

Reconsideration work plan

CHEMICAL	Polihexanide	
REMAINING SCOPE	Toxicology (3.3), OHS (6.3)	
RECONSIDERATION ASSESSMENT PERIOD	25 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: 1 August 2017
WORK PLAN DATE	1 July 2015, amended 13 May 2016 (revision of expected dates for supplementary reports, for PRF/PRD and for public consultation)	

Stage	Details	Timeline
1. Nomination	Polihexanide products were nominated in June 2005 by the Office of Chemical Safety, on the basis of human health concerns, especially its potential as a carcinogen.	
2. Prioritisation	Link to gazette. The APVMA placed polihexanide under review – Published in August 2005.	
3. Scoping and work plan	Link to scope. Scope published in August 2005 Scope – toxicology and OHS. Work plan – Published 1 July 2015.	
4. Notice of reconsideration	Link to gazette. Notice of Reconsideration – Published in 2005. s32 notices sent to product registration holders in 2005. 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	<u>Component assessment reports published prior to July 2015</u> Link to carcinogenic risk assessment report – Published in June 2011.	
	<u>Component assessment reports to be completed after July 2015</u> Toxicology assessment Work Health & Safety assessment	<u>Publication Dates:</u>
6. Draft regulatory	Preliminary review findings report	
7. Consultation	<u>Details of consultation undertaken to date</u> Link to gazette. One month period was undertaken in August 2005.	
	<u>Consultation to be undertaken</u> 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.	
8. Regulatory decision	<u>Regulatory decisions to be made</u> The APVMA will determine whether to: <ul style="list-style-type: none"> Vary, suspend or cancel actives, products or labels (s34AB) Affirm actives, products or labels (s34AC) 	

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<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
END DATE (regulatory decision)		01/08/2017
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 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		5	
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		N/A	
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		25 months	