



# **Quarterly Performance Report**

1 July 2025 to 30 September 2025

### **Overview**

In Quarter 1 of the 2025–26 financial year, the Australian Pesticides and Veterinary Medicines Authority (APVMA) completed 1,505 activities related to regulatory decisions, including 463 product registrations / permits and 17 emergency permits. We completed 99 compliance investigations, 23 manufacturing audits, and processed 781 adverse experience reports.

#### Approvals, Registration and Permits

**80.2 per cent** of all applications for approval of an active or a label, registration of a product or the issuing of a permit completed in Quarter 1 were completed within statutory timeframes, against a target of 90%, similar to the previous quarter (81.1 per cent in Quarter 4 FY2024–25).

The proportion of permit applications completed within legislative timeframe improved in Quarter 1 as the result of a strategic temporary redeployment of resources from the agricultural chemicals team in May 2025.

Area	Received	In progress	Finalised	Finalised on time
Agricultural Chemicals	213	616	137	76.6%
Veterinary Medicines	252	358	188	83.5%
Permits (excl. emergency permits)	142	273	138	73.9%
Emergency permits <sup>1</sup>	12	18	17	N/A
Active constituents	105	260	66	90.9%
Total	724	1525	546	80.2%

Considering the many changes underway across the APVMA, the fact that 80 per cent of all applications were finalised within statutory timeframes, is a strong result and on par with the previous quarter (81 per cent). The APVMA forecasts that the next two quarters will have lower overall timeframe performance as we finalise a backlog of overdue applications. These are mainly applications that rely on reference products.

One of our most closely monitored results relates to the processing of technical applications for agricultural chemicals (previously described as pesticides majors). This result, at **58.9 per cent**, reflected a continued improvement since the previous quarter (53.7 per cent), reversing the forecast decline in previous quarters arising from the temporary diversion of resources to the permits team.

During Quarter 1, the APVMA finalised 1 application for approval of a new active constituent in conjunction with registration of a new end-use product. This application was finalised within the timeframe in the agreed plan on the day that it was due, as detailed in Table 2.

<sup>&</sup>lt;sup>1</sup> Emergency permits (Item 22) do not have a numerical statutory timeframe. The APVMA must determine the application as soon as is practicable in the circumstances of the case.

During this period, evaluation commenced on **9** new applications for a new active constituent with accompanying new product. These were:

- 3 applications for assessment under item 2
- 6 applications for assessment under item 27.

As at 30 September 2025, the APVMA had a total of 72 item 1, 2 and 27 applications under evaluation. Of these 71 per cent of applications are currently within legislative timeframe.<sup>2</sup>

This performance measure is likely to move around a lot throughout the year and is heavily impacted by the inherent complexity of these long-timeframe applications.

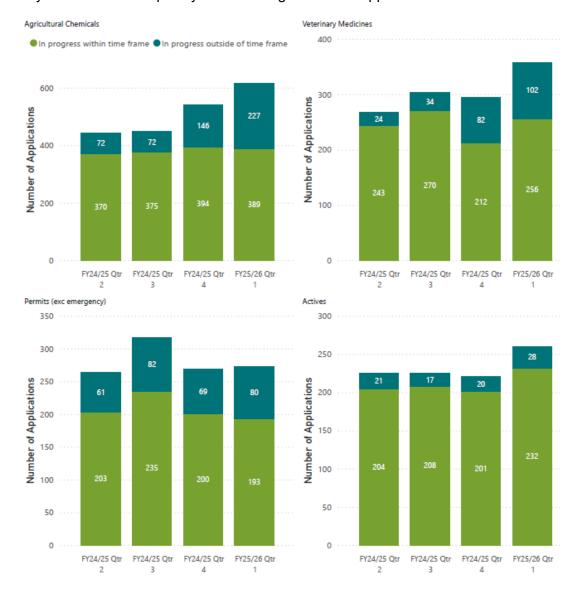


Figure 1: Applications in progress within and outside of timeframe

The number of in-progress overdue applications increased in Quarter 1 in both agricultural chemicals and veterinary medicines. Most of the **234** applications that went overdue during this

<sup>&</sup>lt;sup>2</sup> One application is excluded from reporting as it is an outlier due to an administrative process

reporting period were item 7 applications, which were affected by the changes announced in the 11 June 2025 *Update on Application Requirements for 'closely similar' Item 6 and 7 Applications*.

Completion of Item 7 minor applications within legislative timeframe decreased in Quarter 1 to 33.3 per cent for agricultural chemicals and 28.6 per cent for veterinary medicines. Historically, timeframe performance of Item 7 is close to 100 per cent. The decrease was a consequence of the APVMA reengineering the processes to assess applications that rely on reference products. The APVMA has recommenced evaluation of these applications using the new process, which will result in a decline in timeframe performance over the next two quarters.

Deficiencies in submitted applications continue to cause delays in timeframe performance. The APVMA is strengthening its requirements for applicants, to make the best use of APVMA resources.

#### Post market regulatory actions

**Chemical reconsideration** activity continued at a high intensity throughout Quarter 1, with two reconsiderations being finalised and released and a proposed suspension announced:

- Fenitrothion Final Regulatory Decision, 19 August 2025
- Neomycin Final Regulatory Decision, 16 September 2025
- Proposed suspension of dimethoate 1 August 2025

Concurrent resourcing of multiple, extremely complex chemical reviews is a major challenge for the APVMA and impacts capacity to process technical applications for agricultural chemicals. Strategies are being implemented to respond to this pressure point, including expansion of use of external science reviewers and other measures to realise the full value of separating post-market and premarket activities in the recent restructure.

The proportion of serious **adverse experience reports** received, and assessments completed within 20 business days, is a new reporting metric initiated by the APVMA with performance at **84 per cent** against a 75 per cent target.

Table 2: Adverse Experience Reporting Program

Summa	ry	2024-25^3	2024-25 Q1^	2025-26 Q1^
	Performance	43.7%	87.2%	84.0%
AERP	Number of serious individual reports received		652	791
AERP	Number of serious individual reports closed	2485	436	781
	Number of serious adverse incidents received	2423	568	636

84.0 per cent of serious adverse experience reports were received and initial assessments completed in Quarter 1 within the 20 working days timeframe. This is slightly down compared to what has been calculated for the same period last financial year (87.2 per cent in Quarter 1 FY2024–25).

<sup>&</sup>lt;sup>3</sup> ^This is the first year calculating this metric for serious adverse experience reports. Values for 2024-25 have been calculated for comparison only and were not reported previously.

In Quarter 1 on a year-on-year basis there has been an approximate 20 per cent increase in serious adverse experience reports (652 to 791).

In the first quarter, the APVMA continued its rigorous program of **compliance action**, initiating the removal of **328** unauthorised products from online marketplaces (on track for a full year figure to exceed the 1,277 in 2024–25). Investigations were initiated into **96** compliance matters, including generating 38 forfeiture actions under the *Customs Act 1901* – a figure on track to be at least 200 per cent higher than the full year for 2024–25.

Table 3: Summary of investigations

Summary of investigations	2024-25	2025-26 Q1
Commenced	289	96
Closed	297	99
Remaining open	22	37

Table 4: Summary of investigation outcomes

Summary of investigation outcomes	2024-25 Cases	2025-26 Q1 Cases
Negotiated Compliance / Education	161	15
Formal Warnings	77	36
Infringement Notices	10	3
Enforceable Undertakings	0	0
Civil Proceedings	0	0
Prosecutions	0	0
Customs Act Forfeiture	56	38
No Offence / Insufficient Evidence	32	0
Online product removals	1277	328

The Manufacturing Quality and Licensing (**MQL**) performance target is 90 per cent of all audit reviews finalised within a 4-month timeframe. 87.0 per cent of all audit reviews completed in Quarter 1 were completed within 4-month timeframe. This is on par with the previous quarter.

Table 5: Manufacturing Quality and Licencing (MQL)

Summa	ry	2024-25	2025-26 Q1
	Performance	86.7%	87.0%
MQL	Number of audits commenced	86	22
	Number of audits closed and reviewed	98	23

The **Recalls** performance target is 100 per cent of all voluntary recall notices published to the APVMA website within 3 working days and gazetted within 14 days as per Agvet Code requirements.

Table 6: Recalls

Summary		2024-25	2024-25 Q1	2025-26 Q1
Recalls	Performance	100%	100%	100%
Recails	Number of voluntary recalls	29	3	13

The APVMA is achieving 100 per cent for all Recalls. There has been a significant increase in voluntary recalls compared to the same period last financial year (from 3 to 13). Most products recalled are sterile injectable veterinary chemical products due to sterility or particulate matter concerns from both domestic and overseas manufacturers.

**Table 7: Hormonal Growth Promotants** 

Summary		2024-25	2024-25 Q1	2025-26 Q1
HGP	Performance	99.4%	95.5%	100%
пор	Number of applications	180	22	24

The Hormonal Growth Promotants (HGPs) performance target is 90 per cent of all notification number applications processed within 5 working days. Most renewal applications (~70-80 per cent) occur in Quarter 4 of each financial year. The APVMA is achieving 100 per cent for HGP applications in Quarter 1.

# **Concluding comments**

Overall, the first quarter report indicates the scale of actions being taken across the agency to fulfil its responsibilities and reveals a range of crucial decisions that have been made on agricultural chemicals and veterinary medicines. The report also provides a baseline for measuring improvement in performance as we move into 2026 where we will be progressing the following initiatives:

- Sustainable funding with a primary focus on cost recovery policy in conjunction with the Department of Agriculture, Fisheries and Forestry
- Implementing critical elements of our ICT Roadmap
- Productivity Initiatives use of international assessments; and increasing the onus on applicants to submit quality applications
- Structure and resources maximising the gains inherent in our new organisational structure; and expanded use of external science reviewers.

While achieving reliable timeframes for the work we do is undoubtedly important, the APVMA is also committed to maintaining the trust of the Australian public, as that is critical to maintaining confidence in Australian agricultural chemicals and veterinary medicines.

\*In line with other changes to the APVMA quarterly reports, references to 'pesticides' have been updated to refer to 'agricultural chemicals' and references to 'pesticide majors' have been changed to refer to 'technical agricultural chemical applications'.

# Analysis by application type (1 July-30 September 2025)

Table 8: Summary of activities related to regulatory decisions

Types of regulatory decisions	Received	In progress	Finalised
Pre-application assistance	66	97	34
Product registration—agricultural chemicals	213	616	137
Product registration—veterinary medicines	252	358	188
Permits (exc emergency)	142	273	138
Emergency permits (Item 22)	12	18	17
Actives	105	260	66
Items 8L, 8M, 8P	281	21	287
Technical assessment (Item 25)	4	14	5
Notifiable variations	357	0	357
Import consents	193	31	165
Certificate of export	90	21	111
Interchangeable constituent determination	0	0	0
Total	1715	1709	1505

#### **Applications processed**

**Table 9: Applications processed** 

Туре	Received	In progress	Finalised	Finalised on time	In progress still on time
Actives	105	260	66	90.9%	89.2%
Emergency permits (Item 22)	12	18	17	N/A	N/A
Permits (exc emergency)	142	273	138	73.9%	70.7%
Agricultural Chemicals	213	616	137	76.6%	63.1%
Veterinary Medicines	252	358	188	83.5%	71.5%
Total	724	1525	546	80.2%	71.0%

Table 10: Applications processed continued

Туре	Finalised on time	Finalised outside timeframe	Went overdue in reporting period
Actives	60	6	14
Permits (exc emergency) <sup>4</sup>	102	36	49
Agricultural Chemicals	105	32	117
Veterinary Medicines	157	31	54
Total	424	105	234

### **Applications in evaluation**

Table 11: Applications in evaluation

Туре	Evaluations in progress	Evaluations in progress and overdue
Actives	214	28
Emergency permits (Item 22)	18	N/A
Permits (exc emergency)	230	77
Agricultural Chemicals	520	224
Veterinary Medicines	308	104
Total	1290	434

<sup>&</sup>lt;sup>4</sup> Emergency permits (Item 22) do not have a numerical statutory timeframe. The APVMA must determine the application as soon as is practicable in the circumstances of the case (see <u>Emergency permits</u>).

### Pre-application assistance (1 July-30 September 2025)

Pre-application assistance (PAA) is an optional, three-tiered, fee-based service for applicants to provide them with advice before they submit an application for registration. PAAs do not have a numerical statutory timeframe; the target timeframe for each tier is based on the anticipated complexity of the proposed application and effort required to provide the assistance.

Table 12: Pre-application assistance

Туре	Received	In Progress	Finalised	Processed on time (%)
PAA Tier 1	15	10	14	42.9%
PAA Tier 2	47	80	19	15.8%
PAA Tier 3	4	7	1	0.0%
Total	66	97	34	26.5%

Table 13: Permits

Category Name	Received	In Progress	Finalised	Issued	Refused	Withdrawn / Other
Ag Chemical and Vet Medicines	0	0	0	0	0	0
Agricultural Chemicals	116	226	104	92	0	12
Other	0	0	0	0	0	0
Veterinary Medicines	26	47	34	27	0	7

#### **Emergency Permits**

Emergency Permits (Item 22) do not have a numerical statutory timeframe. The APVMA must determine the application as soon as is practicable in the circumstances of the case. In this reporting period, the APVMA issued 14 emergency permits, taking an average of 129 days, with a range of 21 to 356 days.

Table 14: Emergency permits

Types of regulatory decisions	Received	In Progress	Finalised	Issued	Refused	Withdrawn / Other
Emergency permits (Item 22)	12	18	17	14	2	1

# Technical assessment, notifiable variations, holders and nominated agents

Table 15: Technical assessment, notifiable variations, holders and nominated agents

Types of regulatory decisions	Received	In Progress	Finalised	Finalised on time (%)
Items 8L, 8M, 8P	281	21	287	99.7%
Technical assessment (Item 25)	4	14	5	80.0%
Notifiable variations	357	0	357	100.0%

#### **Consents to Import**

Consents to import are issued to allow importation – in limited circumstances – of unregistered products or unapproved actives into Australia when a legitimate reason exists for a person or company to have possession of the chemicals in Australia. There is no statutory timeframe for consents to import – the APVMA seeks to process these within 14 days.

Table 16: Consents to import

Types of regulatory decisions	Received	In Progress	Finalised	Finalised on time (%)
Import consents	193	31	165	96.4%

#### **Certificates of Export**

Before accepting exports of a chemical product from Australia, many countries require an assurance from the government authority responsible for regulating the product in Australia. This is provided by the APVMA in the form of a Certificate of Export. There is no statutory timeframe for certificates of export – the APVMA seeks to process these within 20 working days. Please note that an application may request multiple certificates.

Table 17: Applications for certificates of export

	Received	In Progress	Finalised	Finalised	Finalised on time (%)
Applications	90	21	111	109	75.7%

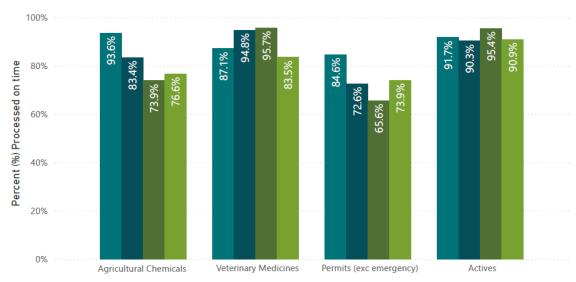
Table 18: Certificates of export

	Received	In Progress	Finalised	Finalised	Finalised on time (%)
Certificates	256	32	288	286	62.2%

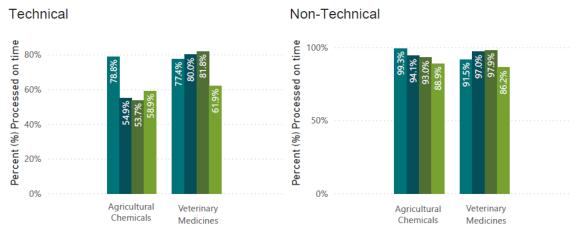
# **Application in detail**

### **Timeframe performance**

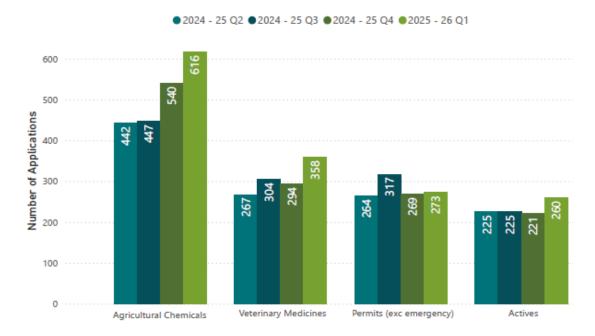
● 2024 - 25 Q2 ● 2024 - 25 Q3 ● 2024 - 25 Q4 ● 2025 - 26 Q1



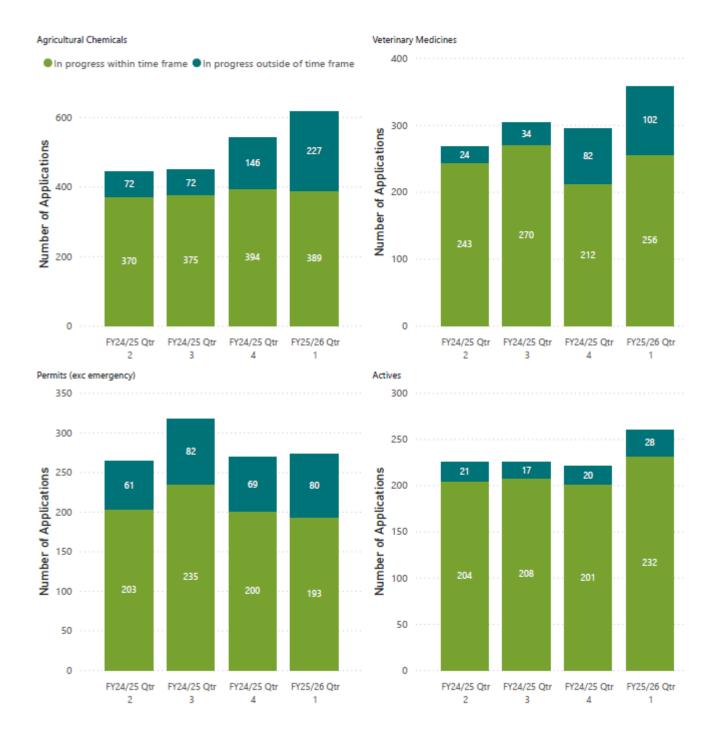
#### Technical vs Non-Technical Performance



### Work in progress



### Work in progress still within timeframe



# Application by item number

Table 19: All applications by item number

Types of application	Received	In Progress	Finalised	Finalised on time (%)
Products	465	974	325	80.6%
1	0	0	0	N/A
2	3	29	0	N/A
3	0	0	0	N/A
4	8	23	1	0.0%
5	5	15	1	100.0%
6	40	246	13	30.8%
7	58	68	22	90.9%
8	4	4	0	N/A
9	49	208	28	42.9%
10	7	7	15	73.3%
10A	1	1	0	N/A
11	96	123	71	77.5%
12	1	1	14	100.0%
13	156	58	113	99.1%
14	31	146	46	69.6%
27	6	43	1	100.0%
27V Actives	0 <b>105</b>	2 <b>260</b>	0 <b>66</b>	N/A 90.9%
1	0	1	0	90.9% N/A
2	4	29	0	N/A
5	0	0	0	N/A
6	0	0	0	N/A
10	0	0	0	N/A
14	0	0	0	N/A
15	0	3	0	N/A
16	0	0	0	N/A
17	45	129	40	90.0%
18	16	23	4	100.0%
24	18	33	16	87.5%
24V	17	22	5	100.0%
27	5	20	1	100.0%
27V	0	0	0	N/A
Permits	154	291	155	73.9%
19	13	13	7	85.7%
20	51	64	77	81.8%
21	56	152	38	57.9%
22	12	18	17	N/A
23	20	39	15	66.7%
112A	2	5	1	100.0%
Other	0	0	0	N/A
24	0	0	0	N/A
Ingredient determination	0	0	0	N/A
28	0	0	0	N/A
29	0	0	0	N/A
Total	724	1525	546	80.2%

Table 20: Agricultural chemicals applications by item number

Types of application	Commenced	In Progress	Finalised	Processed on time (%)
Products	213	616	137	76.6%
1	0	0	0	N/A
2	2	11	0	N/A
3	0	0	0	N/A
4	0	0	0	N/A
5	8	18	1	0.0%
6	5	13	1	100.0%
7	31	188	6	33.3%
8	46	50	19	100.0%
9	4	4	0	N/A
10	39	150	23	39.1%
10A	7	7	5	100.0%
11	1	1	0	N/A
12	49	60	37	86.5%
13	1	1	14	100.0%
13A	0	0	0	N/A
14	20	100	31	74.2%
27	0	11	0	N/A
27V	0	2	0	N/A
Permits	126	240	115	70.2%
19	12	12	2	100.0%
20	45	56	61	80.3%
21	47	124	32	50.0%
22	10	14	11	N/A
23	10	29	8	62.5%
112A	2	5	1	100.0%
Other	0	0	0	N/A
24	0	0	0	N/A
Total	339	856	252	73.9%

Table 21: Veterinary medicines applications by item number

Types of application	Received	In Progress	Finalised	Finalised on time (%)
Products	252	358	188	83.5%
1	0	0	0	N/A
2	1	18	0	N/A
3	0	0	0	N/A
4	0	0	0	N/A
5	0	5	0	N/A
6	0	2	0	N/A
7	9	58	7	28.6%
8	12	18	3	33.3%
9	0	0	0	N/A
10	10	58	5	60.0%
10A	0	0	10	60.0%
11	0	0	0	N/A
12	47	63	34	67.6%
13	0	0	0	N/A
13A	156	58	113	99.1%
14	11	46	15	60.0%
27	6	32	1	100.0%
27V	0	0	0	N/A
Permits	28	51	40	85.3%
19	1	1	5	80.0%
20	6	8	16	87.5%
21	9	28	6	100.0%
22	2	4	6	N/A
23	10	10	7	71.4%
112A	0	0	0	N/A
Other	0	0	0	N/A
24	0	0	0	N/A
Total	280	409	228	83.8%

### Average decision time

Table 22: All Applications - Average Decision Time

	Standard Extended						
Type of application	Finalised	Average Duration	Assessment Period	Finalised	Average Duration	Assessment Period	
Products	265	2.9		60	12.0		
1	0	N/A	18	0	N/A	25	
2	0	N/A	~	0	N/A	~	
3	0	N/A	18	0	N/A	25	
4	0	N/A	18	0	N/A	25	
5	0	N/A	8	1	21.8	12	
6	0	N/A	8	1	N/A	12	
7	9	6.1	3	4	7.9	5	
8	21	3.0	3	1	8.2	5	
9	0	N/A	2	0	N/A	4	
10	12	8.6	5.8	16	18.7	12.7	
10A	15	2.0	2.0	0	N/A	~	
11	0	N/A	10	0	N/A	14	
12	61	3.1	3	10	6.5	5	
13	14	2.8	3	0	N/A	5	
13A	113	0.9	1	0	N/A	2	
14	20	7.4	6.6	26	10.0	8.4	
27	0	N/A	N/A	1	10.7	10.7	
27V	0	N/A	~	0	N/A	~	
Actives	49	5.1		17	13.7		
1	0	N/A	18	0	N/A	25	
2	0	N/A	~	0	N/A	~	
5	0	N/A	8	0	N/A	12	
6	0	N/A	8	0	N/A	12	
10	0	N/A	~	0	N/A	~	
14	0	N/A	~	0	N/A	~	
15	0	N/A	14	0	N/A	20	
16	0	N/A	9	0	N/A	13	
17	28	6.3	7	12	15.6	10	
18	4	7.0	7	0	N/A	10	
24	11	2.8	4.0	5	9.0	9.0	
24V	5	2.5	0.0	0	N/A	N/A	
27	1	N/A	N/A	0	N/A	N/A	
27V	0	N/A	~	0	N/A	~	
Permits	133	4.3		22	10.3		
19	7	2.6	3	0	N/A	5	
20	74	3.0	3	3	5.0	5	
21	28	10.5	5.5	10	14.7	10.6	
22	12	2.9	N/A	5	7.9	N/A	
23	11	3.3	2.8	4	7.9	6.5	
112A	1	0.0	0.0	0	N/A	N/A	
Other	0	N/A		0	N/A		
24	0	N/A	~	0	N/A	~	
Ingredient determination	0	N/A		0	N/A		
28	0	N/A	~	0	N/A	~	
29	0	N/A	~	0	N/A	~	
Total	447	3.6		99	12.0		

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<sup>~=</sup> Modular Assessment Period. Please refer to the Table of assessment periods and fees in Schedule 6 of the Agricultural and Veterinary Chemicals Code Regulations 1995 for further details.

#### Notes for average decision times

Average decision time is the average time taken to complete processing from commencement to when a regulatory decision is made or the average time is calculated by adding the decision times and dividing these by the number of applications finalised in that period in that category. Decision time is calculated by subtracting the lodgement date from the processed date and dividing by 30.4375 to get the decision time in months (accounting for leap years). The assessment period for each application type and item number is set in the legislation - this is the standard decision time. However, there are 2 conditions which allow the APVMA to vary or extend the assessment period:

- A change in the category of an application may be made once in the life of the application under regulation 70B of the Agvet Code.
- One extension of 1.33 times the original assessment period (rounded up) plus one month may be applied under section 159 of the Agvet Code.

N/A means no applications were finalised for that item in the reporting period, the application was withdrawn or voided, or there is no statutory assessment period.

~ applies to items that have a variable legislated assessment period because they are modular in nature. Each application will have a different expected duration, as determined by the mix of modules required for the application.

Table 23: Agricultural Chemical product applications by Item Number - Average decision time

	Standard			Extended		
Type of application	Finalised	Average Duration	Assessment Period	Finalised	Average Duration	Assessment Period
Products	106	4.1		31	15.4	
1	0	N/A	18	0	N/A	25
2	0	N/A	~	0	N/A	~
3	0	N/A	18	0	N/A	25
4	0	N/A	18	0	N/A	25
5	0	N/A	8	1	21.8	12
6	0	N/A	8	1	N/A	12
7	6	6.3	3	0	N/A	5
8	19	2.8	3	0	N/A	5
9	0	N/A	2	0	N/A	4
10	10	8.9	5.9	13	19.9	12.8
10A	5	1.8	2.0	0	N/A	~
11	0	N/A	10	0	N/A	14
12	37	2.9	3	0	N/A	5
13	14	2.8	3	0	N/A	5
13A	0	N/A	1	0	N/A	2
14	15	7.8	6.9	16	10.5	8.6
27	0	N/A	N/A	0	N/A	N/A
27V	0	N/A	~	0	N/A	~
Permits	98	4.8		17	10.8	
19	2	2.7	3	0	N/A	5
20	59	3.0	3	2	5.7	5
21	24	11.3	5.7	8	15.7	10.1
22	7	2.5	N/A	4	7.0	N/A
23	5	5.0	3.6	3	6.7	6.0
112A	1	0.0	0.0	0	N/A	N/A
Other	0	N/A		0	N/A	
24	0	N/A	~	0	N/A	~
Total	204	1.4		48	13.7	

Table 24: Veterinary medicine product applications by item number - Average decision time

Standard			E	Extended		
Type of application	Finalised	Average	Assessment	Finalised	Average	Assessment
		Duration	Period		Duration	Period
Products	159	1.8		29	8.6	
1	0	N/A	18	0	N/A	25
2	0	N/A	~	0	N/A	~
3	0	N/A	18	0	N/A	25
4	0	N/A	18	0	N/A	25
5	0	N/A	8	0	N/A	12
6	0	N/A	8	0	N/A	12
7	3	5.9	3	4	7.9	5
8	2	4.7	3	1	8.2	5
9	0	N/A	2	0	N/A	4
10	2	6.4	5.1	3	14.3	12.3
10A	10	2.1	2.0	0	N/A	~
11	0	N/A	10	0	N/A	14
12	24	3.4	3	10	6.5	5
13	0	N/A	3	0	N/A	5
13A	113	0.9	1	0	N/A	2
14	5	6.3	5.4	10	9.1	8.0
27	0	N/A	N/A	1	10.7	10.7
27V	0	N/A	~	0	N/A	~
Permits	35	2.9		5	8.4	
19	5	2.6	3	0	N/A	5
20	15	3.1	3	1	3.7	5
21	4	2.9	3.5	2	7.8	14.0
22	5	3.3	N/A	1	10.6	N/A
23	6	1.6	2.0	1	11.4	8.0
112A	0	N/A	N/A	0	N/A	N/A
Other	0	N/A		0	N/A	
24	0	N/A	~	0	N/A	~
Total	194	2.0		34	8.6	

### Average decision time - Cumulative quarters to date

Table 25: Average decision time, all applications for completed quarters this financial year

Types of application	Number finalised	Average duration	Assessment period
Products	325	4.5	18
1	0	N/A	18
2	0	N/A	~
3	0	N/A	18
4	0	N/A	18
5	1	21.8	8
6	1	N/A	8
7	13	6.8	3
8	22	3.3	3
9	0	N/A	2
10	28	14.7	10.0
10A	15	2.0	2.0
11	0	N/A	10
12	71	3.5	3
13	14	2.8	3
13A	113	0.9	1
14	46	8.8	7.6
27	1	10.7	10.7
27V	0	N/A	~
Actives	66	7.4	18
1	0	N/A	18
2	0	N/A	~
5	0	N/A	8
6	0	N/A	8
10	0	N/A	~
14	0	N/A	~
15	0	N/A	14
16	0	N/A	9
17	40	9.2	7
18	4	7.0	7
24	16	4.7	5.6
24V	5	2.5	0.0
27	1	N/A	N/A
27V	0	N/A	~
Permits	155	5.2	3
19	7	2.6	3
20	77	3.1	3
21	38	11.7	6.9
22	17	4.1	N/A
23	15	5.1	4.3
112A	1	0.0	0.0
Other	0	N/A	~
24	0	N/A	~
Ingredient determination	0	N/A	~
28	0	N/A	~
29	0	N/A	~
Total	546	5.1	

# Glossary

# **Item Number Descriptions**

Item	Description
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product
2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring assessment of the active constituent and chemical product
3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:
	(a) there is no registered chemical product containing the active constituent; and
	(b) a full assessment of the chemical product is required
4	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:
	(a) there is a registered chemical product containing the active constituent; and
	(b) a full assessment of the chemical product is required; and
	(c) there are no relevant maximum residue limits; and
	(d) poison schedule classification is required
5	Application for:
	(a) registration of a chemical product containing an approved active constituent and approval of the product label; or
	(b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or
	(c) registration of a chemical product and approval of the product label; if:
	(d) the chemical product is similar to a registered chemical product; and
	(e) chemistry and manufacture data, efficacy data and target species safety data are the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and
	(f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia; and
	(g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged
6	Application for:
	(a) registration of a chemical product containing an approved active constituent and approval of the product label; or
	(b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or
	(c) registration of a chemical product and approval of the product label; if:
	(d) the chemical product is closely similar to a registered chemical product; and
	(e) chemistry and manufacture data are the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and
	(f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopeia; and
	(g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged
7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:
	(a) the chemical product is closely similar to a registered chemical product; and
	(b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and
	(c) chemistry and manufacture data are not required
8	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:

	(a) the chemical product is the same as a registered chemical product; and			
	(d) the chemical product is the same as a registered chemical product; and (d) the chemical product is to be registered with a different name			
9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the Code			
10	Application for:  (a) registration of a chemical product containing an approved active constituent and approval of the product label; or  (b) registration of a chemical product and approval of the active constituent in the chemical product; or			
	(c) registration of a chemical product and approval of the product label (but only if a separate application for the approval of the active constituent in the chemical product has been lodged); for all situations other than those described in items 1 to 9			
10A	Application for approval of a label for containers for a registered chemical product			
10B	Application under subsection 14C(1), 14D(1) or 14E(1) of the Code			
11	Application to vary relevant particulars or conditions of registration or label approval where a full assessment of the chemical product is required			
12	Application to vary relevant particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required			
13	Application to vary relevant particulars or conditions of registration or label approval if:  (a) the variation is to allow a minor change; and  (b) no data of a technical nature is required; and  (c) the variation is a change required by the APVMA			
13A	Application to vary a relevant particular of an approval or registration where the variation of the relevant particular is a prescribed variation under section 26B of the Code			
14	Application to vary relevant particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 13A			
15	Application for approval of an active constituent requiring a full assessment			
16	Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment			
17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment (unless item 5, 6 or 10 applies)			
18	Application to vary relevant particulars or conditions of an approved active constituent			
19	Application for a permit, or extension of a permit, to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product, where no data of a technical nature is required			
20	Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required			
21	Application for a permit, or extension of a permit, where the proposed use is a minor use			
22	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use			
23	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the application is not of a kind described in any of items 19 to 22			
24(a)	Application made under section 10 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17			
24(b)	Application made under section 27 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 11 to 14 or 18			
25	Applications made under s8AS of the Agricultural and Veterinary Chemicals Code Regulations 1995. These are technical assessments used to determine if a data package addresses the safety, efficacy and trade criteria prior to submitting a product application. An outcome of a technical assessment can be used by an applicant as part of a future application.			
27	Timeshift application (see regulation 3BA)			
28	Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination			
29	Application made under regulation 19AEB to make an interchangeable constituent determination			

### **Definition of terms**

Term	Definition	
8L, 8M and 8P	Applications to either change the holder or nominated agent of an approval or registration or nominate a nominated agent for an approval or registration.	
Actives	The component(s) of an agricultural chemical or veterinary medicine product that is primarily responsible for its action. Applications for active constituents are covered under Item numbers 1, 2, 15, 16, 17, 18. Actives can also be included in applications under Item numbers 5, 6, 10, 14, 24, 27 and 27V.	
Certificates of export	Before accepting exports of a chemical product from Australia, many countries require an assurance from the government authority responsible for regulating the product in Australia. This is provided by the APVMA in the form of a certificate of export. There are no statutory timeframes for the APVMA to process an application for a certificate of export.	
Emergency Permits	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use. Emergency Permits applications are made under Item number 22.	
Finalised	Includes all applications that the APVMA completed processing during the reporting period. This includes applications for which a regulatory decision was made as well as applications that were withdrawn by the applicant or voided having been lodged in error.	
Import consents	Import consents are permits that allow unregistered or unapproved chemicals into Australia when a legitimate reason exists for a person or company to have possession of the chemicals in Australia. Legitimate reasons include possession for research, chemical trials or special veterinary applications in zoos. There is no statutory timeframe for the APVMA to process import consents, but the APVMA aims to process them within 14 days of lodgement.	
Item numbers	Item numbers are defined in Table 2.1 of Schedule 6 of the Agricultural and Veterinary Chemicals Code Regulations 1995. They are used to determine the assessment periods and fees for different kinds of applications.	
Major assessments	Applications that have assessment periods of more than 3 months and that require one or more technical assessments. These include Item numbers 1, 2, 3, 4, 5, 6, 10, 11, 14, 27 and 27V.	
Non-technical assessments	Applications that have assessment periods of 3 months or less and that do not require a technical assessment. These include Item numbers 7, 8, 9, 10A, 12, 13 and 13A.	
Notifiable variations	A minor change, as defined by Agricultural and Veterinary Chemicals Code Regulations 1995, to the details of a registered product, active or label without having to register a new product. This process commenced on 1 January 2015. There is no statutory timeframe for the APVMA to process these as they are deemed to be accepted upon lodgement by the applicant after some checks of the information.	
Permits (exc emergency)	Applications to use or possess an unregistered agricultural chemical or veterinary medicine or for an off-label use of a registered agricultural chemical or veterinary medicine. Permit applications include applications under Item numbers 19, 20, 21, 23 and can also be made under s112A of the Agricultural and Veterinary Chemicals Code Act 1994.	
Product applications	Applications made for the registration of products that are pesticides or veterinary medicines.  Product applications include applications under Item numbers 1 to 14, including 10A and 13A, as well as Item numbers 24, 27 and 27V.	
Received	Includes all applications that were received by the APVMA during the reporting period.	