

Reconsideration work plan

CHEMICAL	Fipronil	
REMAINING SCOPE	Environment [7.2], Finalisation [11.2]	
RECONSIDERATION ASSESSMENT PERIOD	27 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: September 2020
WORK PLAN DATE	1 July 2015; amended 30 June 2016, and May 2017 (revision of expected dates for publication of component reports, PRD report and consultation period). 4 July 2019 (revision of expected completion date based on the timing of the proposed regulatory decision).	

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. 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. Notice of reconsideration – Published in Gazette 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	<u>Component assessment reports published prior to 1 July 2015</u> Toxicology, OHS, safety assessments (part 1). Environment assessment (part 2). Component assessment reports published prior to 1 July 2015. No change proposed at this stage, standard is already aligned with FAO.	
	<u>Component assessment reports to be completed</u> Environment assessment	Expected 2020
6. Draft regulatory measure	<u>Draft regulatory measures proposed prior to 1 July 2015</u> Link to preliminary review findings report part 1 – Published in 2011.	
	<u>Draft regulatory measures to be completed</u> Proposed Regulatory Decisions report.	Expected 2020

Reconsideration work plan

Stage	Details	Timeline
7. Consultation	<p><u>Details of consultation undertaken to date</u></p> <p>Public consultation on preliminary review findings report part 1 for toxicology, OHS and animal safety – June 2011 to August 2011.</p>	Expected 2020
	<p><u>Consultation to be undertaken</u></p> <p>A 3-month public consultation period is planned following the publication of the Proposed Regulatory Decisions report. Any further data or information submitted during consultation will be taken into consideration before making the final regulatory decision.</p>	
8. Regulatory decision	<p><u>Regulatory decisions to be made</u></p> <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 2020
END DATE (regulatory decision)		2020
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		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		7	
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 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		3	
TOTAL TIMEFRAME		27 months	