Reconsideration work plan

CHEMICAL	First and second generation anticoagulant rodenticides	
ASSESSMENTS	Chemistry [2.2], Toxicology [3.2], Environment [7.1], Occupational Health and Safety [6.1], Residues and Trade [5.2], Finalisation [11.1]	
ASSESSMENT PERIOD	42 months, see Attachment 1	
TIMEFRAME	START: January 2022	FINISH: July 2025
WORK PLAN DATES	The timeframe for the review commences at the end of the period specified in the s 32 notice.	

Stage	Details	Timeline
1. Nomination	Nominated for review following identification of new worker exposure, public health and environmental safety risks (2015).	
2. Prioritisation	Prioritised based on consideration of key criteria, including worker exposure, public health, environmental safety, and the potential for residues in food (2021).	
3. Scoping and work plan	Scope: chemistry, toxicology, worker and public exposure, environment, residues, trade and adequacy of label instructions (2021).	
4. Notice of reconsideration	S 32(1) notices sent to holders upon commencement of the review on 2 November 2021. Notice of reconsideration – Published in Gazette on 2 November 2021.	
START DATE (clock starts)		**January 2022**
5. Assessment	*Component assessment reports to be completed* Chemistry, toxicology, worker and public exposure, environment residues and trade.	**Expected 2024**
6. Draft regulatory measure	*Draft regulatory measures to be completed* Proposed regulatory decisions.	**Expected 2024**
7. Consultation	*Consultation to be undertaken* 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 2024**
8. Regulatory decision	The legislated timeframe for the final regulatory decision is 42 months, although it may be completed sooner. *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)	**Expected 2024**
END DATE (final regulatory decision)		**July 2025**
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.	

Reconsideration work plan

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	**13**	13

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	**13**	13

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 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**