

Reconsideration work plan

CHEMICAL	Neomycin	
REMAINING SCOPE	Residues [5.1], Efficacy and safety [8.3], Finalisation [11.2]	
RECONSIDERATION ASSESSMENT PERIOD	32 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: December 2020
WORK PLAN DATE	1 July 2015, amended 4 April 2016, 12 September 2016, 9 December 2016 and May 2017 (revision of expected dates for component reports) 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	Nominated in 2002.	
2. Prioritisation	Concerns about residues and trade (exceeding standards and tolerances, and adequacy of withholding periods) and animal safety. Prioritisation decision.	
3. Scoping and work plan	Scoping document – Published 2007. Work plan – Published on 1 July 2015.	
4. Notice of reconsideration	s32(1) notices sent to holders on 31 January 2007. s32(2) notices sent to other stakeholders on 27 March 2007 – Gazetted on 6 February 2007. 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	Efficacy and safety assessment Residues and trade assessment	Published 23 January 2017 Expected 2020
6. Draft regulatory measure	Proposed regulatory decision report	Expected 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 2020
8. Regulatory decision	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 2020
END DATE (regulatory decision)		2020
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. Anticipated date(s) will be included in the future.	

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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		0	
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 3 = 6	
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 2 = 6	
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		32 months	