



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



**Guidelines for applications to update spray drift instructions,
update the spray drift risk assessment and recognise new
drift reduction technology**

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INTRODUCTION

In July 2019, the Australian Pesticides and Veterinary Medicines Authority (APVMA) implemented a new approach to spray drift management. The new approach can be found within a series of documents and files including the [spray drift risk assessment manual \(SDRAM\)](#). Collectively these documents constitute the APVMA's current spray drift policy.

The [spray drift policy](#) is now being applied to all applications for new active constituents and active constituents under chemical review. It will also be used for all new applications where spray drift assessment is required. The policy may be extended to existing registered products on a priority and risk basis, and registrants may choose to use the new policy when submitting applications to vary an existing product.

The following guidance is provided for applicants who seek to update spray drift instructions and / or re-calculate buffer zones that currently appear on their product labels. It provides advice as to the assessment modules, fees and timeframes that would apply to such applications. This guidance also provides advice as to how the APVMA will evaluate applications for inclusion of new drift reducing technology (DRT) into the [spray drift management tool \(SDMT\)](#).

Scope of this guideline

All applications in which the applicant is seeking to update label instructions in line with the latest spray drift policy and/or recalculate existing buffer zones or include new buffer zones on their product label as well as applications to update the SDMT with new DRT and custom deposition curves.

General principles

Buffer zones are calculated using the regulatory acceptable level (RAL) relevant to each sensitive area (that is, natural aquatic, pollinator, vegetation, bystander and livestock areas) and the spray drift curves relevant to the application method(s) sought.

Holders/registrants may wish to update existing buffer zones on their label. The SDMT includes a number of parameters that, adjusted individually or in combination, will allow for an adjustment to the existing buffer zone(s). Please note this currently excludes vegetative barriers for which further validation work is required.

The options for boom sprayer, aircraft and vertical sprayer are shown in Table 1 from which one or more application parameters can be adjusted alone or in combination to derive new buffer zones.

Table 1: Application to parameters available within the SDMT

Application parameters	Application equipment		
	Boom sprayers	Aircraft (fixed wing or helicopter)	Vertical sprayer
A reduced application rate (noting that this can be no lower than the minimum rate appearing on the label)	✓	✓	✓
A droplet size other than that currently on the label	✓	✓	X
Boom heights other than those currently on the label (that is, 0.5 and 1.0m)	✓	X	X
Maximum release height other than those currently on the label	X	✓	X
Maximum wind speeds of 7, 14 and 20km/hr	✓	✓	X
Revised maximum application site width	✓	X	X
Canopy type other than that currently on the label	X	X	✓
Or any combination of the above	✓	✓	✓

1 PART 1: UPDATING SPRAY DRIFT INSTRUCTIONS

The document [Guidelines for updating spray drift instructions on labels when a full spray drift risk assessment has not been undertaken](#) sets out how product labels will be updated in line with the spray drift policy for all applications submitted for purposes other than spray drift. In order to facilitate updating labels for products for which no application is planned the APVMA invites registration holders to submit an Item 13 application¹. The application should include a copy of the label with the updated spray drift instructions. Please note that no other changes to the label will be permitted. Requests to recalculate buffer zones will not be considered via this route (see Part 2 of this guidance).

Table 2: Item 13 – no data of a technical nature is required

This application type is used solely to update the existing spray drift instructions in line with the current spray drift policy.

Module	Time	Cost	Comment
N/A	3 months	N/A	The Item 13 route is available to registration holders to update their label in line with the APVMA spray drift policy where no consideration of a technical nature is required.

¹ If you are planning on making an application to vary your product for other purposes in the next 12 to 18 months, it is suggested you combine the spray drift instruction update with this.

2 PART 2: AMENDING/UPDATING BUFFER ZONES

Application requirements to amend existing buffer zones will be dependent upon whether the regulatory acceptable level (RAL) for each relevant sensitive area has been established.

Where all RALs are known, the applicant should submit a summary of the scenarios from the [spray drift risk assessment tool \(SDRAT\)](#) or [SDMT](#) used to calculate the buffer zones and submit a revised draft label including the recalculated buffer zones. [Pre-application assistance \(PAA\)](#) is available to give applicants advice on the application requirements prior to submission.

In cases where some or all the RALs are not known, then the applicant can apply via the PAA process to request the APVMA to identify the appropriate RALs. In this case a Tier 2 PAA will be charged.

Alternatively, where the applicant has already identified the RALs and only confirmation is sought, a Tier 1 PAA will be charged. In both cases, if the RALs are confirmed in advance of submitting an application then the application to update the buffer zones can be assessed as an Item 12 application.

If a PAA has not been sought and the RALs cannot easily be confirmed during the evaluation planning stage then the application would need to be re-categorised as an Item 14 and the appropriate modules applied. In this case, the total cost and timeframe may be greater than the PAA and Item 12 processes combined.

Table 3: PAA – to confirm the RALs in advance of making an Item 12 application

Module	Time	Cost	Comment
Tier 1	1 month	\$577.50*	Tier 1 is used to confirm RALs and Tier 2 used when some or all the RALs are not known.
Tier 2	2 months	\$962.50*	For both Tier 1 and 2 no meeting is required and a written response only is appropriate.

* If you seek pre-application assistance, then make an application, you receive a rebate on the application fee.

Table 4: Item 12 – no data of a technical nature is required

This application type is used when the RALs are established and the application is only to amend the buffer zones.

Module	Time	Cost	Comment
N/A	3 months	\$2,018	The Item 12 route can be used for applications to amend existing buffer zones where the RAL(s) have previously been determined* using current methodology and it is simply a matter of entering revised parameters into the SDRAT/SDMT to determine new label instructions and buffer zones. Where this is not the case and specialist consultation at the evaluation planning stage confirms further work is required to confirm the RAL(s) the application would be re-categorised and considered via the Item 14 route.

* RALs may be contained within Public Release Summary (PRS) documents for product assessments or technical review report for recent review substances such as [2.4-D](#).

Table 5: Item 14 – technical modular application

All applications not described in any of Items 11 to 13A – this application type is used to confirm the RALs (no PAA was requested) and to amend the buffer zones.

Module	Time	Cost	Comment
1.0	Up to 1 month	\$902	Applies to all modular application items.
10.2	7 months	Nil	Module descriptor 10.2 – Confirmation of RALs for spray drift risk assessment (where this has not already been confirmed through pre-application assistance).
11.2	2 months	\$3,090	A variation where fewer than three modules between 2.1 and 10.3 apply.
Total	9 months	\$3,992	

3 PART 3: APPLICATIONS FOR NEW DRT

The SDMT has been designed to accommodate new technologies that will facilitate the reduction of spray drift. Applicants may submit data for APVMA consideration of custom deposition curves and inclusion of new DRTs within the SDMT. Further information about the addition of custom deposition curves can be found in Section 7 of the SDRAM and in the [spray drift data guidelines \(SDDG\)](#) which should be read in conjunction with the advice below.

3.1 New DRT – product specific application

Holders of a product registration (or applicants registering a product for the first time) can request consideration of new DRT in an application for a new or existing product via the usual process for which the relevant modular charges would apply. In the absence of a specific module associated with the evaluation of DRT and custom deposition curves, these data would be considered within the environment modular fee structure either as standalone data (that is, no other environment assessment was required) or as a 'top up' to the environment module which may serve to increase the modular fee from what would otherwise have been applied. Tables 6 and 7 below relate to a new or existing product for which up to date RALs exist for all sensitive areas and technical consideration is to evaluate the DRT and reconsider existing buffer zones.

By default, the resulting new deposition curve will remain product specific and consent is required for other applicants to use these data. Applicants can however provide consent for the use of their custom deposition curve(s) to be added to the SDMT and therefore be available for use with other products.

Table 6: Item 14 – technical modular application with no other changes proposed other than the consideration of new DRT (for an existing registered product)

Module	Time	Cost	Comment
1.0	Up to 1month	\$902	Applies to all modular application items.
7.3	4 months	\$2,979	Module descriptor 7.3 – assessment of a new drift reduction technology and/or deposition curve.
11.2	2 months	\$3,090	A variation where fewer than three modules between 2.1 and 10.3 apply.
12	NA	\$460	Data protection (if applicable).
Total	6 months	\$7,431	

Table 7: Item 10 – technical modular application for consideration for a new product plus consideration of new DRT

Module	Time	Cost	Comment
1.0	Up to 1 month	\$902	Applies to all modular application items
Modules 2 to 8 as appropriate depending on the areas to be assessed.			
7.3	4 months	\$2,979	Module descriptor 7.3 – assessment of a new drift reduction technology and/or deposition curve.
Or			
7.1	13 months	\$26,390	A 7.3 module would be applied where no environmental risk assessment was otherwise required. If an environment assessment is required in addition to DRT consideration then a single environment module reflecting both components would be applied.
7.2	7 months	\$7,659	
Module 11.1 to 11.3 as appropriate depending on the total number of modules to be assessed.			
12	NA	\$460	Data protection (if applicable).

3.2 New DRT – not linked to a product

Applicants may apply via an Item 25 for technical consideration of the DRT data and inclusion of a custom deposition curve into the SDMT. In this case the application may come from a third party (for example, equipment/nozzle manufacturer or industry representative group). Only those DRT for which full and free access is permitted by the data owner will be included in the published version of the SDMT on the APVMA website. The third party can chose to restrict access in which case the original data and a letter of consent would need to be provided to applicants wishing to make an application to update their label based on the new DRT. Please note that an efficacy and crop safety consideration may need to be considered for a new DRT but would normally be undertaken as part of a product registration but can, if chosen, be considered as part of the Item 25.

Table 8: Item 25 – technical consideration to add a new custom deposition curve to the SDMT

Module	Time	Cost	Comment
1.0	Up to 1 month	\$902	Applies to all modular application items.
7.3	4 months	\$2,979	Module descriptor 7.3 – assessment of a new drift reduction technology and/or deposition curve.
11.2	2 months	\$3,090	An application where less than three modules between 2.1 and 10.3 apply.
Total	6 months	\$6971	

4 EXAMPLES

Each application needs to be considered on a case by case basis, however the following examples demonstrate how the general principles may be applied.

1. My product was assessed in 2016 prior to the implementation of the new spray drift policy and required a 10 m aquatic buffer zone. The RALs have already been established. To update the buffer zones for the current use patterns (including potentially adding new ones for pollinators and bystanders), can I apply under Item 12 (so there are no technical modules) or does it need to be an Item 14? If so what, if any, technical modules are required?

An Item 12 would apply where appropriate RALs are available. The preferred approach is that the status of the RALs is established via a PAA so the Item 12 can be confirmed prior to submission of an application. If a PAA is not requested then the status of the RALs would be established as part of the assessment of the application. Where it is determined that further technical consideration is required to establish the RALs then the application would be re-categorised to an Item 14 application and the relevant modules applied.

2. I wish to apply for a new use at half the currently approved label rate (same application method). There is an existing 50 m aquatic buffer but nothing else. Would the APVMA undertake a spray drift risk assessment in this case? Can I ask for one to be done?

As the new use is at half the current approved rate and the method of application is the same, no spray drift risk assessment needs to be done and the 50 m aquatic buffer would apply. However, if you requested it, the APVMA could undertake a new spray drift risk assessment across all risk assessment areas (that is, pollinator, vegetation, bystander and livestock areas) for which the appropriate modules would be applied.

3. If I generated droplet size data on a registered product under the Spray Drift Data Guidelines (SDDG) and found that it had a drift-reduction effect, what application type (and modules) can I apply to have these data assessed for a custom deposition curve to be established and used in the SDMT to determine buffer zones?

These data would be considered within a specific product variation assessment for which an Item 14 application would be required. Modules 1.0, 7.3, 11.2 and 12.0 would apply providing no other consideration is required to establish RALs in the other risk assessment areas.

4. My product is based on a reference product for which the existing buffer zones have been reduced and additional buffer zone scenarios have been included on the label. Can I apply to amend my label to reflect these new buffer zones?

Assuming there are no limits on use of information supporting the changes to the reference product (for which a letter of access would be required) you can make an application under an Item 12 to update your label.

5. My product label has spray drift instructions which need updating. How do I go about this?

If you had planned to make an application for other purposes then the APVMA will automatically update your label in line with the new instructions as part of that application. If this is not the case then you may make an Item 13 application provided no other changes to the label are requested.

6. I am submitting an application for a new product based on an existing product as an Item 10 application. I have deposition data for a new DRT. I want to add this DRT to my label with reduced buffer distances compared to the existing product. What modules are required to assess these data and can the data be protected so it is limited to use with my product?

If RALs have been established, a Module 7.3 would be required to assess the custom deposition curve and new buffers calculated. The data submitted with the application would be subject to standard data protection procedures and use cannot be copied to other products without consent from the owner of the data. This DRT would not be included in the published version of the SDMT.

The other modules required for registration of a new chemical product would also be applied.

7. We are an industry body and have funded considerable research to investigate the suitability of a new DRT for our industry. We would like to have a new custom deposition curve established for use of this DRT that will then be available for any product. How can we achieve this?

You or a nominated agent may apply for an Item 25 application to add a new deposition curve to the SDMT which would then be available for use by other holders when applying to register or vary their products. Modules 1.0, 7.3 and 11.2 would be applied.

8. I have access to data from a third party for a new DRT that I wish to include on my existing product label. How do I go about making an application?

Assuming the RALs have been identified this would be considered as an Item 12.



Appendix

ABBREVIATIONS

DRT	Drift reducing technology
PAA	Pre-application assistance
RAL	Regulatory acceptable level
SDDG	Spray drift data guideline
SDMT	Spray drift management tool
SDRAM	Spray drift risk assessment manual
SDRAT	Spray drift risk assessment tool
