

Reconsideration work plan

CHEMICAL	Paraquat	
REMAINING SCOPE	Toxicology [3.3], Residues [5.2], OHS [6.2], Environment [7.2], Finalisation [11.1]	
RECONSIDERATION ASSESSMENT PERIOD	31 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: September 2020
WORK PLAN DATE	1 July 2015, amended 10 May 2016 (revision of expected dates for component reports) 4 July 2019 (revision of expected completion date based on the timing of the proposed regulatory decision).	

Stage	Details	Timeline
1. Nomination	<p>Invitation to nominate agricultural and veterinary chemicals for review – Gazetted on 1 November 1994.</p> <p>Link to nomination decision.</p>	
2. Prioritisation	Prioritisation decision – 1998.	
3. Scoping and work plan	<p>Scope – toxicology, OHS, residues and environment – 1998.</p> <p>Work plan – Published on 1 July 2015.</p>	
4. Notice of reconsideration	<p>s32(2) notices sent to holders upon commencement of the review – 1997.</p> <p>s32(1) notice – Gazetted on 2 December 1997.</p> <p>s33 call for information – Gazetted on 7 April 1998.</p> <p>Additional s32 notices sent to holders on 1 July 2015 to include all approved actives and registered products in the review.</p>	
START DATE (clock starts)		01/07/2015
5. Assessment	<p>Toxicology assessment</p> <p>No change needed, standard was updated in 2011 to align with FAO 2008.</p> <p>Residues assessment</p> <p>OHS assessment</p> <p>Environment assessment</p>	<p>Published October 2016</p> <p>Expected 2019/2020</p>
6. Draft regulatory measure	Preliminary review findings report	Expected 2019/2020
7. Consultation	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.	Expected 2019/2020
8. Regulatory decision	<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) 	Expected 2019/2020
END DATE (regulatory decision)		2020

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<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
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 is 12-months</p> <p>Anticipated dates 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		7	
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		8	
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		31 months	