

# Reconsideration work plan

CHEMICAL	Dimethoate	
REMAINING SCOPE	Residues [5.4]	
RECONSIDERATION ASSESSMENT PERIOD	20 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: 6 March 2017
WORK PLAN DATE	1 July 2015 updated 26 October 2016	

Stage	Details	Timeline
1. Nomination	Invitation to nominate agricultural and veterinary chemicals for review – Gazetted on 1 November 1994.	
2. Prioritisation	Dimethoate was added to the priority candidate review list in 1995 – Gazetted on 2 May 1995. Scored against agreed selection criteria (public health, OHS, environment and agricultural concerns).	
3. Scoping and work plan	Scope – toxicology, public health, residues and dietary exposure, residues impact on trade and OHS. <a href="#">Link</a> to dimethoate and omethoate scoping document – Published in April 2004.	
4. Notice of reconsideration	s32(1) notices sent to holders (with data requirement) and s32(2) notices sent to States and Territories – 17 March 2004. <a href="#">Link</a> to gazette. s32(2) notices sent to stakeholders on 24 to 26 March 2004 (submissions were due on 2 July 2004) – Published on 6 April 2004. Additional s32 notices sent to holders on 1 July 2015 to include all approved actives and registered products in the review.	
<b>START DATE (clock starts)</b>		<b>01/07/2015</b>
5. Assessment	<i>Component assessment reports published prior to 1 July 2015</i> <a href="#">Link</a> to toxicology assessment – Published in January 2011. <a href="#">Link</a> to residues assessment – Published in August 2011. s159 notice for residues data – sent 7 May 2012 <a href="#">Link</a> to OHS assessment – Published in March 2013.	
	<i>Component assessment reports after 1 July 2015</i> <a href="#">Link</a> to Supplementary residues assessment	<b>Published 16 June 2016</b>
6. Draft regulatory measure	<a href="#">Link</a> to proposed regulatory decisions: Volume 1 <a href="#">Link</a> to proposed regulatory decisions: Volume 2- submissions and technical reports	<b>Published 26 October 2016</b>
7. Consultation	<i>Details of consultation undertaken to date</i> After the publication of the first residues report the APVMA proposed that all dimethoate products be suspended and new instructions for use issued to mitigate identified dietary risks – August to September 2011.	

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<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
8. Regulatory decision	<p><u>Consultation completed in January 2017</u></p> <p>A 3-month public consultation period was conducted. Any further data or information submitted during consultation will be taken into consideration before making the final regulatory decision.</p>	<p><b>26 October 2016 – 27 January 2017</b></p>
	<p><u>Regulatory decisions made prior to 1 July 2015</u></p> <p>All products were suspended to apply new label instructions to reduce the dietary risks identified in the residues report – October 2011.</p>	
	<p><u>Regulatory decisions to be made</u></p> <p>The APVMA has:</p> <ul style="list-style-type: none"> <li>• Affirmed the approvals of existing dimethoate active constituents</li> <li>• Cancelled the registrations and label approvals of the dimethoate home garden products (s34AB)</li> <li>• Varied the instructions for use of agricultural dimethoate products and removed pack sizes of 1 litre or less from their particulars</li> <li>• Affirmed those products and the new, varied labels (s34AC)</li> <li>• Published the <a href="#">dimethoate regulatory decision report</a></li> </ul>	<p><b>6 March 2017</b></p>
<b>END DATE (regulatory decision)</b>		<b>6/03/2017</b>
9. Implementation	<p>The APVMA will publish details of any applicable phase out periods if any approvals of actives, registration of products or label approvals are cancelled.</p> <p>The maximum phase out period cancelled products or labels specified in the legislation is 12-months.</p> <p>The maximum period for supply of previous versions of varied labels in the legislation is 2 years.</p>	

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## Attachment 1

<b>AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 – S78B</b>			
<b>PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RECONSIDERATIONS</b>			
<b>A + B + 2E + 3C + J + D + X</b>			
<b>A = the longest of the following periods (in months) relevant to the scope of the reconsideration</b>			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
3.1	Toxicology – Level 1	13	
3.2	Toxicology – Level 2	9	
3.3	Toxicology – Level 3	5	
4.1	Toxicology (requiring poison schedule classification)	13	
7.1	Environment – Level 1	13	
7.2	Environment – Level 2	7	
7.3	Environment – Level 3	4	
<b>TOTAL TIME FOR A</b>		<b>0</b>	
<b>B = the longest of the following periods (in months) relevant to the scope of the reconsideration</b>			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
2.1	Chemistry – Level 1	13	
2.2	Chemistry – Level 2	9	
2.3	Chemistry – Level 3	6	
5.1	Residues – Level 1	13	
5.2	Residues – Level 2	8	
5.4	Residues – Level 4	4	●
6.1	Occupational Health and Safety – Level 1	13	
6.2	Occupational Health and Safety – Level 2	7	
6.3	Occupational Health and Safety – Level 3	4	
9	Non-food trade	6	
10.1	Special data – Level 1	13	
10.2	Special data – Level 2	7	
10.3	Special data – Level 3	7	
<b>TOTAL TIME FOR B</b>		<b>4</b>	
<b>2E = the longest of the following periods (in months) relevant to the scope of the reconsideration</b>			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
8.1	Efficacy and safety – Level 1	6	
8.2	Efficacy and safety – Level 2	4	
8.3	Efficacy and safety – Level 3	3	
<b>TOTAL TIME FOR E</b>		<b>0</b>	
<b>3C = the longest of the following periods (in months) relevant to the scope of the reconsideration</b>			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
11.1	Finalisation – type 1	3	●
11.2	Finalisation – type 2	2	
11.3	Finalisation – type 3	2	
<b>TOTAL TIME FOR C</b>		<b>3 x 3 = 9</b>	
<b>J = whichever is relevant</b>			
	Consultation with jurisdictional coordinator	3	●
	In any other case	0	
<b>TOTAL TIME FOR J</b>		<b>3</b>	
<b>D</b>	<b>TOTAL TIME FOR D</b>	<b>4</b>	●
<b>X = whichever is relevant</b>			
	Appointment of an arbitrator under s.64	3	
	In any other case	0	●
<b>TOTAL TIME FOR X</b>		<b>0</b>	
<b>TOTAL TIMEFRAME</b>		<b>20 months</b>	