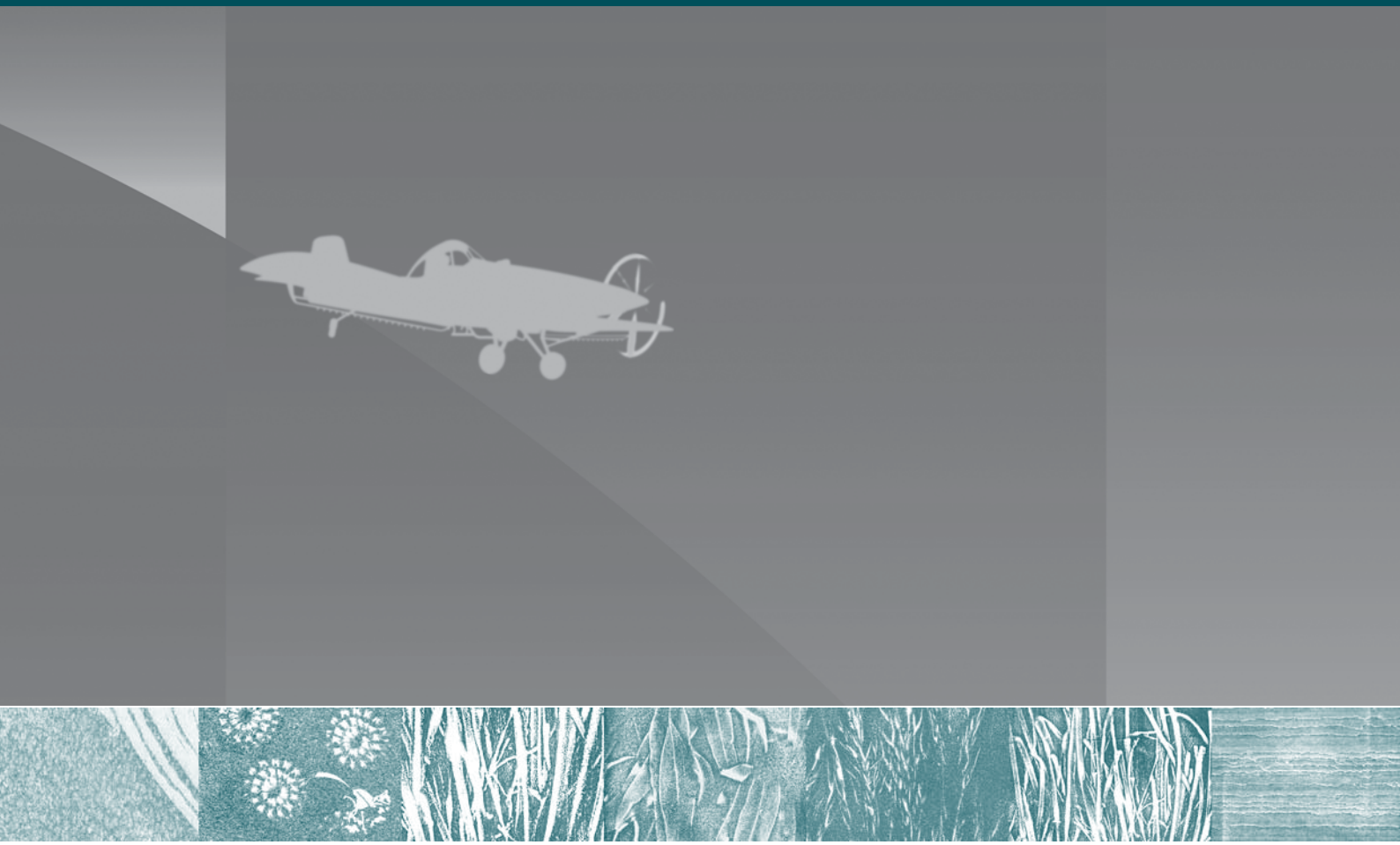
Australian Government
Australian Pesticides and
Veterinary Medicines Authority



RESULTS OF PUBLIC CONSULTATION

DRAFT OF APVMA OPERATING PRINCIPLES IN RELATION TO SPRAY DRIFT RISK

15 JULY 2008

Results of Public Consultation for 20 February 2008 Draft of *APVMA Operating Principles in Relation to Spray Drift Risk*

The most recent draft of the spray drift discussion paper – *APVMA Operating Principles in Relation to Spray Drift Risk* – published on 20 February 2008 and submitted for public consultation resulted in 12 written submissions to the APVMA. The large majority of the submissions support the APVMA's approach to spray drift risk assessment and its efforts to further strengthen that approach.

Many of the comments received relate to technical issues or misunderstanding of portions of the discussion paper. These types of comments have been addressed by changes made to the final version of the discussion paper – changes that are aimed at improving its clarity.

Other comments relating to broader issues are compiled below along with a brief APVMA response to each.

Community Comments

Comment	APVMA Response
Concern that the APVMA does not take into account the potential risk from formulation excipients during its risk assessment process	The APVMA does take risk from excipients into account. Formulated products, each of which includes its excipients, are assessed separately (that is, from the assessment of the active ingredient) in a battery of standard toxicology studies. Moreover, the Departments of Health and Ageing (DOHA) and the Environment, Water, Heritage and the Arts (DEWHA) possess extensive databases on each excipient that allow them to assess risk from these compounds with a high level of confidence.
Concern that the APVMA does not explicitly assess risk from mixtures of different pesticides that people might be exposed to simultaneously	The APVMA along with the Department of Health and Ageing views the very large safety margins built into its current risk assessment procedures as being adequate to protect against possible additive or even synergistic effects from incidental simultaneous exposure to different pesticides. This complex issue is one of ongoing interest to both the APVMA and to international regulators and reaches beyond the specific scope of spray drift risks. The APVMA plans to publish a discussion paper on its website within the next six months that will outline the current international views on this issue.
Allegation that the APVMA does not have any evidence to support its assessment of bystander exposure risk from spray drift onto roof-mounted water collection systems or onto residential areas.	The APVMA has data from two recent sampling surveys of chemical analysis of roof-mounted water collection systems that shows no measurable risk from spray drift contamination of drinking water. The APVMA is introducing a new bystander spray drift risk assessment model that provides a highly protective assessment of risk based on rigorous science. The model is presently being refined in collaboration with the Department of Health and Ageing and, when ready, will be described in detail on the APVMA website.
Question as to why the APVMA did not provide specific examples of modelled risk assessment for forestry applications over hilly terrain – situations that require higher release	The spray drift discussion paper was not intended to be an encyclopaedic reference document that compiled every possible situation. It was intended as an overview of APVMA policy and processes in relation to its assessment of spray drift risk and risk management. The paper mainly describes broad-acre situations which comprise the bulk of Australian pesticide use. The APVMA plans to publish a series of

heights of pesticides and have different risk profiles	worked examples of risk assessment on its website. These examples will include modelling for forestry and orchard applications.
Question as to why the APVMA does not support a national certification of aerial agriculture pilots	The APVMA does indeed support such a national scheme as was described in the discussion paper. The mechanism to achieve this outcome is currently being developed collaboratively with the Dept of Agriculture Fisheries and Forestry, the States and Territories and industry bodies.
Advice that the APVMA should immediately suspend the uses of all existing chemicals that have not yet been reviewed with modern assessment methods for spray drift risk.	Parliament established in the AgVet Code that chemical actives and agricultural and veterinary products approved or registered by States and Territories at the time the Code was enacted (and the APVMA was established – then called the NRA) were deemed to be approved or registered under the new national scheme. That legal status of those older products does not permit the APVMA to arbitrarily suspend their use without clear evidence-based concerns. The APVMA will work its way through these older products in a systematic way with actives prioritised according to potential risk on the basis of the best current information.
Do APVMA spray drift risk assessment processes "apply to existing chemicals now incorporating nanotechnology techniques?"	No existing registered agricultural chemical product incorporates nanotechnology. The APVMA is currently developing, in concert with other Commonwealth agencies, a comprehensive risk assessment framework for all aspects of nanotechnology.

Industry Comments

The APVMA's legislative mandate is to protect human health, the environment and Australia's international trade, but it should also specifically assess for risk and protect "property" addressing issues such as crop damage from spray drift.	The APVMA already considers spray drift risks to property such as risk to aquacultural operations, apiary operations and crops sensitive to herbicide damage. These risks are considered under the broad category of environmental risk. The APVMA is continuing to expand its database with information about potential risk to sensitive crops from herbicide drift.
More details are needed on what environmental concerns will be considered in risk assessments	The APVMA plans to publish this kind of information in greater detail as a part of its overview of the APVMA risk assessment framework that is currently being written. In the meantime, a general discussion of how DEWHA assesses environmental risk can be found in the *Environmental Risk Assessment Guidance Manual for Agricultural and Veterinary Chemicals*. A pdf file of this manual can be downloaded from http://www.ephc.gov.au/ephc/chemicals_mgt.html
Industry would like the proposed standard APVMA data output sheets to be published in the final version of the discussion paper along with justification for the selection or each modelling parameter used by the APVMA	The discussion paper is intended to be an overview of APVMA policy and processes in relation to its assessment of spray drift risk and risk management. It is not a collection of all possible steps and methods including intricate details which are subject to periodic modification and refinement. The APVMA has planned all along to separately publish its standard modelling output data sheets and will of course include the specific modelling parameters. The reasons these parameters have been chosen will be explained in

	relation to the APVMA's role as the national regulator to define appropriate safety margins during risk assessment.
Concern was expressed that some issues were not covered among the example label statements in section 10 of the discussion paper	As mentioned in the preceding item, the discussion paper is intended as an overview. Section 10 was provided to show examples of label statements that are likely to be of interest to most users. Other label statements will be applied as appropriate. The APVMA may develop in coming months a document that attempts to list example label statements more comprehensively.
Advice that use of the standard data output sheets mentioned above should not preclude more flexible modelling for specific restrictions that the applicant may wish to place on a product label	The APVMA will accommodate such requests when they can be shown to be consistent with practical agricultural methods. More commonly, a better outcome can likely be achieved by encouraging use of newer drift reducing technologies – an approach the APVMA is extensively developing. (See next item.)
More detail is needed about how the APVMA will accommodate and encourage new drift reducing technologies	The discussion paper provided an overview of how the APVMA plans to move forward in this area. The various technologies and methods are still rapidly emerging. The APVMA will provide further, more detailed information in a staged manner as new methods become supported by scientific studies.
Concern was expressed about the trade-off between increasing droplet size and efficacy – industry would like applicators to be given the option of using smaller droplets when they perceive risk to be low	The APVMA has been clear that there is no point in applying an expensive pesticide with its potential risks to large areas of land unless the pesticide can achieve its intended purpose. Within that constraint, the APVMA will always press for the minimum risk from spray drift. When mandatory no-spray zones are expressed on a product label, the no-spray zone will be linked to a specific risk at a specific distance downwind from the application area. A permitted droplet size spectrum will be specified that still maintains efficacy of the pesticide.
The APVMA was urged not to make product labels overly restrictive and thereby limit the flexibility of choice for applicators	This issue was explained at length in the discussion paper in section 6.3. In essence, the APVMA will not place restrictions on labels unless they are needed to manage a specifically assessed risk. Following those label instructions, including restrictions, will allow the application to be made without exceeding risk thresholds.
Concern that environmental no-spray zones greater than 100 metres are not practical because the definition of off-target vegetation is not sufficiently restricted	In its obligation to protect the environment, the APVMA must consider risk to off-target vegetation, both crops and native vegetation. The need to clearly define what constitutes native vegetation has arisen in the current 2,4-D review. The APVMA is currently refining this issue in collaboration with DEWHA and will publish it as soon as possible.
Industry urged the APVMA to specify a consultation process that it will follow when prioritising products for targeted spray drift reviews	The APVMA plans to avail itself of all information sources in prioritising products for spray drift risk assessment and review and will include the community, industry and the states and territories. Two groups of herbicides (the phenoxy family and glyphosate products) have already been identified as high priority. The APVMA will initiate a consultation process for further candidates soon.

Concern that the APVMA had not included as a cost to industry the future need to test product efficacy using larger droplet spectra – a necessity that could increase cost because existing hand-held equipment would need to be replaced with larger, powered equipment	The APVMA did not include this potential cost because it was considered to be a normal research and development cost that would always have been present for an industry with good product stewardship standards that aim to reduce spray drift as much as possible. The Preliminary Regulatory Impact Statement explained that the estimated costs of complying with anticipated review outcomes was provided only to give industry an indication of the likely maximum review-related costs it might incur. Research and development costs to maintain or gain market share were felt to be outside the scope of this objective.
Concern that the APVMA excluded some products – home garden products and animal treatments – from the scope of spray drift risk assessment	The APVMA continues to believe that these products as a group do not constitute significant risk for the reasons stated in the discussion paper in section 3.2. At present it proposes to focus on the very large task of dealing with the agricultural products that do fall within its scope. As always, however, if specific concerns arise within the home garden or animal treatment group of products, the APVMA will address those concerns.
Question as to what performance measures the APVMA will use to monitor the effectiveness of its spray drift risk assessment methods	In the case of some reviews that have begun as a result of adverse experience reports to the APVMA, the APVMA will look for a decrease in the number of such adverse reports. For all cases including those where problems have not been serious and frequent enough to motivate adverse experience reports, the APVMA will monitor the degree of label compliance (through state and industry auditing programs) as a measure of effectiveness.
The APVMA was asked to assure industry that only data sourced from tests within Australia would be used to assess spray drift risk	The discussion paper explained that data principally from the USA, Canada and Germany as well as available Australian studies (which are limited) would be used for the assessment of spray drift risk when appropriate to the situation. In particular, aerial application risk will be assessed with computer modelling developed in the USA and validated with studies carried out there. The APVMA uses the most scientifically robust and validated studies it can obtain, and at present the American data sets are the most extensive and scientifically sound and at the same time closely match Australian conditions. Under identical conditions of temperature, humidity, wind and the like, a spray droplet behaves the same way in North America, Europe or Australia. The APVMA will take into account relevant differences specific to Australia when appropriate.
Concern that a ground application risk assessment model mentioned in the discussion paper is not yet available, and the question was asked how such assessment would be done at present.	Although a flexible and validated model based on first principles is not available for ground applications as it is for aerial applications, other means exist. A number of extensive data sets have been developed overseas. Spray drift deposition from typical ground applications can be estimated from these data sets. The APVMA and DEWHA preferentially use data sets from North America because of their comprehensiveness, scientific validity and their greater applicability to Australian conditions. In future when a fully validated ground model becomes available, Australia will be able to assess ground applications with greater flexibility. Some of the data needed to validate such a model may originate in Australian studies.

Some were concerned that the APVMA would not allow for unique situations such as those spraying in partially covered shade cloth structures common to the nursery industry or the special needs related to mosquito control or plague locust control.	The APVMA will take into account the special circumstances of each risk assessment situation. The discussion paper highlighted those situations common to the majority of risk assessments, but the APVMA recognises that unusual circumstances are associated with certain industries. Those special circumstances will be fully considered in risk assessments for those industries.
A request was made that farmers be given a minimum of 12 months to make necessary changes to their equipment after the APVMA's spray drift assessment principles are adopted.	The spray drift risk assessment methodologies described in the discussion paper are in the main already in practice. Only a few refinements and particularly the initiation of a systematic targeted spray drift review effort will begin with the formal adoption of the principles. No specific equipment changes will be mandated to be taken up by a specific date. Rather, chemical users will see an ongoing shift in label statements, including limitations to practice, that will first appear on new products and later will appear on newly reviewed products as reviews are completed. New nozzles that can deliver a coarser droplet size will likely be the most common equipment upgrade needed.
Advice was given that the APVMA should be careful that spray drift instructions should be prominent on the label so that they would not be overlooked.	The APVMA agrees with this advice and plans to place within the 'RESTRAINTS' portion of the label any mandatory limitations on practice that are related to spray drift. General advisory statements (referred to as Tier 1 statements in the discussion paper) will be placed in the appropriate advisory section of the label. The APVMA will endeavour to make the advisory statements helpful by providing important information.

State and Territory Comments

Recommendation that mandatory limitations on application practices be located in the 'RESTRAINTS' portion of the label	Please refer to the item above at the end of the Industry Comments section.
Recommendation that when the severity of risk justifies unusually prescriptive spray application limitations, the APVMA should make use of the Restricted Chemical Product provisions of the AgVet Code.	The APVMA agrees in principle with this advice and will consider the option of invoking a Restricted Chemical Product status when the ability to properly use a product requires special training or qualifications or when the gravity of the consequences of improper use are severe.
Recommendation that the APVMA should provide information to competent operators that compliments their training and guides choice of risk management solutions.	The APVMA agrees with this advice. Space on labels is quite limited, but some advisory information will be placed there. The APVMA plans to create an extensive web-based site for more detailed advisory information on how spray drift can be reduced. It may develop this resource in cooperation with industry groups that have the same goal.