions

As explained in the OBPR *Users Guide to the Best Practice Regulation Handbook* (http://www.obpr.gov.au), the total social or economic costs or benefits to the community of an activity are made up of the private benefits or costs experienced by those directly engaged in the transaction, plus the external social and economic benefits or costs not accounted for by the individuals or firms engaging in the activity.

An 'externality' occurs when a transaction between parties creates benefits (which are not paid for) or imposes costs (which are not compensated) on others not directly involved in the transaction.

The current problem is one relating to the potential externality resulting from off-target spray drift imposed on the environment, other farmers (particularly neighbouring properties such as organic growers, aquaculturists and other potentially vulnerable businesses), other human communities, and individuals.

The external cost associated with this problem is not something that can be readily quantified. However, older products/active constituents that have not yet undergone a modern risk assessment and which lack adequate spray drift risk instructions may be legally applied (based on their current label) in a fashion that might result in unacceptable off-target exposure from spray drift. Such drift can expose non-target organisms in the environment (for example, through contaminating nearby stream areas or native vegetation stands), neighbouring livestock and crops, or human bystanders. Often adverse effects may not be noticed or attributed to a particular spray-drift incident. This does not mean they do not occur. Further, contamination of neighbouring crops or livestock may result in a residue problem for affected farmers, including those in the organic farming business. Such contamination can result in significant economic loss to livestock producers and organic businesses through no fault of their own.

Where there are negative externalities, governments can prohibit an activity, impose a tax or charge, impose other requirements or create tradeable property rights. While the existence of an externality on its own does not always justify government intervention, in the present situation the APVMA must intervene. One of the specific reasons in the Agvet Codes for initiating a review is a finding that a product's label instructions are inadequate to protect human health, the environment or Australia's international trade. Uncontrolled off-target spray drift can affect all three of these risk areas. Many existing product labels, some of which were inherited from the

state registration systems (pre–1994), are acutely in need of review to upgrade label instructions to these current standards, thereby reducing the risk of off-target movement at the time of application of these products.

The option considered here is necessary, not just in terms of protecting human health, the environment or trade, but also in removing an unfair competitive advantage afforded to these older products in the market place. A new agricultural product, new uses for existing products and existing chemicals currently under review are already assessed according to modern standards. This leads in some cases to a stricter set of requirements for these products compared to older products where no such assessment has been performed.

Companies marketing agricultural chemical products that fall within the scope of this exercise will be affected by the planned risk assessments and label changes. Through interrogation of the APVMA database, it is estimated that potentially 2800 chemical products may require assessment (encompassing several hundred active constituents), and affecting about 175 companies.

5.2 Identify and categorise the expected economic, social and environmental impacts of the proposed options as likely benefits and costs.

This document follows the general recommended subject headings of the OBPR, and this section heading mentions benefits and costs. To be consistent with that intent, the APVMA here provides its interpretation of benefits and costs. However it must be emphasised that in relation to registration and approval decisions such as those made in review considerations, the APVMA is not permitted under the Agvet Codes to weigh costs against benefits in making its decisions. Decisions can only be made on the basis of scientific information in relation to the criteria of protecting human health, the environment and international trade with no consideration of potential economic costs to industry in relation to the loss of a chemical use or the potentially higher expense of an alternative chemical.

For this preliminary assessment, a full cost benefit analysis is not being undertaken. The OBPR uses a three-tiered approach for determining the extent of regulatory impact assessment required. First, all proposals must undergo a preliminary assessment such as this one to establish whether they are likely to involve an impact on business and individuals or the economy. For the second tier, if the preliminary assessment shows a likely ‘medium’ impact on business compliance costs, then a full cost assessment is carried out and documented in a Business Cost Calculator report (BCC). For the third tier, if the preliminary assessment shows a ‘significant’ impact on business and individuals (whether compliance costs or other impacts), then a full Regulatory Impact Statement (RIS) is required including the BCC. (Note that the OBPR does not define the meaning of ‘medium’ and ‘significant’ impact but attempts to weigh relevant issues on a case-by-case basis.)

For the single option being considered here, the costs related to the APVMA's spray drift risk assessment activities fall upon the APVMA itself. Although registrants in future may need to adjust some efficacy testing methods for new product studies (such as to shift to coarser spray categories for product testing), such changes are appropriately considered as normal research and development adjustments rather than as additional compliance costs. New spray drift risk-related studies will not be required for review situations, but following the review some registrants may voluntarily choose to upgrade their products with new studies in order to gain a market advantage over competitors.

The planned process will benefit industry by bringing consistency to label instructions and greater transparency to how the APVMA makes decisions for regulating spray drift risk. In particular, it will help provide a level playing field between older unassessed products and those new products recently assessed using these requirements. The process is also expected to result in more realistic assessments that will benefit both industry and the community.

Nonetheless, some additional burden as with most review activities may fall on industry and to address this an analysis of potential business compliance costs based on the methodology of the OBPR BCC has been included.

5.3 Will spray drift risk assessment changes result in significant costs to industry?

The proposed refinements to spray drift risk assessment are not expected to add significant additional compliance costs to industry. The assessment process with respect to spray drift risk will continue as before except that improved modelling software along with a standardised approach will strengthen risk assessment outcomes.

For new applications (new uses as well as new products), the APVMA will continue to assess environmental risk (through the DEWHA) and trade risk. Eco-toxicological and residue studies will already be supplied as a normal data requirement. These data combined with standard spray drift deposit scenarios developed by the APVMA will enable the APVMA to complete the assessments at no additional cost to the applicant.

APVMA spray drift risk reviews will be limited to product labels and driven by the need to provide adequate spray drift risk mitigation instructions on each label. (Note that the APVMA does not need to justify undertaking a review with a RIS.) Where a family of existing products, for example all with the same active and general array of uses, needs to have labels upgraded to contemporary standards, registrants will not incur costs additional to those of any other APVMA review.

For almost all existing chemicals, human toxicology, eco-toxicology and residue studies or study summaries are available. In unusual cases where existing, non-proprietary data cannot be found it may be necessary for one or more owners of historical studies to provide the necessary data to support review outcomes. In such cases, those data may be protected and, if so, other registrants

would need to arrange access to the data as is done with all APVMA reviews under existing legislation.

At completion of the review, registrants will be issued with new instructions that must be included on product labels. As with other reviews, these label changes are accomplished without additional APVMA fees to the registrant.

In the following section, some costs for upgrading and reprinting labels are identified and estimated. These costs are identified as resulting from review outcomes and it should be emphasised that this is not the same situation as costs resulting from proposed new regulation. The APVMA has always had the responsibility to undertake reviews as a result of valid safety concerns. The potential costs estimated in the following sections are associated with review activities and should be understood as ongoing safety compliance costs for industry that were established by Parliament in the Agvet Codes. They are provided not as new compliance costs but only as an estimate of what costs might eventuate (on an industry-wide basis) as a result of the APVMA's spray drift risk review activities.

5.4 Quantify the compliance costs on business using the BCC (or equivalent)

In order to understand the likely compliance costs, it is necessary to first consider the broad process followed for a chemical review. New chemical products and product uses are not considered within the compliance costs as the spray drift risk assessment is performed as required for new products based on the data submitted by industry for their overall assessment. It does not entail any further data being provided.

The broad process for a chemical review is available on the APVMA website (http://www.apvma.gov.au) and is summarised as follows:

The time taken to conduct reviews will be influenced by the number of different stakeholders that need to be consulted, the amount of data submitted, the number of products and uses currently registered, the complexity of the issues, and the extent of review outcomes that require implementation.

The process for reviewing chemicals can be outlined as:

1. The APVMA becomes aware of concerns about a chemical, product or label and determines if a review is warranted.
2. The review is prioritised, scoped, and scheduled based on the urgency and nature of the concern.
3. Chemical companies that have registered products and active constituent approvals for the review chemical are notified and are required to submit specific data relevant to the review.

4. The APVMA calls for public submissions that address the benefits of, or problems with, the continued registration of the chemical under review.
5. All submissions and scientific data are evaluated by the APVMA and external advisory agencies (OCS and DEWHA) as appropriate.

Based on these evaluations, a draft regulatory approach is developed. The Preliminary Review Findings Report is generally released for public comment (for a period of 6–12 weeks) prior to any final regulatory decisions

This broad approach shows that the main compliance costs borne by industry will be at point 3 and to a lesser extent during the period of comment following release of the Preliminary Review Findings Report. For a complex review, the impost on business can be understandably high, particularly at point 3 above, with time and resources taken to compile data packages. In the case of the risk assessments being performed for the spray drift label reviews, this burden will not need to be imposed. The APVMA expects that adequate amounts of data are available in the public domain for the purposes of these targeted risk assessments. Companies marketing agricultural chemical products undergoing review for updating labels to include current spray drift statements and information will be advised by the APVMA prior to the time of the review commencing, but will not be required to submit data. While individual companies may choose to submit data, this will not be a requirement and so is not factored into the compliance cost calculations.

Following evaluation of the available data and determination of the relevant spray drift instructions and information to go onto a product label, the affected registrants will be advised by the APVMA of the review outcomes and label changes needed. This part of the process will result in compliance costs by industry, for example, time taken to read the risk assessment and understand the outcomes and re-draft and print labels. The extent to which each company will be exposed to these costs would depend on the number of different products each is responsible for.

6 Business compliance cost—calculations

The broad approach used in the OBPR BCC has been followed here. However, the actual BCC has not been used since some steps are inconsistent with this situation. It is important to recognise that the potential cost burden on industry will not be evenly distributed. Companies with more affected products will necessarily bear the greater load.

The APVMA has estimated that as many as 2845 products may need to be assessed with the following break-up:

Product category	Products
Fungicide	480
Herbicide	1510
Insecticide	695
Miticide	75
Mixed function pesticide	50
Plant regulator	35
TOTAL	2845

The total in each category is approximate and fluctuates daily. In addressing these figures, it should be understood that they are a likely to be a significant overestimate of the numbers that will be confirmed after the products are examined in detail. These numbers were obtained from database categories that also contain products that will not fall within the scope of spray drift risk concerns as explained in section 3.2 of the discussion paper. In that sense, all of the calculation results that follow can be considered as significant overestimates of potential costs to industry.

It should also be understood that many of these products are image products or are similar products that contain the same active constituent, but at different concentrations and with different uses. While different cropping situations may apply to these different products, actual application rates of the active constituent could well be the same or similar and therefore the outcomes of the risk assessment for one product may be applicable to other products containing the same active constituent. Therefore, where one registrant may sell several products with the same active but used on different crops/situations, that registrant may only need to consider the outcome of one risk assessment.

It also needs to be recognised that there is a large difference in the numbers of products registered between companies. The 2800 products are supplied by approximately 175 different companies. Some companies may only have a few products registered compared to many products from other companies. For instance, the registrant with the largest range has almost 170 products. A number of other large companies have almost as many. If the potentially affected

products are related to the 175 companies that supply them, there is an average of about 16.3 affected products per company.

Costs potentially borne by industry have been arrived at through consultation with industry representatives. To estimate the cost of the option, the BCC provides a list of tasks that may be required. In this case, there are two main tasks. The first is to consider the risk assessment and set of label requirements for spray drift management as determined by the risk assessment (cost category of 'Other' in the BCC as the task can not be categorised in any other category). The second task is categorised as 'Publication and Documentation', where businesses are required to amend their labels to include the mandatory drift management statement(s).

Task 1: Costs associated with consideration of the risk assessment

The wide variety of companies associated with this exercise means this task will be performed by different levels of employees in different companies. In larger businesses that typically develop new chemicals, it is expected that specialist regulatory affairs officers will undertake this task. In smaller companies that typically are not involved in pioneering new product development, the task would most likely be performed at management level as agreement from this level would be required. Some larger companies are subsidiaries of international companies and for them the task may even be performed overseas. For the purpose of this exercise, it will be assumed that costs will be borne locally.

While different companies will obviously have different cost structures, a representative hourly rate will be used for cost estimation. The rate of $185.00 per hour has been taken as representative and encompasses salary and overheads along with other costs such as lost opportunity that will be borne by smaller operators.

The time taken to perform this task will depend on the level of expertise and understanding of the individual assigned the task. It has been estimated that up to two (eight hour) days of effort may be required for each affected product.

The task will need to be performed once per product (noting comments above that companies with several products of the same active may not need to undertake this task for every product). Businesses will not be required to purchase any extra equipment for performing this task. Given these assumptions, the following cost for this task has been estimated:

Task 1: Consideration of risk assessment and consequent label statements	
Number of companies affected	175
Average number of products per company	16.257
Hourly rate	$ 185.00
Number of hours per product	16
Estimated compliance cost per product	$ 2,960.00
Estimated compliance cost per company	$ 48,121.00

Total compliance cost for whole industry	$ 8,421,200.00

As stated previously, these estimated values are likely to be a significant overestimation since a number of products containing the same active constituent at different concentrations have the same uses. Moreover the total product estimate is likely to be high, and some of the products that would be confirmed as low risk might need no label changes. The cost will not be distributed evenly among the companies. Those with fewer products will have a proportionately lower compliance cost than those with more products. These costs would be spread over the four to five years needed to work through the products affected.

Task 2: Publication and documentation

The other compliance cost that will be faced relates to updating label instructions. The APVMA would arrange for companies to update labels in a common product family at the same time. There would be a direct cost attributable to this exercise for a given product unless that label update is timed to coincide with a normal production schedule that includes placement of labels onto new product containers. The APVMA expects that many products will not require urgent label changes and can wait for normal product replacement schedules. However, where such delays would be excessively protracted and particularly in cases where a number of different companies with similar products need to comply at the same time, the APVMA will specify a date for compliance.

In such cases the APVMA would use its recall powers to require an amended label to be on products by the nominated date. In most cases the APVMA would be satisfied with less costly over-sticker methods of changing the label.

Prior to completing all the assessments, there is no reliable way to judge what proportion would require timely label changes. The APVMA estimates that 20% of the whole is a conservative estimate; that is, the proportion needing more urgent changes is unlikely to be greater than that figure.

The cost for label over-sticker amendments has been estimated by industry representatives and is summarised in the following table:

Task 2: Publication and documentation		
Cost if replacing labels as a sticker to amend existing labels until the next reprint. This takes into account preparing revised labels, printing of stickers and applying to existing labels/containers.		
Number of companies potentially affected	175	
Average number of products per company	3.25	*[16.257 x 0.2]*
Estimated compliance cost per product	$ 5,000.00	
Estimated compliance cost per company	$ 16,250.00	
Total compliance cost for whole industry	$ 2,843,750.00	

Again, it is worth repeating that the costs outlined for Tasks 1 and 2 are not compliance costs for new regulation. Rather, these are normal costs typically associated with chemical reviews. They would be spread over a likely time frame of the four to five years needed to work through the products affected.

7 Consultation

The APVMA document, *APVMA operating principles in relation to spray drift risk*, outlines its responsibilities and describes its approach to spray drift risk assessment and risk management.

This document has been published previously in three earlier draft versions (1 July 2003, 5 August 2005 and 24 July 2006) each of which was followed by an extensive period of public consultation. All comments from previous submissions to the APVMA have been considered in the preparation of this document.

In addition, the APVMA has hosted two national forums of industry, community, and state and territory representatives to discuss the issues raised in the paper. Finally, the APVMA has made presentations on this matter at numerous industry annual meetings and conferences as well as at academic symposia during the last four years.

In terms of business compliance, the affected parties are the registrants of products where labels will require updating following the targeted risk assessment. However, the consultation has been much wider than this group with public consultation forums held for all interested parties to attend. Written submissions were received on earlier versions of the document outlining the proposed process. The views received have been separated into those from industry and those from the wider community. These views are summarised below.

7.1 Industry comments

Comments from industry and state/territory submissions can be divided into two categories. One group comprised of small points of disagreement with statements in the document. Almost all involved points where the APVMA had not been clear enough about what it meant and could be addressed by rewriting the document text to be clearer or by adding in a small point which had not previously been made explicit.

The second group of comments was less diverse and centred mainly around two issues—concern that the APVMA would take away operator flexibility by making product labels too restrictive and concern that useful chemicals would be lost to industry as a result of onerous new data requirements.

In relation to the first issue, concern over loss of operator flexibility in how applications should be carried out, correspondents made the point that the applicator was better able to judge how best to apply the chemical because only that person knew the conditions and circumstances at the site and time of application. The APVMA recognises the importance of the applicator's skill and judgment, and this is addressed in Section 6.3 ('Expertise of applicators') of the document *APVMA operating principles in relation to spray drift risk*.

In relation to the second issue, industry has expressed concern that older chemicals still of value to farmers but no longer under patent may not produce enough revenue to registrants to justify the expense of new data requirements. Therefore registrants may choose to withdraw these chemicals rather than attempt to meet new APVMA data requirements. The aerial application industry in particular has expressed concern that it will suffer loss of currently available chemicals.

These concerns may have arisen due to a misunderstanding about what kinds of data the APVMA will need for implementation of its spray drift risk assessment proposals. Since the APVMA will rely on modelling data and available data sets for spray drift risk assessment there is no expectation that new field studies to assess potential drift quantities would be needed. Further, for chemical actives already approved and in registered products data will already exist relating to human and environmental toxicity and, in most cases, to aspects of trade risk.

An earlier proposal was that industry would be required to complete preliminary spray drift risk assessments and provide them to the APVMA along with proposed amended labels. If that proposal had remained the case the principal cost to industry would have been assembling and assessing a data package that included appropriate spray drift deposit profiles and either existing toxicological and environmental studies or already agreed upon safety thresholds for the chemical active in question. Significant expertise would have been needed by each company either through extensive staff training or through paid consultants.

However, this cost has now been removed due to the revised approach outlined in this document. The APVMA will now assume complete responsibility for undertaking the risk assessment using currently available data for existing chemicals rather than having industry assemble the data package and undertake the risk assessment. At the completion of each risk assessment the APVMA will provide appropriate label instructions to be incorporated into the product's label.

7.2 Community comments

There were two main concerns expressed in the few community comments received. One was in relation to the higher release height for forestry applications, and the other was over the general way the APVMA assesses risk.

In the original discussion paper (1 July 2003), references to forestry practices had not been included but were later added into the second version of the paper (5 August 2005). That addition raised a concern in some readers that it meant a relaxation in allowable release heights rather than a correction of an earlier oversight. Forestry applications require a higher release height as a matter of safety to pilots because of uneven tree heights and typically hilly terrain.

One correspondent was concerned that spray released over forested hilltops adjacent to a town would cause large amounts of spray drift onto the town because of the height of the hill added to the high release height over trees. The APVMA telephoned the aerial application company operating in that area and was assured that no spray operation would be carried out under

circumstances when wind was blowing from a hilltop toward a nearby town. Spray operations would always be suspended until the wind was blowing away from the direction of the town. As part of the implementation of the new spray drift proposals, the APVMA plans to specifically assess risk for such circumstances and strengthen product label requirements when appropriate.

The second major issue was expressed in a number of ways but can be summarised as dissatisfaction with the way the APVMA approaches risk assessment, particularly in relation to the concept of a 'safe' threshold. The correspondents were concerned that existing toxicological studies were not adequate to expose hazards arising from mixtures of chemicals or chemicals believed to be related to endocrine disruption, cancer, multiple chemical sensitivity, epigenetic effects, death of aquatic life, and other related matters.

This concern encompasses a very complex area that transcends spray drift issues and extends to all aspects of APVMA hazard and risk assessment. The areas of concern are the subjects of intense and ongoing international research that the APVMA continuously monitors. For the present, the APVMA and its cooperating agencies follow current international best practices in the way risk is assessed. These methods conform to the requirements of the APVMA's founding legislation and are internationally agreed to provide an adequate level of protection to risks from agricultural chemical use. The APVMA is currently developing a comprehensive document to describe how it assesses risk throughout its areas of responsibility. In the meantime, the APVMA continues to monitor new scientific developments to consider for inclusion in its risk assessment methods.

8 Implementation and review

The APVMA will undertake to complete all spray drift risk assessments as described in its discussion paper, *APVMA operating principles in relation to spray drift risk,* without requiring applicants or registrants to provide a preliminary risk assessment. The APVMA risk assessment will be based on spray drift specific information for those products falling within the scope of this exercise.

This approach is sufficiently flexible to adapt to various situations and circumstances. The APVMA plans to prioritise product groups so that those judged as having a higher range of spray drift risk will be assessed and have their labels upgraded first. To prioritise product groups an established list of risk criteria will be used (as outlined in the discussion paper). These criteria are based primarily on toxicity characteristics of the chemical, its persistence, bioaccumulation potential, use patterns, application methods, and MRLs.

Lower priority groups, meaning those of lower risk, will be updated as soon as possible after that. Those products not meeting the additional risk criteria will in most cases not require spray drift related information. An initial assessment will determine whether more extensive examination is needed.

In most cases, the needed data is already supplied with applications (for example, toxicity data, environmental stability data, animal transfer data, depuration data) or is already available for older chemicals. That data combined with AGDISP spray drift modelling and ground application data sets will enable the APVMA to undertake the risk assessment.

Only application methods that have been assessed for risk will be approved for use. If an application method has not been assessed or the risk from an assessment has been determined to be unmanageable, then the label will need to state that that method must not be used.

As part of its risk assessment process and to ensure clarity and consistency in the way spray drift risk management methods are stated on labels, the APVMA will construct the appropriate label statements and provide them to applicants and registrants for inclusion on labels.

The regulatory strategies described in the *APVMA operating principles in relation to spray drift risk* will be applied consistently to all registration applications from the date the refinements are adopted. These include applications for new products and variations to existing products that fall within the scope of spray drift risk.

When the outcome of an application for variation to an existing product would lead to more stringent label requirements than those of competitive products with the same active, the other product labels will be brought up to the same standard through review action or else the varied product's label will be kept equivalent to the other competing products until all can be reviewed simultaneously. The approach that is chosen will depend on an evaluation of risk for that product

group and comparison to other groups already prioritised for review. In either case, like products will be reviewed as a group so that newer uses or products are not assessed in isolation and possibly disadvantaged.

It is expected that four to five years may be needed to work through the potentially 2800 existing products affected. Product groups considered higher risk will be addressed first with the lowest risk products being finished last. The timing of the schedule is contingent upon the availability of key data components (human toxicity data, environmental toxicity and stability data, etc.), and there may be delays for some older products that might lack some of those components.