Reconsideration work plan

Chemical	Fipronil	
Remaining Scope	OHS [6.2], Environment [7.2], Finalisation [11.2]	
Reconsideration Assessment Period	27 months, see Attachment 1	
Timeframe	Start: 1 July 2015	Finish: 1 September 2017
Work plan date	1 July 2015; amended 30 June 2016 (revision of expected dates for publication of component reports, PRD report and consultation period).	

Stage	Details	Timeline
1. Nomination	Nominated for review following the receipt of a number of adverse experiences in humans and animals.	
2. Prioritisation	Prioritised by concerns regarding toxicology, OHS and safety concerns – 2003. Concerns regarding the environment saw the scope extended in 2012.	
3. Scoping and work plan	Scope – toxicology (skin irritation and sensitisation), OHS, animal safety, adequacy of label instructions – 2003. Link to fipronil review scoping document – 2003. Scope – environmental considerations – 2012. Link to fipronil environment review scoping document – 2012. Work plan – Published on 1 July 2015.	
4. Notice of reconsideration	s32(1) notices sent to holders upon commencement of the review – 2003. Link to gazette. Notice of reconsideration – Published on 7 October 2003 Link to gazette. Notice of reconsideration – Published on 14 August 2012. s32(2) notices sent to other stakeholders – September 2012. 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	*Component assessment reports published prior to July 2015* Toxicology, OHS, safety assessments (part 1). Environment assessment (part 2). Link to component assessment reports published prior to 1 July 2015.	
	Component assessment reports to be completed after July 2015 Environment assessment Supplementary OHS assessment	**Publication Dates:**
6. Draft regulatory measure	*Draft regulatory measures proposed* Link to preliminary review findings report part 1 – Published in 2011.	
	Draft regulatory measures to be completed Proposed Regulatory Decisions report.	

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Stage	Details	Timeline
7. Consultation	*Details of consultation undertaken to date* Public consultation on preliminary review findings report part 1 for toxicology, OHS and animal safety – June 2011 to August 2011.	
	Consultation to be undertaken A 3-month public consultation period is planned following the publication pf the Proposed Regulatory Decisions report. Any further data or information submitted during consultation will be taken into consideration before making the final regulatory decision.	
8. Regulatory decision	*Regulatory decisions to be made* The APVMA will determine whether to: • Vary, suspend or cancel actives, products or labels (s34AB) • Affirm actives, products or labels (s34AC)	
END DATE (regulatory decision)		**01/09/2017**
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			
Item	*Module level or type*	*Period for completion*	*Scope*
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			
Item	*Module level or type*	*Period for completion*	*Scope*
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	**7**	
2E = the longest of the following periods (in months) relevant to the scope of the reconsideration			
Item	*Module level or type*	*Period for completion*	*Scope*
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			
Item	*Module level or type*	*Period for completion*	*Scope*
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		**27 months**	