Australian Government

Australian Pesticides and Veterinary Medicines Authority

APVMA OPERATING PRINCIPLES IN RELATION TO SPRAY DRIFT RISK

15 JULY 2008

APVMA operating principles in relation to spray drift risk

First Published 15 July 2008

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Important information

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has prepared this document to describe its approach to spray drift risk assessment and risk management.

This document has been published previously in four earlier draft versions (1 July 2003, 5 August 2005, 24 July 2006 and 20 February 2008) each of which was followed by a period of public consultation. All comments from previous submissions to the APVMA have been considered in the preparation of this document.

This document is now in final form as an overview of APVMA spray drift risk regulation. The methods and principles described herein will apply uniformly to both new applications and reconsiderations.

The APVMA will continue to improve its risk assessment methods to strengthen their reliability. The APVMA will publish minor changes on its website as they occur and will announce a consultation period for stakeholders to comment on any major changes that may be contemplated.

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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 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 such products prior to registration and determines how those products may be used by putting instructions and limitations on product labels. The individual states and territories are responsible for user compliance with these instructions and limitations.

The APVMA acknowledges its responsibility to address the potentially harmful effects of off-target spray drift associated with chemical use that can occur at times with applications of agricultural chemicals. In this document, the APVMA explains what factors it considers and how it assesses and takes measures to mitigate spray drift risk. 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.

In its latest refinement of these principles, the APVMA has followed a risk management approach consistent with its past experience, with current scientific understanding of spray drift risk and with current international methodologies.

2 APVMA's responsibility in relation to spray drift

The legislation under which the APVMA derives its powers (*Agricultural and Veterinary Chemicals Code Act 1994*) 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. User compliance with these instructions and limitations falls under the enforcement powers of the states and territories.

Ideally, a product would only be applied to the intended target. However, the APVMA recognises that measurable off-target spray drift can occur at times even when the product is applied with care. The APVMA therefore has an obligation to consider the potentially harmful consequences of that associated spray drift and determine whether it would be likely to harm human health, the environment or unduly prejudice Australia's international trade.

If the APVMA finds that spray drift associated with a chemical application would be likely to cause harm, the APVMA cannot allow that product to be used unless a way can be found to prevent that harm from occurring.

3 Purpose and scope

3.1 Purpose

This document sets out how the APVMA assesses risk from spray drift and the general methods it uses to control that risk. The APVMA intends to maintain a consistent and transparent process for making spray drift related registration decisions and provides this information to promote understanding among applicants, chemical users and within the community regarding its approach to spray drift risk assessment and risk reduction.

3.2 Products affected

The risk assessment and risk management approaches described in this document 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 turf.

These risk assessment methods 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 for these products 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 described in this document will be applied consistently to all applications for new products and variations to existing products that fall within the scope. In addition existing products will be assessed and labels upgraded for spray drift concerns according to prioritised need. Please refer to Section 9.2 for more detail.

4 Definition of spray drift

Many pesticides are applied as a spray of liquid droplets and, for a few products, as a fine dust. The droplets of liquid or particles of dust can be carried by wind to places outside the intended area of application during and shortly after the application. Agricultural chemicals can also move away from the intended area of application by other means such as by being carried out of fields on soil particles moved by wind or running water or by evaporating (volatilisation) directly into the air.

Most attention has been focussed on potential droplet drift arising from spray applications. The APVMA also recognises that applications of dust formulations can drift, can give rise to the same kinds of concerns and, except for evaporation effects, follow the same physical principles as spray drift. In this document, the APVMA uses the term ‘spray drift’ to include dust drift from applications of dust formulations.

The APVMA intends the term ‘spray drift’ to mean the following:

> Spray drift is the physical movement of spray droplets (and their dried remnants) through the air from the nozzle to any non- or off-target site at the time of application or soon thereafter. Spray drift shall not include secondary movement of agricultural chemicals to non- or off-target sites caused by volatility, erosion, surface or groundwater transport or windblown soil particles that occurs after application.

This definition is intended to encompass the uninterrupted flight of a droplet from the nozzle to impact and capture by a physical object such as soil or plant surfaces. The words ‘soon thereafter’ typically refer to a time period of less than an hour. However, if an application were done during a surface temperature inversion condition, it is possible for very small droplets to remain suspended in the air for a number of hours until atmospheric conditions change and air movement carries the droplets to some impact point. The essential concept is that spray drift occurs during the flight of the droplet from nozzle to eventual impact and capture off target and is not properly defined to include secondary movement of a chemical due to transport by other mechanisms such as subsequent soil erosion or direct volatility.

The APVMA recognises that pesticide vapour and off-target movement of pesticides by other means not included in this definition can present risks. However, these other routes of movement are not included with spray drift because they need to be assessed and regulated differently. For example, spray droplet movement is largely independent of the chemical used (for a droplet of specific size and when specific gravity is taken into account), and droplet movement can be predicted mathematically according to physical laws.

By contrast, volatility risk is highly dependent on each chemical’s properties (such as its inherent vapour pressure and Henry’s constant), and since the chemical is moving as a gas rather than in liquid droplets, it must be assessed with different mathematical models and managed according to different methods. The APVMA addresses these alternate routes of potential off-target movement separately during its risk assessment, prior to registration of each product, and makes appropriate label adjustments as necessary.

5 Assessing the risk of a chemical that drifts off target

Assessing risk can be a complex task but in its simplest form can be generalised as a two-step process of first understanding the nature of the hazard and secondly understanding the type and degree of exposure to the hazard. Without exposure to a hazard, there is no risk.

The properties that make pesticides useful can also make them potential risks for human and/or environmental health. The toxicity of a pesticide is an inherent property of each and is a measure of its hazard. It is important to realise that an insecticide can be highly toxic to insects but possibly much less toxic to mammals or aquatic life. Similarly, a fungicide or herbicide is expected to have a strong effect on its target pest but may have little effect on people. By contrast, there are some pesticides that are highly toxic to people and other organisms as well as to their target pests. It is important to remember that all pesticides are not the same. Each chemical has its own unique properties and must be assessed individually for its hazard.

Relevant properties include the measured toxicity of the chemical to humans, animals, and plants (short term and long term), the persistence of the chemical in the environment, the persistence of the chemical within an animal's body and the tissues or organs where it may accumulate and to what degree it might accumulate. Some pesticides do not cause significant concern because they have very low toxicity to non-target organisms, may break down rapidly in the environment and/or do not accumulate in animals bodies.

Risks arising from off-target spray drift are caused by the potential exposure of people, plants, and animals in the environment to a chemical that has drifted to a place where it should not be. The amount of potential exposure is determined first by estimating how much chemical is deposited off-target and secondly by assessing the different ways people and other organisms might interact with that chemical deposit. When a drift deposit profile has been estimated (see Section 7), the APVMA can determine at what distance from an application a particular type of risk may be present by analysing the features of the active ingredient (the hazard) and the different kinds of exposure that may occur. Specific features of the chemical, the environment and the physiology of an organism that might be harmed all interact to result in outcomes potentially different for each combination.

For risks to human health, the environment and trade, the APVMA considers each risk in relation to a threshold of exposure for the chemical in question – an exposure level above which risk is deemed not acceptable and below which risk is considered negligible. For human health issues, the threshold is related to health standards for each chemical determined by the Office of Chemical Safety in the Australian Government Department of Health and Ageing (OCS). In most cases, these human health standards are very similar to or identical with equivalent health standards set by overseas regulators.

For environmental risks, the Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA) determines the threshold for each chemical in relation to specific ecological compartments and conducts an analysis of potential exposure to appropriate indicator organisms. DEWHA then advises the APVMA of the outcome of the risk assessments.

The APVMA has its own staff of experts to assess spray drift risk to international trade as a result of pesticide residues. The risk is assessed by considering knowledge of spray drift deposition, scientific studies used to set maximum residue limits and knowledge of international market restrictions.

In all cases, whether for human health, the environment or trade, large safety margins are incorporated into any exposure threshold that the APVMA uses. That is why the risk for exposures below the threshold for each chemical can be considered to be negligible.

5.1 Risk to human health

For example, in considering possible harm to human health, a pesticide with high mammalian toxicity might be found to present an unacceptable risk to people standing or residing a certain distance downwind from the application site. Such a risk can be evaluated by estimating the quantity of that pesticide falling at that distance per unit area, the amount of pesticide likely to be absorbed through the skin, transferred to the mouth and inhaled by a person over a given period of time and the calculated potential dose of the pesticide compared to the relevant health safety standard set by the OCS.

Looking at a different example, calculations of risk related to roof-collected drinking water incorporate the environmental stability of the pesticide, its stability in water, typical rainfall patterns and estimates of overall domestic water usage and water ingested in all forms per person.

Fortunately, very few pesticides are sufficiently toxic to cause human health risks from these kinds of bystander exposures. Calculations for both direct exposure and indirect exposure only rarely yield a concern and more rarely one that extends beyond 50 metres downwind.

5.2 Risk to the environment

A pesticide with toxicity to fish or aquatic macro-invertebrates might be assessed for environmental risk in a similar way. In this example, the risk would be determined by considering the amount of pesticide likely to fall on an area of water, calculating the final concentration of the pesticide after considering water depth and comparing that calculated concentration to the toxic sensitivities of particular aquatic indicator species. Conceptually similar approaches are used to assess risk to terrestrial plants and animals. Depending upon the toxicity of the chemical, the application rate and the frequency of application, such analyses can sometimes yield a concern to a range of 500 metres downwind and occasionally beyond.

5.3 Risk to international trade

A trade risk is often a more complex situation because additional factors, some to do with international trade standards, also play a role. Once again, the first step is determining the amount of a pesticide likely to be deposited per unit area at distances downwind. Next, four key questions must be considered:

- How stable is the pesticide over time in an open environment, typically on a plant surface that may be capable of metabolically degrading the chemical?
- How much time is likely to pass before the plant material is grazed or harvested?
- What is the concentration of the chemical in the final plant material affected by spray drift?
- Are maximum residue limits (MRLs) for the pesticide established for relevant commodities by key trading partners?

Trade risk problems can be caused by plant commodities affected by spray drift (such as horticultural products), but the more common trade risk situation is found with livestock that have grazed on pasture or forage that has been contaminated with spray drift. In these cases, additional factors relating to the animals' characteristics and physiology must be considered. Several questions are important:

- How much of the contaminated plant material is an animal likely to eat?
- How readily is the pesticide absorbed by the animal's digestive system?
- Does the pesticide tend to accumulate in particular tissues, organs or products (milk, eggs)?
- How long does the pesticide persist in those tissues or organs?

Although it may seem surprising, trade risk is typically the most sensitive of the three main types of risk, meaning that unacceptable risk can occur at the greatest distances, sometimes reaching beyond 1000 metres downwind. This is due mainly to situations where trading partners have not established a maximum residue limit (MRL) in the affected commodity for a particular chemical that Australia uses. In such a case, the trading partner typically does not tolerate any detectable trace of the chemical even though that trace may be far below any relevant human health standards.

6 General application concerns

6.1 Ground application

In relation to spray drift risk, ground application has some distinct advantages such as being able to keep spray release height low, operating at slower speeds that do not shatter droplets and being able to use wind-shielding hoods or shrouds around nozzles in some circumstances.

However, ground applications, both broadacre and orchard, can also result in unacceptable amounts of spray drift in some circumstances. For example, the slower speed of ground machines (compared to aerial application) can lead to spraying through changing wind conditions and to all night spraying during surface temperature inversion conditions that can result in significant spray drift. The temptation to increase machine ground speed to finish the job more quickly can also lead to greater bouncing of the spray boom over rough ground that also increases spray drift.

Orchard applications with radial airblast machines can cause significant spray drift when the machine is not properly set up to avoid driving spray above tree tops or when outer nozzles are not shut down on row turns or outside rows. Modern tower and tunnel airblast machine designs perform better but are not yet the most common types in use.

6.2 Aerial application

Aerial application has great advantages in speed of coverage, in being able to access crops when fields are too wet for ground machines and in avoiding soil compaction and crop damage from ground machinery. However, aircraft have some inherent properties that can add to spray drift risk. One of the most significant is that aircraft need to release spray droplets high enough for safe operation, and higher release heights add to spray drift risk. Moreover, the high speed air moving past aircraft-mounted nozzles can shatter droplets delivered by the nozzles into smaller droplets that are more drift prone. Wake disturbances to the air from large and necessarily fast moving aircraft also contribute to spray drift by lofting droplets higher.

Some of these inherent features of aircraft can be compensated for by proper set up of accessory equipment such as ensuring that a nozzle design is chosen that will deliver a coarse enough spray to compensate for droplet shatter. Booms can also be positioned optimally and shortened in relation to wingspan to avoid much of the droplet lofting effect from wingtip vortices. However, the higher release height remains a disadvantage in comparison to ground application that has not been overcome.

Numerous field studies done overseas and in Australia show that even when equipment is set up in an optimal fashion by experts and operations are carefully executed, aerial application tends to produce more spray drift than ground application when meteorological conditions are the same. Computer modelling relying on physical principles supports that result. (For example, see Figure 1, page 14.) The difference mainly originates in the higher release heights and wake disturbances of aircraft. This is why there is an international consensus that aerial application is generally of higher risk.

For both ground and aerial applications, the APVMA assesses risk on their merits. The APVMA recognises the great value of aerial application to Australian agriculture and allows it to be used wherever it is shown to meet risk criteria. Spray drift risks from both ground and aerial applications are assessed using methods described in the following pages. An application method cannot be approved for a product use without risk assessment. For example, if a particular product use has not been assessed for aerial application, then that product label would need to state that it must not be applied by air.

6.3 Expertise of applicators

The importance of training

In all discussion about spray drift risk, there seems to be universal agreement that the competence of the people who apply chemicals is the foundation of all further risk mitigation approaches. That competence implies an understanding of all important risk factors affecting spray drift and suggests a responsible and constructive attitude on the part of the operator.

For situations of high risk from spray drift, the APVMA may require that persons applying the chemical have prior special training or qualifications. That requirement can be imposed through the designation of the chemical as a 'Restricted Chemical Product'. The training requirement for access to products containing the insecticide endosulfan is an example of such a restriction currently in force.

At this time the APVMA does not have a legal mechanism to impose chemical access restrictions that are contingent on adequate training other than use of the Restricted Chemical Product status. The APVMA therefore strongly supports voluntary initiatives by industry and state and territory authorities to develop special training and qualification standards to reduce spray drift risk. Programs providing qualifications that are recognised across state and territory boundaries are encouraged for both aerial and ground applicators. A system of national qualifications would be particularly useful so that an operator, who was suspended or placed under restrictions in one jurisdiction, would similarly be suspended or restricted in all other jurisdictions.

In addition to such new approaches, there is a need for easily accessible information in relation to spray drift risk. The APVMA intends to work with training providers to help develop better information sources that can be easily accessed.

Where basic competence needs additional support

Claims are often made that a competent user needs complete flexibility to optimally adjust the way an application is made and should have no label restrictions that would constrain that flexibility. Certainly a user is able to make judgements at the time of application to reduce risk from spray drift such as changing to a coarser droplet spectrum (if efficacy considerations allow it) and suspending application until the wind direction changes or the wind speed drops. Making choices such as these are vital risk management options that the APVMA expects of all competent operators. However, for almost all pesticides there are times when circumstances call for more in-depth information about the nature of the risk and general competence alone is not enough.

For example, a fully competent user, on the basis of experience and general knowledge, does not know answers to the following questions for each pesticide that might be used:

- How many grams per hectare of an active ingredient might be deposited at specific distances downwind for a particular size of droplet spectrum and wind speed?
- How quickly and how much of a particular chemical might be absorbed through the skin of a child playing in a back yard at a certain distance downwind from an orchard spraying operation?
- How likely is the risk that spray drift could result in a bystander’s exceeding the acute reference dose (ARfD) or even the acceptable daily intake (ADI) for a particular pesticide if positioned at a certain distance downwind?
- How rapidly does a particular chemical break down in sunlight or by plant metabolic activity and will it be fast enough to prevent a serious trade risk?
- What are the values of ecotoxicity thresholds of any given pesticide for critical indicator species of animals and plants?
- How much of a particular chemical that drifted onto pasture would be taken up by grazing stock animals, into which tissues would it be distributed and how long would it remain in those tissues before being metabolised or excreted?

These are only some of the questions that need to be considered in fully understanding the risk. Scientists at the APVMA and its cooperating federal agencies devote much time to analysing these questions and other similar issues for each chemical product using extensive scientific studies. Such analysis usually requires computer modelling and substantial consultation to arrive at a balanced answer. All of this effort is necessary to determine what special actions or restraints might be required and appropriate for the unique properties of each chemical. An equivalent analysis such as this cannot be done ‘on the fly’ just prior to or during an application by even the most competent operator.

One of the principal roles of the product label is to inform the user of how that product needs to be used so that safe outcomes are achieved. When thinking of a highly competent and responsible chemical user, ideally there would be no conflict between label requirements and what that user would voluntarily choose to do if fully informed of the risks appropriate to the particular chemical product.

The role of the label is to provide critical information to enable the competent chemical user to achieve the safest and best result. Sometimes that means that the label must impose limitations as well as inform. For chemical use situations where identified risks necessitate specific restrictions, the label also provides a backup for state and territory control of use powers to support prosecution of those who might choose not to follow label instructions.

6.4 Addressing risk concerns

It is clear that many factors contribute to overall risk and that there are ways of addressing many of these factors to reduce risk. In relation to the nature of each chemical product, its uses, the equipment used and whether application is by ground or by air, the APVMA attempts to consider all aspects in completing a final risk assessment. Much of the discussion that follows will focus on how the APVMA approaches that task.

7 How the APVMA estimates the amount of spray drift

A large amount of scientific research into spray drift risk assessment has been done in the last fifteen years worldwide with a significant amount done in Australia. This research has led to a better understanding of the factors affecting spray drift risk and to a collection of scientifically sound studies comprising a database that supports contemporary risk assessments. Both of these outcomes have made possible the refinement of computer models that can be used to predict spray drift quantities under a set of defined conditions. The APVMA takes advantage of these tools and other sources of information in making its assessments.

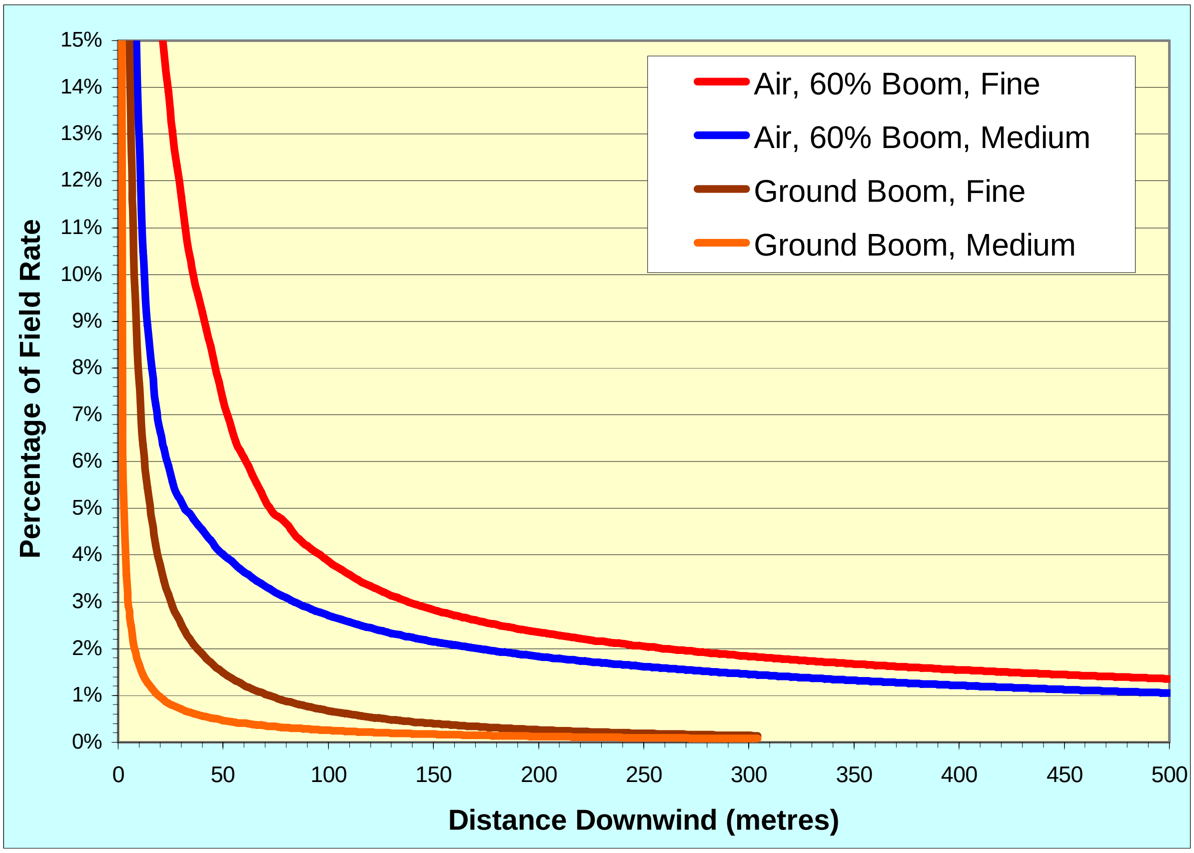
7.1 Assessing the quantity of a chemical likely to drift—the role of computer modelling

The first step in assessing spray drift risk is determining how much active ingredient is likely to be deposited downwind from an application site. A number of factors influence how far a drift deposit will reach and how much will be deposited. The major factors are droplet size, wind speed and release height. Computer modelling can be used to predict the behaviour of droplets influenced by these various factors (see below). When the APVMA estimates drift quantities, it does so using the droplet size range recommended on the product label, the highest wind speed permitted on the label and the highest spray release heights typically used by applicators for various situations. In this way, the APVMA considers risk at the higher end of what would commonly be expected from real applications. Depending upon the nature of the product and its use, other parameters are assessed at values ranging between typical field conditions and higher risk conditions that might be likely to occur (see Section 8).

As an example, Figure 1 illustrates computer-generated profiles of downwind drift deposits from two types of applications, aerial and ground, expressed as a percentage of the normal field application rate [profiles generated with AgDRIFT version 2.0.07, Tier III Aerial (Agricultural) and Tier I Ground (Agricultural)]. The spray release height is 3 metres for the two aerial examples and 1.27 metres for the two ground boom examples. The wind speed is 20 kilometres per hour for these four examples. Zero on the horizontal axis of the graph refers to the downwind edge of the application area where the spray application stops, and the wind direction is from left to right.

The top two curves, red and blue, are drift deposit profiles for aerial applications and show the greater drift potential for the smaller droplets in the 'Fine' range as compared to the 'Medium' range. Note that the aircraft setup has been adjusted to reduce spray drift. For both aerial applications, the aircraft is using a dropped boom and the active boom width has been limited to 60% of wing length to reduce the spray drift increasing effect of wing tip vortices. The lower two curves, brown and orange, show deposit profiles for ground boom applications of the same two droplet size ranges as used for the aerial applications. The notable difference between aerial and ground application shown here is due mainly to the greater release height of the aerial application and aircraft wake disturbances.

Figure 1 Example of spray drift deposit profiles from computer modelling



On this graph, zero on the horizontal axis represents the downwind edge of the application area. The wind is blowing from left to right. The vertical axis is scaled in percent of the intended field application rate. For example, the top curve (red) shows that approximately 4% of the intended field rate is deposited at a distance 100 metres downwind from the downwind end of the application area.

Figure 1 illustrates that the deposit of active ingredient falls off rapidly downwind from the application, and more rapidly for the larger droplet spray, but it also shows that a significant percentage of the applied field rate can be deposited at substantial distances downwind.

The quantity of active ingredient that is likely to fall at a specific distance combined with its physical, chemical and toxicological properties and the characteristics of the organisms exposed determine what specific types of risk need to be considered and how severe those risks might be.

Computer-based spray drift models for aerial application

The APVMA has used two well-validated computer models as tools in its spray drift risk assessments. They are named AGDISP and AgDRIFT; they are closely related and provide equivalent output results for aerial applications when input variables are identical.

The current AGDISP model is descended from an earlier well-established US Department of Agriculture Forest Service version and was originally developed to model aerial applications to forests. It has been strengthened and improved over the years and provides strong modelling capabilities both for forestry and broadacre aerial applications. The US Environmental Protection Agency (US EPA) and the Pest Management Regulatory Agency (PMRA) in Canada use AGDISP for a portion of their spray drift risk assessments.

AgDRIFT, developed to be a more specialised agricultural risk assessment model, was adapted from AGDISP and uses the same underlying code. It was developed under a cooperative research and development agreement between the US EPA, the US Department of Agriculture Forest Service and a chemical industry group called the Spray Drift Task Force. The companies belonging to the Spray Drift Task Force with oversight by the US EPA commissioned a large number of scientific studies to create a database and provide field validation for the model. The US EPA still uses AgDRIFT for some of its risk assessments.

In the past, the APVMA used AgDRIFT for most assessments. Recently, the APVMA has decided to use AGDISP as its main assessment tool for aerial applications. This choice has been made in part because AGDISP has continued to be refined while AgDRIFT has undergone little development in the last five years. Also important, the proprietary interest in AgDRIFT of the Spray Drift Task Force could lead to conflicts of interest if the APVMA used the model for assessment of applications from non-task force companies. By contrast, AGDISP is a freely available software program that can be used without restrictions.

AGDISP has features and tools that allow it to model a range of scenarios including deposition onto terrestrial areas and water bodies. It can take into account wake differences between different types of aircraft and aircraft setups that can affect spray drift deposition patterns downwind. It is able to account for the effects of evaporation on droplets at different temperatures and humidity for different tank mixes and can model for different droplet sizes, wind speeds, release heights, and other significant variables.

Both AGDISP and AgDRIFT have been formally validated by field data to a distance of about 800 metres (for aerial applications) downwind from the end of the application area. A newer version of AGDISP is being developed that will allow predictions to greater distances by means of linkage to a different kind of modelling approach—a puff model. As a practical matter, predictive modelling is less reliable as the distances increase, and the APVMA generally limits modelling to approximately 800 metres. When modelling suggests a concern at such distances and when ways cannot be found to mitigate the risk, the APVMA must consider carefully whether the use in question can be allowed at all because no-spray zones or declared risk areas of such magnitude are rarely practicable for chemical users to manage effectively.

At far-field distances toward the 800 metre validation limit, both models predict deposits greater than the mean values of the field data used to validate them. These differences are likely due to the incomplete collection efficiency of the samplers that were used and their inability to capture many of the very small droplets that drift to those greater distances. However, the differences do not preclude using the model effectively as a conservative assessment tool for such far-field ranges. In all cases, predictive modelling must be kept in perspective.

Field data for ground application

The modelling components of AGDISP and AgDRIFT for aerial application are very reliable and well validated, but AgDRIFT lacks a true ground modelling component, and the ground model in AGDISP has not been validated against field data and sometimes behaves erratically. Therefore, for ground application spray drift risk assessment, the APVMA relies on available field data that have been collected in well-controlled studies. The APVMA uses data sets originating in the USA, Canada and Germany. For most situations, the North American data more closely match Australian conditions. The North American studies are also more comprehensive and well-validated.

7.2 Field studies carried out for specific product applications

There may be reasons why an applicant wishes to submit a specific field study with a product application to the APVMA rather than rely on modelling or existing data sets. The APVMA will assess any such studies an applicant provides, but the applicant needs to be aware that a study of this type that meets adequate standards for scientific validity is very costly. The APVMA will need to be satisfied that the quality and scientific rigour of the study is of an acceptable standard. For example, studies would be expected to follow rigorous scientific protocols with documented quality assurance and peer review. If the new study meets adequate standards, the APVMA will take a weight of evidence approach and consider it with other relevant studies in which the APVMA has confidence.

7.3 Assistance to applicants with modelling—APVMA standard model output datasheets

An applicant may wish to assess a proposed product before application to the APVMA. A more convenient and reliable approach than obtaining and using the computer model directly would be to use APVMA standard model output datasheets for typical risk assessment scenarios. The reason that using AGDISP directly may not be as reliable for an applicant is that the model requires a number of parameter input values before calculations are done. Changing these values can lead to large differences in the model's output and unless the applicant uses the precise values used by the APVMA, the results will be different. The APVMA has chosen its parameter input values to match its risk criteria, and the values chosen are often different for different risk scenarios.

There are a limited number of standard scenarios used for risk assessment, for example, large-scale broadacre applications for aerial and ground, average broadacre applications for aerial and ground, a variety of typical orchard and vineyard scenarios, a number of typical forestry scenarios and so forth. A standard model output datasheet for each type of scenario can be created by computing spray drift downwind deposition values over the appropriate range after the model has been set up with all standardised values that the APVMA uses for the various modelling parameters appropriate for each standard risk assessment scenario. These datasheets are currently being developed by the APVMA and will be published on the APVMA website when available. By using the standard model output summaries, the applicant can more accurately anticipate an APVMA outcome.

Provision of these datasheets is consistent with the transparency of the APVMA process, and those with only an occasional interest can be spared the need to obtain and learn how to use the model. Finally, these datasheets, when made widely available, could be useful and simple tools for chemical users to assess the potential for spray drift in a variety of typical situations.

8 Operational risk factors and mitigation measures that the APVMA considers

As stated earlier, the APVMA must link its consideration of chemical risk to the need to protect human health, the environment and Australia's international trade. The specific issues discussed in the following paragraphs should be viewed from that perspective.

Many factors affect how much off-target spray drift might occur. Among them are droplet size, weather conditions, the type of equipment and methods used, local landforms where the application is made and the expertise of the applicator. In reducing risk, the APVMA uses a range of integrated strategies to mitigate the potentially harmful effects of spray drift and at times may need to impose restrictions or qualifications on one or more of the risk factors. Normally the APVMA would prefer to rely on industry best practices and the competence of applicators whenever it can be satisfied that such would be adequate.

Some examples of how instructions relating to these factors are incorporated into label statements are presented at the end of this document in Section 10. More information on these risk factors can be found in a publication sponsored by the Primary Industries Standing Committee and titled, *Spray Drift Management—Principles, Strategies and Supporting Information*, published by CSIRO Publishing, 2002, ISBN 0 643 06835 X. (This book is also available for download from the internet at <http://www.publish.csiro.au/pid/3452.htm>)

8.1 Factors affecting spray drift that are not related to the specific chemical

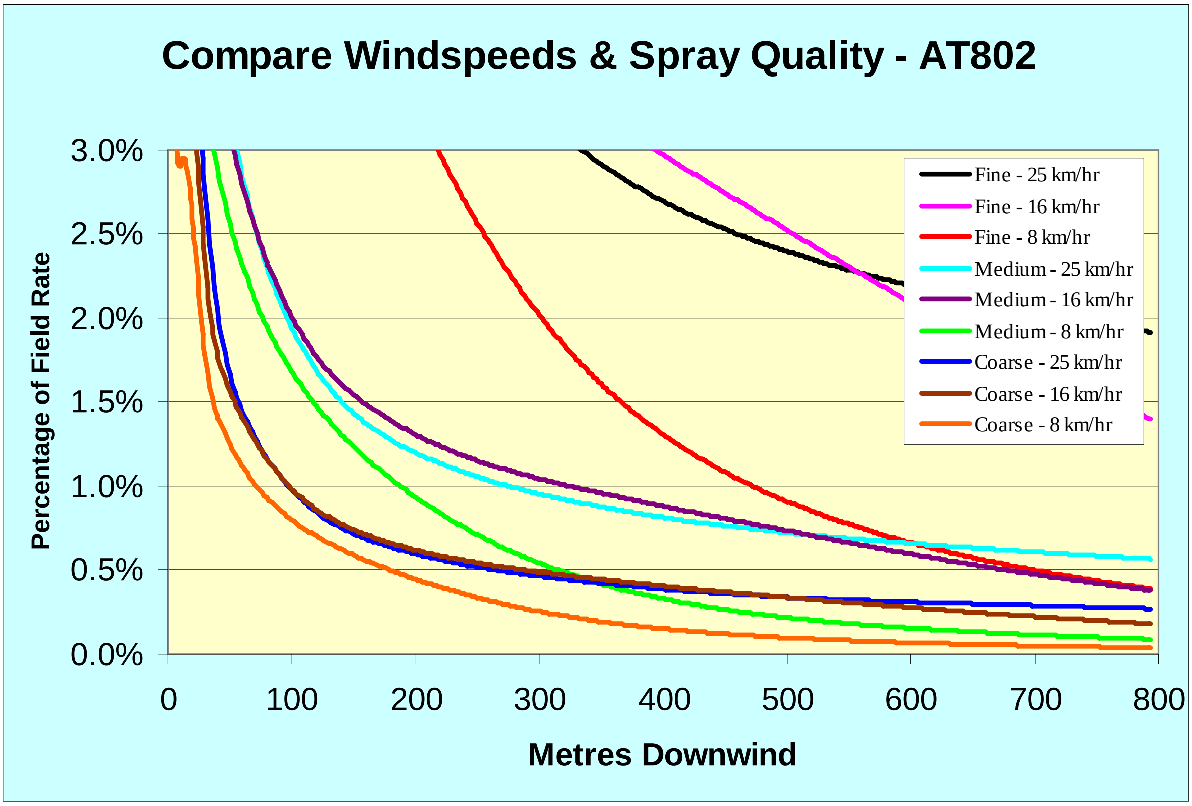
Droplet size

Spray droplet size (which is directly proportional to droplet mass) is the most important single factor in spray drift risk. Smaller, lower mass droplets have greater potential for drifting off target. In most circumstances, the APVMA imposes a limitation on the range of droplet sizes that can be used for applications. An acceptable droplet size range is influenced by the need for adequate coverage to achieve efficacy of the chemical product. As long as risk standards are not exceeded, the APVMA balances the need for efficacy with the need to limit spray drift. For dust formulations, the dust particle size is fixed during manufacture, and except where information shows dust particles are further fragmented by handling, the APVMA uses the nominal particle size range (backed by measurement data) in assessing risk.

Nozzles do not deliver droplets of only one size or nearly of one size. The total collection of droplets delivered by a nozzle at a specific pressure and flow rate consists of droplets of widely different sizes ranging from a few microns to hundreds of microns in diameter. This collection is often referred to as a droplet size spectrum. Nozzles of different design produce characteristic droplet size spectra at a specific pressure and formulation mixture. The various droplet spectra can be classified based on the volumetric size distribution of droplets using standard categories that act as a simple way of describing the performance characteristics of any nozzle. The standard categories range from 'Very Fine' to 'Extremely Coarse'.

Intuitively, one might expect that wind speed would be the dominant factor in spray drift risk; however, within acceptable wind speed ranges that is not the case. Computer modelling illustrates the greater importance of the size of the droplet spectrum as shown in the figure below for aerial application [AgDRIFT version 2.0.07, Tier III Aerial (Agricultural)].

Figure 2 Relative influence of droplet size and wind speed



There are nine spray drift deposit profiles in the graph above—3 different wind speeds (25, 16 and 8 km/hr) for each of 3 different droplet spectra (Fine, Medium and Coarse). Beginning at the top right and moving down toward the left, the pink, black and red curves are for 'Fine', the light blue, purple and green curves are for 'Medium' and the blue, brown and orange curves are for 'Coarse' droplet spectra. Notice that the nine curves are clustered in groups of three related to the droplet size range rather than in groups of three related to the three wind speeds. For example, the three curves for Fine as a group have much greater drift deposits than those for Medium or Coarse regardless of wind speed. (The AT802 in the title refers to the type of aircraft used in this example, an Air Tractor AT802.)

The modelling summarised in Figure 2 shows that the droplet size range is more influential overall on spray drift deposits than the wind speed (within the range of acceptable wind speeds). For example, the 8 km/hr profile for the Fine range is well above the 25 km/hr profiles of the

Medium and Course ranges for the bulk of the downwind distance only dropping to the vicinity of the Medium profiles beyond 600 metres.

A droplet size range can be set by using specific types of nozzles, nozzle angles, rotary atomizer speeds and system pressures. In the case of aerial application, high airspeeds can cause excessive fragmentation of droplets delivered by the nozzle system when the droplets are impacted by fast moving air flowing relative to the wing boom. Aerial operators must choose a nozzle that will provide a sufficiently coarse droplet spectrum to partially compensate for droplet shatter. With the highest speed aircraft, that can be difficult and the number of suitable nozzles is limited. The aerial agriculture industry in Australia with chemical company support has sponsored wind tunnel tests to determine which nozzles can be relied upon for situations requiring the ASAE Coarse spray category (see below) such as is required for all 2,4-D products.

Many industry organisations support the use of the droplet size standard, ASAE S572, adopted by the American Society of Agricultural Engineers. This standard defines a set of droplet spectra that can be used to describe the output of specific nozzle types under defined conditions. Manufacturers categorise most commonly available nozzles in terms of this standard. The APVMA has adopted ASAE S572 as a uniform way of describing droplet spectra on its labels for both aerial and ground application. (See Section 8.3 for discussion of the new ISO droplet spectrum standard currently under development.)

When specifying a droplet size range on a product label, the APVMA prescribes a particular droplet size classification as defined in the ASAE standard. That prescribed size classification along with the needed application rate then specifies the nozzle options that can be selected by the user.

It is important to emphasise that a chemical user must not rely on tank mix products advertised as ‘drift retardants’ to achieve the correct droplet spectrum. The APVMA has no consistent data supporting the efficacy of these products. For the present, chemical users should always rely on proper nozzle choice and system pressures to achieve optimal droplet size rather than using unproven tank-mix additives.

Although correct nozzle choice is always critical, there is a different kind of tank-mix strategy that does have merit and can further improve the benefits of correct nozzle choice. It is the use of non-volatile tank-mix additives that have the effect of reducing drift deposits from fine droplets at the greater downwind distances by imposing a minimum mass limit on each evaporating droplet. This strategy is discussed in greater detail in the next section under ‘Humidity and temperature’.

Droplet size classification categories for nozzles in manufacturers’ catalogues are largely based on tests done with water. The APVMA recognises that product formulations and final tank mix ratios can have a significant influence on the droplet spectra actually delivered by nozzles. By specifying a standard droplet size classification on labels, the APVMA provides a standard that must be met, and chemical users will need to use the best available information in meeting that standard. At the present time, that would be catalogue specifications in most cases. In the future, further work by scientific testing laboratories and wind tunnel facilities will provide updated and reliable information for product formulations and tank mixes relative to nozzle choice. As new information becomes widely available, chemical users can more accurately achieve the label standard. In the meantime, choosing appropriate nozzles based on current best information will be a great improvement on choices often made in the past.

Weather conditions

Wind speed and direction

Weather conditions are critical factors influencing spray drift risk. Wind speed and wind direction must be taken into account. In an important sense, wind direction is the most critical factor of all because spray droplets move only downwind. As was pointed out in Figure 2, the droplet size range is the single most important factor affecting spray drift in the downwind direction, but wind speed is perhaps the second most important factor that must be considered.

The APVMA may require that the label provide advisory information or mandatory limitations in relation to wind direction and speed. For example, the label may specify a maximum and minimum wind speed during spray operations and may state where the wind speed must be measured as, for example, outside an orchard at a specified distance upwind from the trees (or if not possible, 2 metres above the tree tops). Wind direction will always be taken into account in the description of any mandatory no-spray zone or declared spray drift risk area (see Section 8.2 for more detail). Both restricted areas will only exist in the downwind direction from the application site at the time of application.

The APVMA does not specifically require use of an anemometer to make accurate wind speed measurements. However, state and territory laws and the courts require a demonstration of duty of care so that an applicator should be capable of proving, if necessary in court, that a reliable method was used to measure wind speed and direction on site at the time of application. When other factors are favourable, applications can be made safely at wind speeds of between 3 and 20 km/hr, but in higher risk situations, the maximum speed allowable may be reduced. In assessing risk, the APVMA first uses 20 km/hr as the wind speed in modelling and then assesses at reduced wind speeds if the higher figure points to unacceptable risk.

A minimum speed of 3 km/hr is required because times of no wind (essentially below 3 km/hr) often precede or accompany periods of highly stable air and surface temperature inversion conditions both of which can greatly increase spray drift risk. Moreover, when wind resumes after periods of calm, its direction is not predictable. Spraying only when there is at least some wind ensures that wind direction is known (so that drift onto sensitive areas can be avoided) and greatly reduces the likelihood of surface temperature inversions forming during or shortly after application.

When the APVMA sets a declared spray drift risk area or a mandatory no-spray zone on a label (see Section 8.2), it will specify three wind speed ranges for aerial applications, usually 3–8, 9–14 and 15–20 km/hr. Each wind speed range will be associated with either a mandatory no-spray zone or a declared spray drift risk area specifically calculated for that wind speed and the appropriate risk conditions for that product. Providing three wind speed options will allow chemical users greater flexibility in matching label requirements to actual wind conditions at the time of application. The distances associated with each wind speed will also give chemical users a better appreciation of how to manage risk.

At this time, the APVMA cannot model different wind speeds for ground applications because validated and flexible modelling programs for ground applications have not yet been developed. Since ground application no-spray zones and risk areas are substantially smaller than those for aerial application, the differences obtained for different wind speeds would be less significant. The APVMA expects to have access to modelling capability for ground applications in the future (see Section 8.3). When such modelling is available, the APVMA can introduce this option for ground applications in situations where it is needed.

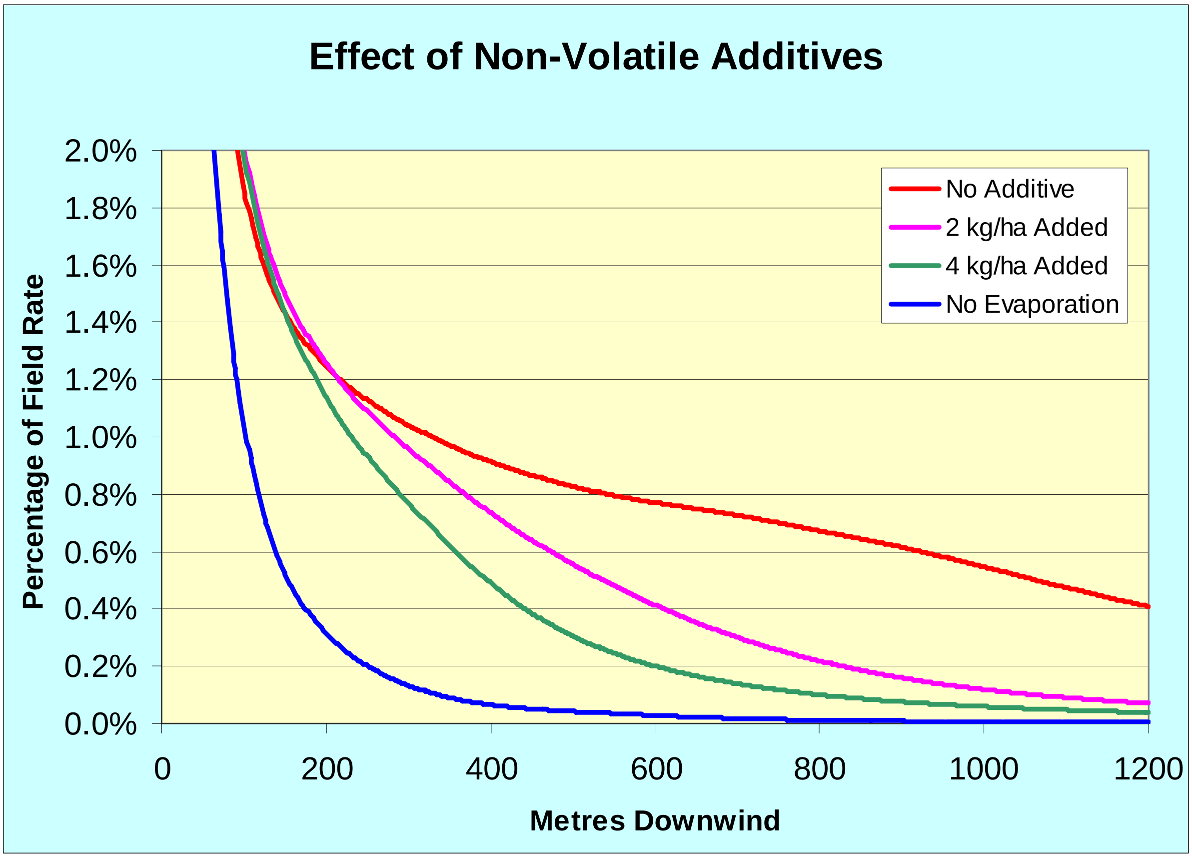
Humidity and temperature

For water based tank mixes, humidity and temperature affect droplet evaporation rates and can make a surprisingly large difference in drift deposits at longer downwind distances due to shrinkage in droplet size (and therefore mass). Spray operations cannot be suspended during summer months when temperatures are high and humidity is low, and one way of compensating is to increase both the droplet size spectrum (so that larger droplets on average leave the nozzle) and the carrier water volume applied per hectare to provide adequate droplet numbers for coverage. In cases where the APVMA specifies a minimum carrier volume on the label, it is expressly stated as a ‘minimum’ volume to allow the user to increase the volume if desired.

Increasing the carrier water volume is sometimes not practicable, particularly for aerial operators. A different management approach is to make the spray droplets less vulnerable to the effects of evaporation. A simple method is to add dispersible non-volatile material to the tank mix. The added non-volatile material in each droplet imposes a minimum mass value on the droplet, and as the droplet shrinks due to evaporation, acts as a humectant (depending on the properties of the added material) further slowing evaporation. The added material might be a non-volatile crop oil adjuvant, ammonium sulphate, urea, molasses or other substances that have been found to be safe to apply and compatible with the particular tank mix and application equipment.

Figure 3 illustrates how significant a difference can be achieved using this approach [modelled with AgDRIFT version 2.0.07, Tier III Aerial (Agricultural)].

Figure 3 Effect of adding non-volatile material to the tank mix



In the graph above, the deposit profiles are modelled for an aerial application all using a Medium droplet spectrum and a wind speed of 20 km/hr. Ambient conditions were set at 30º Centigrade and 50% relative humidity for the three upper curves. The top red curve is the profile where only the product formulation and carrier water are in the tank. The pink curve is a case where an additional 2 kg/ha of non-volatile material has been added to the tank mix, and the green curve is where an extra 4 kg/ha has been added. The lowest curve (blue) is an example where evaporation has been suppressed by setting the model conditions to 1º C and 99% relative humidity. (Note that the curve for 'no additive' does not look the same as the comparable curve in Figure 1 because the scale is different, a different aircraft was used and different model input parameters were used.)

In Figure 3, comparison of the blue curve (negligible evaporation) and the red curve (significant evaporation), both with no added non-volatile material, shows how significant the effect of evaporation on the drift profile can be. In this example, adding 2 or 4 kg/ha of non-volatile material to the tank mix has a surprisingly large beneficial effect in reducing off-target drift deposits. The effect does not become important until the deposits have dropped below about 1% of the field rate, but the differences are very significant at greater downwind ranges for chemicals that have a very sensitive impact threshold such as 2,4-D or typical trade risk scenarios. For example in Figure 3, if the acceptable deposition threshold was 0.2% of field rate, the unaltered tank mix would fail by a large margin even at 1200 metres downwind and the unacceptable risk distances for the 2 and 4 kg/ha additions would extend to 830 and 602 metres respectively, a substantially lesser distance.

The APVMA will assist registrants and the application industry in implementing this approach through permits, where necessary, when scientific data or acceptable argument has been provided to show that a proposed non-volatile tank supplement meets all safety and efficacy criteria.

Surface temperature inversion conditions

The potential for or presence of a surface temperature inversion condition is a very important factor in spray drift risk management. The ability to recognise a surface inversion condition or the atmospheric conditions likely to lead to one requires training beyond what can be included in label instructions.

Pilots are well trained in weather related issues and an aircraft's speed of coverage can be a great advantage in fitting applications between adverse weather conditions such as surface inversions. The slower rate of coverage of ground application makes it important that ground applicators should also be well-trained in recognising weather conditions signalling an impending surface inversion. Where the properties of the product and use situation present an exceptional risk from surface inversion conditions, the APVMA may find it necessary to invoke a Restricted Chemical Product status for the product to limit chemical access to those who are properly trained.

Height of spray release

Spray release height is another of the major factors affecting spray drift risk: the higher the release height, the greater the potential for off-target drift. In practice, release height is usually controlled within relatively narrow limits (see below). Because the release height will be accounted for in APVMA risk assessments and because operators have little motivation to depart from good practice norms, the APVMA will not specify release heights on labels in most cases. In unusual cases where it might be desirable to limit release heights on labels, the APVMA will be able to consult with its Application Technical Reference Group which includes people with expertise in application technology from both industry and academia.

Aerial applicators in broadacre situations seek a compromise between optimal spray placement and safety and generally maintain a release height of approximately 3 metres. In its risk assessments using computer modelling, the APVMA uses an aerial release height of 3 metres as a standard.

Aerial applications to forests have different requirements due to the fact that tree tops are uneven and forests are often located in hilly areas. For pilot safety, a release height of 15 metres above the general forest canopy is typical, and the APVMA uses this value in its risk assessments. In relation to risk, the higher release height in forestry applications is largely compensated for by the efficient droplet trapping properties of forest canopies. Localised turbulence eddies caused by wind interacting with uneven tree tops help move droplets down into the canopy volume more quickly for capture.

Exceptional aerial application situations and methods such as those relating to plague locust control authorities and regional mosquito control programs will be assessed on their own merits and appropriate instructions placed on labels when needed. Representatives from the authority in question and the APVMA Application Technical Reference Group may be consulted in such circumstances.

Applicators using ground boom equipment are constrained in most cases by nozzle design and placement that fix release height to a narrow range in order to achieve uniform spray deposition. The most common release height is 50 cm for 110º nozzles with 50 cm spacing on the boom. Different boom heights apply to setups with different nozzle spray angles (such as 80º) and different nozzle spacing. The release height is not always set from ground level (as for bare ground applications) but often from the general surface of a maturing crop canopy or over high weed infestations. In addition, rough ground and higher machine ground speeds can cause boom bounce that disturbs a uniform release height.

The overseas data sets that the APVMA uses for ground application assessment used typical application heights for the various studies undertaken. In using these data sets, the APVMA applies a conservative safety factor by using the 90th percentile of the data.

Release height is not easily related to orchard applications because spraying usually takes place under the trees and is directed sideways and upward into the tree canopy rather than being applied from above the canopy. Radial airblast machines that are improperly set up and that drive droplets above the tree canopy or do not turn off outside nozzles at turns or outer rows present a significant added risk. For orchard ground applications, the APVMA may impose limitations on how airblast and other spray applications are done.

With vineyards, the spray needs to be directed sideways into the vines or with tunnel-type equipment, sideways and down into the vines. The key feature for applications in orchards and vineyards is that spray must be directed into the foliage and not above it or below it (i.e. to the trunk area) where there is no foliage to intercept the spray.

Time of application

The time of day of application is important only in the way it relates to atmospheric conditions. Evening hours are frequently associated with stable air conditions. Night-time hours are often associated with surface temperature inversion conditions. Both are conditions of high spray drift risk. In particular, spray operations should not be conducted during inversion conditions. The APVMA encourages better training for all applicators to recognise and avoid spraying in these conditions and may at times require such training (see Section 8.2).

In rare circumstances, the APVMA may also find it necessary to limit application of a product to a particular period of the year in order to control spray drift risk. This type of restriction is sometimes needed because of a crop's stage of development or to constrain the risk period to a defined calendar interval so that an industry under risk can limit the time during which commodities must be monitored for that chemical. The current calendar restrictions on endosulfan applications to cotton are an example of such a limitation.

Stage of crop development

Spray drift risk from ultra-low volume (ULV) applications (which use very fine oil droplets) is substantially increased when a crop is too small to act as an adequate ‘trap’ to capture small spray droplets. Dormant deciduous orchards also present a higher risk situation during spray or airblast applications. Clearly, if a product is specifically designed to be used on dormant orchards, then its risk profile must be able to meet APVMA risk criteria before it can be registered for use. If found to be necessary after a product’s risk assessment, the APVMA may place crop size or crop development limitations in relation to how and when applications can be made.

Number of applications

Spray drift risks for some products may be acceptable for one or for a small number of applications, but where the residue effect is persistent, more applications may have an additive result that raises risk to an unacceptable level. In such cases, the APVMA may impose a maximum number of applications of a product per crop per growing season or in some cases impose a minimum interval of time between applications.

Application equipment specifications and set up

A variety of additional risk factors relating to application equipment type and setup also play a role in spray drift risk. The APVMA recognises that many applicators promote good industry practices and use appropriate equipment and methods to control spray drift. Both the aerial application industry and the ground application industry are working to promote a high level of training and innovation in ways to improve safety and reduce spray drift risk. This applies to broadacre and forestry practices. The application industries also support the development of a sense of professionalism and good practice standards within their ranks.

The APVMA recognises that new technology, such as new types of nozzles, continues to improve upon what is currently optimal. The APVMA would therefore prefer to rely on industry best practices when possible and would prefer not to specify equipment details on labels since doing so establishes current best approaches as requirements that inevitably become outdated with time.

However, in cases where the chemical or its use creates conditions of exceptional risk, the APVMA may find it necessary to consider limits on certain equipment factors in order to be satisfied that the product would be used safely. In such situations, the APVMA will consult its Application Technical Reference Group. Some of the relevant equipment factors are listed below.

Aerial application

- maximum effective boom width (distance between the outermost active nozzles) in relation to the wingspan of fixed wing aircraft or the rotary blade length of helicopters
- placement of the boom in relation to the wing
- nozzle angle with respect to slipstream
- minimum volume of spray mix applied per hectare (to ensure adequate coverage for efficacy when coarser droplets have also been required)
- possible addition of non-volatile additives to the tank mix.

Ground application

- booms with hoods or shields designed to limit spray drift
- shut-off controls for outside nozzles on equipment intended for orchard applications
- minimum volume of spray mix applied per hectare or, for orchards/vineyards, volume applied per unit length of row (to ensure adequate coverage for efficacy when coarser droplets have also been required)
- possible addition of non-volatile additives to the tank mix.

Field source width

Field source width refers to the width of a sprayed field as measured parallel to wind direction. This factor is important for crops planted across very large areas such as cotton because spraying a 'wider' field (as measured parallel to wind direction) means that the wind has access to a greater number of small droplets (and therefore a greater mass of the chemical) released into the atmosphere above the field. Every nozzle delivers a proportion of its output as smaller than desired droplets, some very small, and such droplets are the ones most likely to drift long distances. The mass of chemical contained in these smaller droplets and eventually distributed downwind has a predictable additive effect on off-target spray drift deposits that can be highly significant. Wider application areas provide a greater downwind contribution.

For some crops such as cotton, where applications can often have field source widths of 3 to 4 km, the APVMA will take this factor into account in assessing spray drift risk.

8.2 Mitigation measures for higher levels of risk

Mandatory no-spray zones

When necessary, the APVMA uses mandatory downwind no-spray zones as a way of protecting people or places from the effects of spray drift by imposing a spatial separation between the place of spray application and people or areas that need to be protected.

The APVMA has adopted the same definition of no-spray zone as used by the United States Environmental Protection Agency. It is defined as follows:

> A no-spray zone is an area in which direct application of the agricultural chemical is prohibited; this area is specified in distance between the closest point of direct chemical application and the nearest boundary of a site to be protected, unless otherwise specified on a product label.

Any no-spray zone that the APVMA imposes on uses of a specific product is based on an assessment of spray drift risk for that product and linked to either a human health risk, an environmental risk, or an international trade risk. The APVMA only requires no-spray zones to apply when the object or area at risk lies in the downwind direction (at the time of application) from the application area.

- For human health risks, the assessment considers the human toxicity of the chemical and the likelihood that harmful quantities of spray drift would contact people either directly or indirectly such as through contact with plants or structures affected by spray drift or such as through drinking water collected from a roof impacted by spray drift. Particular attention is placed on occupied residences and buildings where people spend significant amounts of time such as schools, day care centres and workplaces.
- For environmental risks, the assessment considers the toxicity of the chemical to animal and plant species and the likelihood that vulnerable populations (both terrestrial and aquatic) might be harmed by typical quantities of spray drift associated with the product's use. Particular attention is focussed on wetlands, surface streams and rivers and similar environmentally sensitive areas.
- For international trade risks, the assessment first considers key elements in trading relationships such as the presence or absence of an MRL for the chemical in the commodity of interest. If a key trading partner has not set an MRL for that chemical in that commodity, then even traces of the chemical caused by spray drift could represent a threat to trade.

  The most common trade risk situation from spray drift arises from livestock feeding on pasture that has been affected by spray drift coming from an application to a nearby crop. In this case, the APVMA must consider a range of factors such as how much of the chemical is likely to fall on the pasture, how long it is likely to remain before breaking down, how much an animal is likely to ingest and how long the chemical is likely to persist within the animal's body. Traces of the chemical still present at slaughter can be a serious threat to trade.

No-spray zones imposed by the APVMA are based on current international scientific methods of risk assessment. Downwind no-spray zones prescribed on product labels are defined in terms of a specified set of factors affecting spray drift such as wind speed and droplet size. The APVMA will maintain a transparent decision making process for determining no-spray zones. Note that the APVMA uses the application area as the frame of reference and all risk concerns are referred to as downwind from the application area. Several examples, worked through step-by-step, of how a no-spray zone is determined will be available on the APVMA website.

The APVMA only imposes a downwind no-spray zone if a risk assessment has shown it to be necessary for the chemical product to be used within acceptable bounds of risk. When a no-spray zone is found to be necessary for a product, it is usually the case that only one of the three risk criteria of human health, the environment, or trade requires such intervention. This perhaps surprising outcome results from the wide range of variables considered for the different criteria as arrayed against the distinct physical, chemical and toxicological properties of the active ingredient of the product. Nonetheless, for some products the APVMA might find that it is necessary to set more than one no-spray zone each of which would apply to different circumstances.

In some cases, unacceptable levels of spray drift risk are found to reach to distances that are too great for industry to manage in a practical way, and the APVMA concludes that the product cannot be registered for that type of use.

Declared spray drift risk areas

Determining the downwind maximum extent of a no-spray zone is actually a determination of the distance downwind of unacceptable risk. That downwind distance perpendicular to the downwind edge of the application area and running along its length forms a 'risk area'. Human health and environmental risk areas require mandatory no-spray zones, but in some circumstances it might be preferable to manage a trade risk area in a more flexible way. For example, if a trade risk could be managed effectively by keeping livestock off the drift-affected area for a time or by providing a period of feeding of non-contaminated feed before animals are sent to market, then a no-spray zone would not be necessary. The user would need to know the extent of the risk area and how the risk should be controlled. Use of such a strategy would permit more effective management of crops and livestock on the chemical user's land.

When a declared spray drift risk area happens to extend across a property boundary onto a neighbour's land, the risk management options require effective communication and cooperation between the chemical user and the neighbour. Past experience has shown that good communication and cooperation do not always occur between neighbours and that the chemical user is sometimes prepared to proceed with a spray operation despite a neighbour's objection provided that the action is not obviously illegal and easily prosecuted. The cost of civil litigation for the neighbour is high and the risk of its occurring may be perceived as so low that the chemical user is not deterred.

If the chemical user proceeds without the neighbour's knowledge of the risk, the situation can be worse. Animal or crop commodities could be affected and go to market carrying chemical residues over the limit. The neighbour would not know to declare the risk on a Commodity Vendor Declaration or a National Vendor Declaration. In such situations, serious damage could be done to international trade markets, and it would be of little help if later the offending chemical user suffered civil litigation.

Therefore, when a declared spray drift risk area is used on a label and when that risk area extends onto a neighbour's land, the label will require that the chemical user must obtain the written consent of that landholder before a spray operation can proceed. (The meaning of ‘neighbour’s land’ may need to be clarified for some product uses depending upon the nature of the risk and the way the neighbour’s land is used.)

The APVMA acknowledges that the declared spray drift risk area concept is highly desirable from a risk management perspective and that provision of such risk information on the label is its responsibility. However, the consideration of the overall risk to international trade must take into account all risk elements when choosing whether to employ a declared spray drift risk area or to impose a mandatory no-spray zone. Some chemical uses may present too high a risk to international trade to allow the flexibility of the declared spray drift risk area approach.

Declaration of Restricted Chemical Product status

If the APVMA decides that access to a chemical product must be limited to people who have particular qualifications, usually special training or competence, it has the power to declare a product to be a Restricted Chemical Product. In the language of the legislation, the person who is allowed access to the chemical product is described as an ‘authorised person’. The APVMA, in agreement with the states and territories, defines what is meant by the term, authorised person, and access is controlled at the level of the chemical reseller. In most cases, a prospective purchaser would need to present a document or identification card verifying the appropriate qualification before the chemical could be purchased. The proof of specific training required for the purchase of endosulfan is a current example.

In cases where the APVMA has concluded that particular training is needed for a user to safely manage the spray drift risks of a particular chemical product, the APVMA may declare it to be a Restricted Chemical Product and limit access to properly trained people.

8.3 Looking to the future

Adopting better technology and better methods

The APVMA would like to provide an incentive to chemical users to take up improved new technologies and better risk management methods. One way of doing this is by rewarding users who do so with less stringent requirements that are justified by the improved approach. For example, incentive could be provided by permitting smaller no-spray zones for users who have adopted better equipment, technologies or other improved ways of controlling spray drift.

Canada's PMRA has proposed such an approach for modifying protective no-spray zones (called 'buffer zones' in the Canadian PMRA proposal) to better suit equipment and environmental circumstances at the time and place of application.

The Canadian proposal is designed to accommodate elements of lower risk for specific applications by allowing the use of a 'multiplier' (which has a value of less than one) defined for each situation so that applicators can reduce a prescribed buffer zone by the value of the multiplier that applies to the situation they are facing. For example, a 100 metre no-spray zone on a label might be reduced to 30 metres by a multiplier of 0.3 justified by using shrouds on ground booms for a particular combination of wind speed and droplet spectrum. In recognition of differing local circumstances, a protective buffer zone for water bodies might be reduced by half (multiplier of 0.5) if the water body exceeds a certain depth.

This multiplier concept relies on the use of a separate information document published by the regulator that contains the multiplier values for each situation, instructions on how to apply them and other necessary information. That document would need to be made widely available and easily obtained. It could be updated readily whenever new information becomes available. In that way, product labels only need to refer to that document, its purpose and how it can be obtained. Canada's PMRA has already invested substantial research into validating their set of standard multiplier values using field studies and information from the scientific literature, and it might be possible for the APVMA to adapt some of these multiplier values to Australian conditions.

Germany and England have already established conceptually similar systems for modifying protective zones if certain tested and approved equipment combinations are used. Australia could benefit from much of the research and organisational effort that has already taken place in those countries. In an important recent development, the US EPA has launched a major new initiative—the spray drift reduction technology program. This program has the potential to identify and support the development of a variety of important new technologies for spray drift reduction over the next few years.

The APVMA intends to investigate how best to implement useful features of such overseas programs already extant or being developed. It will need to establish which elements of these systems can be adapted to Australia and verify them scientifically. In addition to equipment and technology already approved overseas as beneficial in reducing spray drift risk, the APVMA will be open to new concepts currently in development such as new types of ‘feathered’ wingtip modification devices (to reduce wingtip vortex effects on spray droplets), reverse venturi nozzle shrouds (to reduce high speed droplet shatter in aerial application) and rotating boom assemblies (to facilitate control of droplet spectra while in flight).

New spray droplet spectra standard to replace ASAE S572

The ASAE S572 standard for spray droplet size classification was developed some years ago as a true standard and was based on a guideline from the British Crop Protection Council. It has certain features that need improvement for modern spray drift regulation.

A new international ISO standard for spray droplet size classification is currently being developed. It is expected that this standard will be available in late 2008. When appropriate nozzle classification data become available and users can easily identify nozzles according to the new standard, the APVMA will move to shift its label recognition from ASAE S572 to the new ISO standard.

Improved modelling approaches

At present there is no validated ground modelling software that matches the flexibility and scientific rigour of aerial modelling programs such as AGDISP. AGDISP’s ground modelling capability does provide some flexibility but still needs further development and subsequent validation against field studies. Plans are being made to accomplish that end, and a version suitable for making regulatory decisions may be available within several years. The new ground version, when available, is expected to be comparable in sophistication and flexibility to the aerial version.

In addition to these familiar models, a large amount of effort worldwide is being devoted to strengthening predictive modelling of atmospheric conditions and air pollution over long distances. Some of these models have been made capable of linking to regional weather station data for dynamic updating. One of them, CALPUFF, has been proposed for use by the US EPA for making regulatory decisions. A conceptually similar model developed by CSIRO called TAPM may also be useful. The APVMA is investigating how such models might be used in Australia for issues related to both volatility and spray drift risk assessment.

9 Implementation of APVMA's spray drift risk assessment refinements

The APVMA will undertake to complete all spray drift risk assessments as described in this document without requiring applicants or registrants to provide a preliminary risk assessment.

The APVMA will need spray drift specific information for those products falling within the scope of this document as described in Section 3.2 and additionally meeting risk criteria that place them in the higher range of spray drift risk. Those criteria are outlined below.

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 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.

The APVMA will undertake responsibility for the risk assessment process and the development of needed label instructions. 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.

9.1 Risk criteria considered in the initial assessment

The APVMA will refer to the following questions in deciding what kind of risk assessment is needed for a product:

- Is the chemical highly toxic to humans, animals, plants, or aquatic species?
- Is the chemical unusually stable in the environment, particularly in relation to persistence on plant materials or in water?

- Would the chemical be intended for use on forests, pasture and rangeland or broadacre crops such as cotton where applications are likely to cover very large areas in a short period of time?
- Is the product to be applied by air?
- Is the product to be applied as an ultra-low-volume (ULV) formulation?
- Are MRLs for the chemical established for relevant commodities among key trading partners?
- If MRLs are established with trading partners, are any of them lower than the relevant Australian MRLs?
- Does the chemical tend to accumulate in the fat or specific organs of livestock?
- At what rate is the chemical cleared from an animal's body?

Table 1 Summary of risk group and label implications

Category	Label Statements	Assessment
Product meets one or more of the higher-risk criteria (Large scale area application, highly toxic product, no overseas MRLs, aerial application, ULV formulation, etc.) — can include both aerial and ground application	New spray drift cautions or limitation instructions appropriate to risk required on label	Requires specific spray drift risk assessment for all relevant risks (The APVMA will routinely undertake both aerial and ground application risk assessment.)
Ground powered-application (ground boom, orchard air blast etc.) **and** product does not meet a higher-risk criterion	New spray drift cautions or limitation instructions appropriate to risk required on label	Routine assessment but still requiring specific risk assessment for ground application
Back Pack application	Generic spray drift caution and possible limitations	Routine assessment

9.2 When products will be assessed

Applications for new registrations and variations

The regulatory strategies described in this document will be applied consistently to all registration applications from 15 July 2008. 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.

Updating existing products

Registrants of existing products that fall within the scope of these requirements will be advised when those product labels must be updated to reflect assessment by the APVMA for spray drift risk concerns. The APVMA plans to group product types and assess them for label updating according to a prioritised ranking of risk. 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 limited to spray drift related issues.

The APVMA expects that several years will be needed to work through perhaps as many as 2800 products that might be 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, that is, those of lower risk, will be updated as soon as possible after that.

The APVMA will consult widely during its prioritisation of these products. That consultation is likely to take place in two or more phases during the series of reviews.

10 Examples of label statements

Spray drift risk management label instructions will fall into three categories or tiers of risk. The first tier is the lowest level of risk with general warning or alert statements aimed at reducing spray drift. The second tier is comprised of instructions that more specifically address spray drift risk factors and also includes information on declared spray drift risk areas. The third tier relates to the highest levels of spray drift risk and consists of instructions relating to mandatory no-spray zones and other mandatory instructions relating to specific risk factors.

As a general rule, the APVMA will maintain as much consistency as possible with label instructions that apply to similar situations. For example, for describing no-spray zones or declared spray drift risk areas, the APVMA always uses the application area as the reference point and refers to risk areas as downwind.

When specifying mandatory downwind no-spray zones, the APVMA also includes a mandatory instruction of maximum or minimum values for the most significant factors such as droplet size and wind speed.

Presented below are some examples of label instructions that the APVMA could use to address spray drift risk concerns. The list is not intended to be comprehensive but only to illustrate a range of common circumstances.

Examples of Tier 1 instructions

Take all necessary steps to reduce spray drift. Information on how to reduce spray drift can be found at (website and published sources to be developed).

Use nozzles and pressures to obtain larger droplet sizes whenever possible that will still achieve control. Further information on choosing nozzles for reduced spray drift can be found at (website and published sources to be developed).

DO NOT apply when wind speed is less than 3 and greater than 20 kilometres per hour or during weather conditions when surface temperature inversions are likely.

Examples of Tier 2 instructions

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply in orchards or vineyards when the wind speed is less than 3 or more than 20 kilometres per hour as measured 15 metres outside of the orchard/vineyard on the upwind side.

DO NOT direct the spray above trees or vines during airblast applications.

TURN OFF outward pointing nozzles at row ends and outer rows during airblast applications.

USE ONLY medium spray droplet size classification according to ASAE S572 definition for standard nozzles.

USE ONLY coarse spray droplet size classification according to ASAE S572 definition for standard nozzles.

DECLARED SPRAY DRIFT RISK AREA—Spray drift deposits that can cause residue violations in livestock feeding on pasture and forage can result from typical applications out to distances downwind from the application area as shown in the table below.

FOR AERIAL APPLICATION	
Wind Speed Range at Time of Application	**Downwind Risk Area**
3 to 8 kilometres per hour	XXX metres
9 to 14 kilometres per hour	YYY metres
15 to 20 kilometres per hour	ZZZ metres
FOR GROUND APPLICATON	
Wind Speed Range at Time of Application	**Downwind Risk Area**
3 to 20 kilometres per hour	WWW metres

DO NOT allow the risk area to extend onto neighbouring land without the written consent of the adjoining landholder. These deposits can persist for a period of at least xx weeks. Users should manage risk by moving livestock away from affected areas or by feeding livestock on residue free feed for at least yy weeks prior to slaughter.

Examples of Tier 3 instructions

Mandatory no-spray zones

DO NOT apply when there are people, structures that people occupy or parks and recreation areas downwind from the application area and within the mandatory no-spray zones shown in the table below.

DO NOT apply when there are aquatic and wetland areas including aquacultural ponds or surface streams and rivers downwind from the application area and within the mandatory no-spray zone shown in the table below.

DO NOT apply when there are livestock, pasture or any land that is producing feed for livestock downwind from the application area and within the mandatory no-spray zone shown in the table below.

[Note to reader: in the majority of cases, only one of the above three statements would be needed on any given product label. Each of the statements would be linked to its own table as shown below.]

FOR AERIAL APPLICATION	
Wind Speed Range at Time of Application	**Downwind No-Spray Zone**
3 to 8 kilometres per hour	XXX metres
9 to 14 kilometres per hour	YYY metres
15 to 20 kilometres per hour	ZZZ metres
FOR GROUND APPLICATON	
Wind Speed Range at Time of Application	**Downwind No-Spray Zone**
3 to 20 kilometres per hour	WWW metres

DO NOT apply from aircraft unless the active boom width is less than or equal to 60% of the wingspan or 80% of the rotary blade length.