Australia: Regulatory Goals and Approaches

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Abstract

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian regulator of agricultural and veterinary chemicals. It is responsible for many regulatory functions in relation to these chemicals, but most broadly it is responsible for protecting human health, the environment and Australia's international trade from harmful consequences potentially associated with chemical use. Protecting international trade is a responsibility that sometimes requires spray drift risk assessments in the range of 500 to 1500 metres from the application site. The APVMA is currently using AgDRIFT for distances less than about 700 metres and Gaussian Diffusion modelling for greater distances. At times "no-spray zones" must be set to protect vulnerable areas. The APVMA aims to place sufficient spray drift management information on the label to enable users to control risk and is currently refining its label statements.

Introduction

When the Australian Pesticides and Veterinary Medicines Authority (APVMA) considers registering an agricultural chemical product, it has the responsibility of satisfying 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. Compliance with these instructions and limitations falls under the enforcement powers of the States and Territories.

The APVMA recognises that off-target spray drift can occur to some degree even when a product is being applied according to label instructions. It therefore has an obligation to consider the potentially harmful consequences of that associated spray drift, and if it finds that such consequences would exceed safety standards, the APVMA cannot allow that product to be used unless a way can be found to reduce that harmful effect.

Assessing the Impact of a Chemical that Drifts Off Target

Computer modelling can be used to predict the behaviour of droplets influenced by various risk factors. When the APVMA estimates likely drift quantities, it does so using the droplet size range recommended on the product label. It also uses the highest wind speed and highest spray release height permitted on the label to assess risk near the higher end of what could 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 more risky values that might be likely to occur.

The APVMA currently relies on two computer models for spray drift risk assessments. Most assessments are done with AgDRIFT while Gaussian Diffusion modelling, is more appropriate where projections beyond AgDRIFT's validated range are needed.

When a drift deposit profile has been estimated, the APVMA determines at what distance from an application a particular type of risk may be present by analysing the features of an active ingredient and the type of risk. Specific features of the chemical, the environment and the physiology of an organism that might be harmed all interact to result in many possible scenarios.

Risk to Human Health

For example, in considering 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. This risk could be estimated by evaluating the quantity of that pesticide falling at that distance per unit area over a given period of time, the amount of pesticide likely to be absorbed through the skin and inhaled by a person over that period of time and the dose of pesticide that would exceed the relevant health safety standard.

Looking at a different example, calculations of risk related to roof-collected drinking water incorporate the environmental stability of the pesticide, typical rainfall patterns and estimates of overall domestic water usage and water ingested in all forms per person. Very few pesticides are sufficiently toxic to cause health risks of this type. Calculations for both direct exposure and indirect exposure only occasionally yield a concern and rarely one that extends beyond 50 metres downwind.

Risk to the Environment

A pesticide with a high toxicity to fish or aquatic macro-invertebrates might be found to present an unacceptable 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 flow characteristics and comparing that calculated concentration to the toxic sensitivities of particular aquatic indicator species. Such analyses sometimes raise a concern to a range of 500 metres downwind but only rarely reach beyond that distance.

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 chemical likely to be deposited per unit area at distances downwind. Next, four key questions must be considered.

- How stable is the chemical 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 proportion of the edible plant mass affected by spray drift is comprised of the chemical?
- Are maximum residue limits (MRLs) for the chemical established for relevant commodities by key trading partners?

The most 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 chemical absorbed by the animal's digestive system?
- In which tissues, organs or products (milk, eggs) does the chemical tend to accumulate?
- How long does the chemical persist in those tissues or organs?

Although it may seem surprising, trade risk is typically the most sensitive risk of the three main types of risk, meaning that unacceptable risk can occur at the greatest distances. This is due mainly to situations where trading partners have not established a maximum residue limit for the affected commodity for a particular chemical that Australia uses. In such cases, the trading partner typically does not tolerate any detectable traces of the chemical even though the traces may be far below any applicable human health standards.

When all such factors are considered, it might be found that a downwind no-spray zone must be imposed to control risk to trade. In some cases, unacceptable levels of spray drift deposits 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.

Determining the downwind distance of a no-spray zone is actually a determination of the distance downwind of unacceptable risk. That downwind distance running the length along the downwind edge of the application area forms a "risk area". In some circumstances it might be preferable to manage a trade risk in this risk area in a way other than by using a no-spray zone. For example, if risk could be managed effectively by moving livestock off the drift-affected area for a time or by providing a period of feeding on non-contaminated feed before animals are sent to market, then a no-spray zone would not be necessary. Use of such a strategy would permit more flexible management of crops and livestock on the chemical user's land but would also require effective communication and cooperation between the chemical user and neighbours. The APVMA considers all of these aspects in its risk assessments.

Conclusion

In making regulatory decisions in relation to spray drift risk, the APVMA recognises the limitations of models and balances the need to make judgements of risk with the need to provide adequate safety margins. Some issues such as large scale regional applications of a particular chemical within relatively short time frames can pose unusually difficult challenges for regulators. The APVMA is currently re-examining its label statements in an effort to improve the quality of information and guidance in relation to spray drift management for users of each product. Advances in understanding spray drift risk factors will help all regulators with such efforts, and both chemical users and the community will benefit greatly from new knowledge arising from ongoing research into spray drift risk assessment.