

# Reconsideration work plan

L/CHEMICAL	Molinate	
REMAINING SCOPE	OHS [6.3], Environment [7.3]	
RECONSIDERATION ASSESSMENT PERIOD	21 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: June 2020
WORK PLAN DATE	1 July 2015 amended 25 September 2015, 30 June 2016, 12 January 2017. 4 July 2019 (revision of expected completion date based on the timing of the proposed regulatory decision).	

<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
1. Nomination	Molinate was nominated for review by the Health Department following the US EPA publication of its preliminary findings for molinate. This US EPA report noted the potential reproductive toxicity, neurotoxicity and suspected carcinogenicity of molinate – 7 June 2002.	
2. Prioritisation	Molinate was prioritised for review following consultation with Commonwealth and State agencies responsible for the environment and human health – June 2002 to March 2003.	
3. Scoping and work plan	Scope – toxicology, public health, environment, particularly aquatic environments, and OHS – 30 April 2013.  Molinate scoping document – Published in May 2003.	
4. Notice of reconsideration	s32(1) notices sent to holders on 30 April 2003 (data due 18 July 2003). s32(2) notices sent to States and Territories – Gazette published on 6 May 2003.  Additional s32 notices sent to holders on 1 July 2015 to include all registered products in the review.	
<b>START DATE (clock starts)</b>		<b>01/07/2015</b>
5. Assessment	<u>Component assessment reports published prior to 1 July 2015</u> s33 notice sent on 15 April 2011 requiring further OHS data to assess worker safety. Toxicology assessment – Published in June 2013. OHS assessment – Published in June 2013.	
	<u>Requirement notices (s33) Notices</u> Notices requiring additional worker exposure (OHS) and aquatic monitoring (Environment) information or data were sent to holders 25 September 2015.  Aquatic monitoring data submitted 4 April 2016. Extension requested for the worker exposure studies due to climatic circumstances.	<b>Expected 2019</b>
	<u>Assessments of data received in response to the Draft Regulatory measures of 10 Jan 2014</u> Supplementary OHS assessment (anticipated additional work exposure data) Assessment of additional water monitoring data received April 2016)  No FAO specification available	<b>Expected 2019</b>
6. Draft regulatory measure	<u>Draft regulatory measures proposed prior to 1 July 2015</u> Preliminary review findings document – Published 10 January 2014.	

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<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
7. Consultation	The APVMA has assessed the responses to the preliminary review findings and is liaising closely with user groups and holders of registrations regarding issues arising out of those responses.	Expected 2019
8. Regulatory decision	<p>The APVMA will determine whether to:</p> <ul style="list-style-type: none"> <li>Vary, suspend or cancel actives, products or labels (s34AB)</li> <li>Affirm actives, products or labels (s34AC)</li> </ul>	Expected 2019
<b>END DATE (regulatory decision)</b>		<b>2019</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 specified in the legislation for cancellations is 12-months.</p> <p>Anticipated date(s) will be included in the future.</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>4</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>2 x 0 = 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 2 = 6</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>21 months</b>	