

Reconsideration work plan

CHEMICAL	Neonicotinoids	
REMAINING SCOPE	Environment [7.1], Occupational Health and Safety [6.1], Finalisation [11.1]	
ASSESSMENT PERIOD	26 months, see Attachment 1	
TIMEFRAME	START: 4 February 2020	FINISH: August 2023
WORK PLAN DATES	The timeframe for the review commences at the end of the period specified in the s32 notice.	

<u>Stage</u>	<u>Details</u>	<u>Timeline</u>
1. Nomination	Nominated for review following identification of new environmental risks (2019).	
2. Prioritisation	Prioritised based on consideration of key criteria (2019).	
3. Scoping and work plan	Scope: toxicology/OHS, environment, adequacy of label instructions (2019)	
4. Notice of reconsideration	s32(1) notices sent to holders upon commencement of the review (2019). Notice of reconsideration – Published in Gazette on 19 November 2019.	
START DATE (clock starts)		4 February 2020
5. Assessment	<u>Component assessment reports to be completed</u> Environment assessment	Expected 2021
6. Draft regulatory measure	<u>Draft regulatory measures to be completed</u> Proposed Regulatory Decisions report.	Expected 2021
7. Consultation	<u>Consultation to be undertaken</u> A 3-month public consultation period will follow the publication of the Proposed Regulatory Decisions report. Any further data or information submitted during consultation will be taken into consideration before the final regulatory decision is made.	Expected 2021
8. Regulatory decision	The legislated timeframe for the final regulatory decision is 42 months, although it may be completed sooner. <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) 	Expected 2022
END DATE (final regulatory decision)		August 2023
9. Implementation	The APVMA will publish details of any applicable phase out periods if any approvals of actives, registration of products or label approvals are cancelled. The maximum phase out period specified in the legislation is 12-months.	

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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			13
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			13
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			2 x 0 = 0
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			42 months