

Reconsideration work plan

CHEMICAL	Methiocarb	
REMAINING SCOPE	Environment (7.3), Residues (5.4), OHS (6.3)	
RECONSIDERATION ASSESSMENT PERIOD	24 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: January 2020
WORK PLAN DATE	1 July 2015, amended 13 May 2016 (revision of expected dates for component reports, PRD/PRF and public consultation) 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	Invitation to nominate agricultural and veterinary chemicals for review – Gazetted on 1 November 1994.	
2. Prioritisation	Methiocarb was added to the priority candidate review list in 1995 – Gazetted on 2 May 1995.	
3. Scoping and work plan	Scope – chemistry, toxicology, OHS, environment, residues and trade – Gazetted on 2 December 1997. Work plan – Published on 1 July 2015.	
4. Notice of reconsideration	Notice of reconsideration – Gazetted on 2 December 1997. Additional s32 notices sent to holders on 1 July 2015 to include all approved actives and registered products in the review.	
START DATE (clock starts)		01/07/2015
5. Assessment	Link to toxicology assessment – Published in 2005. Link to first update to toxicology assessment – Published in 2013. Link to second update to toxicology assessment – Published in 2018. Link to OHS assessment – Published in 2005. Link to updated OHS assessment – Published in 2017. Link to environment assessment – Published in 2005. Link to updated environment assessment – Published in 2018. Link to residues assessment – Published in 2005. Link to updated residues assessment – Published in 2018.	
6. Draft regulatory measure	<i>Draft regulatory measures proposed prior to 1 July 2015</i> Link to preliminary review findings report – Published in 2005. Link to proposed regulatory decisions report – Published in 2018	

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Stage	Details	Timeline
7. Consultation	<p><u>Details of consultation undertaken to date</u></p> <p>There was a 6-month public consultation period following the 1997 notice of reconsideration. A 3-month public consultation period also occurred following publication of the preliminary review findings in 2005.</p>	
	<p><u>Consultation completed in August 2018</u></p> <p>A 3-month public consultation period is planned. Any further data or information submitted during consultation will be taken into consideration before making the final regulatory decision.</p> <p>Additional consultation to be completed in 2019</p>	<p>27 August – 30 November 2018</p> <p>Expected 2019</p>
8. Regulatory decision	<p><u>Regulatory decisions to be made</u></p> <p>The APVMA will determine whether to:</p> <ul style="list-style-type: none"> • Vary, suspend or cancel actives, products or labels (s34AB) • Affirm actives, products or labels (s34AC) 	<p>Expected 30 August 2019</p>
END DATE (regulatory decision)		2019
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 standard phase out period is 12-months.</p> <p>Anticipated date(s) will be included in the future.</p>	

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Attachment 1

AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 – S78B			
PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RECONSIDERATIONS			
A + B + 2E + 3C + J + D + X			
A = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<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	●
TOTAL TIME FOR A		4	
B = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<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	
TOTAL TIME FOR B		4	
2E = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<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	
TOTAL TIME FOR E		NA	
3C = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<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	
TOTAL TIME FOR C		3 x 3 = 9	
J = whichever is relevant			
	Consultation with jurisdictional coordinator	3	●
	In any other case	0	
TOTAL TIME FOR J		3	
D	TOTAL TIME FOR D	4	●
X = whichever is relevant			
	Appointment of an arbitrator under s.64	3	
	In any other case	0	●
TOTAL TIME FOR X		0	
TOTAL TIMEFRAME		24 months	