



APVMA Performance Report

1 October to 31 December 2024

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Analysis by type of application

Summary of activities related to regulatory decisions

Table 1: Summary of activities related to regulatory decisions (1 Oct - 31 Dec 2024)

Types of regulatory decisions	Received	In progress	Processed
Pre-application assistance	47	52	55
Product registration—pesticides	187	440	188
Product registration—veterinary medicines	171	267	171
Permits (exc emergency)	116	259	117
Emergency permits (Item 22)	19	12	23
Actives	80	225	145
Items 8L, 8M, 8P	462	34	428
Technical assessment (Item 25)	3	9	4
Notifiable variations	315	0	316
Import consents	117	2	140
Certificate of export	77	10	90
Interchangeable constituent determination	0	0	0
Total	1594	1310	1677

Applications processed

Table 2: Applications processed (1 Oct - 31 Dec 2024)

Туре	Received	In progress	Processed	Processed on time (%)	In progress still on time (%)
Actives	80	225	145	91.7%	90.2%
Emergency permits (Item 22)	19	12	23	N/A	N/A
Permits (exc emergency)	116	259	117	84.6%	76.4%
Pesticides	187	440	188	93.6%	83.6%
Veterinary Medicines	171	267	171	87.1%	91.0%
Total	573	1203	644	89.7%	85.0%

Note: 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 *Emergency permits*).

Pre-application assistance

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 3: Pre-application assistance (1 Oct - 31 Dec 2024)

Туре	Received	In Progress	Processed	Processed on time (%)
PAA Tier 1	23	10	24	41.7%
PAA Tier 2	20	39	28	3.6%
PAA Tier 3	4	3	3	66.7%
Total	47	52	55	23.6%

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 17 emergency permits, taking an average of 54 days, with a range of 1 to 262 days.

Table 4: Emergency permits (1 Oct - 31 Dec 2024)

Types of regulatory decisions	Received	In Progress	Processed	Issued	Refused	Withdrawn or Other
Emergency permits (Item 22)	19	12	23	17	0	6

Technical assessment, notifiable variations, holders and nominated agents

Table 5: Technical assessment, notifiable variations, holders and nominated agents (1 Oct - 31 Dec 2024)

Types of regulatory decisions	Received	In Progress	Processed	Processed on time (%)
Items 8L, 8M, 8P	462	34	428	100.0%
Technical assessment (Item 25)	3	9	4	75.0%
Notifiable variations	315	0	316	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 6: Consents to import (1 Oct - 31 Dec 2024)

Types of regulatory decisions	Received	In Progress	Processed	Processed on time (%)
Import consents	117	2	140	95.0%

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 7: Applications for certificates of export (1 Oct - 31 Dec 2024)

	Received	In Progress	Processed	Issued	Processed on time (%)
Applications	77	10	90	88	64.4%

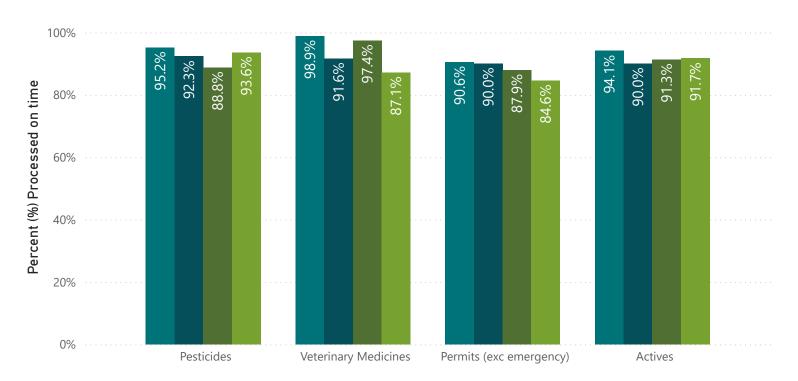
Table 8: Certificates of export (1 Oct - 31 Dec 2024)

	Received	In Progress	Processed	Issued	Processed on time (%)
Certificates	130	11	164	161	79.3%

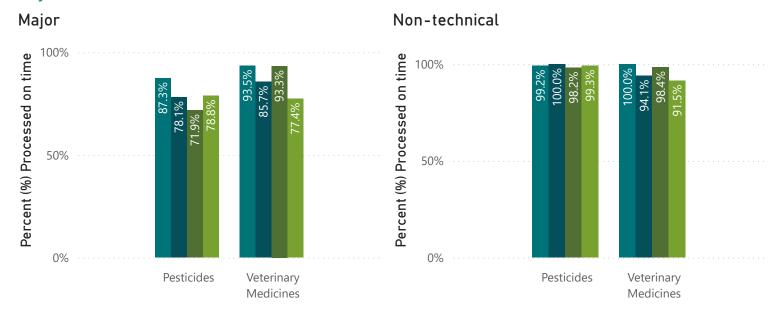
Application in detail

Timeframe Performance

● 2023 - 24 Q3 ● 2023 - 24 Q4 ● 2024 - 25 Q1 ● 2024 - 25 Q2

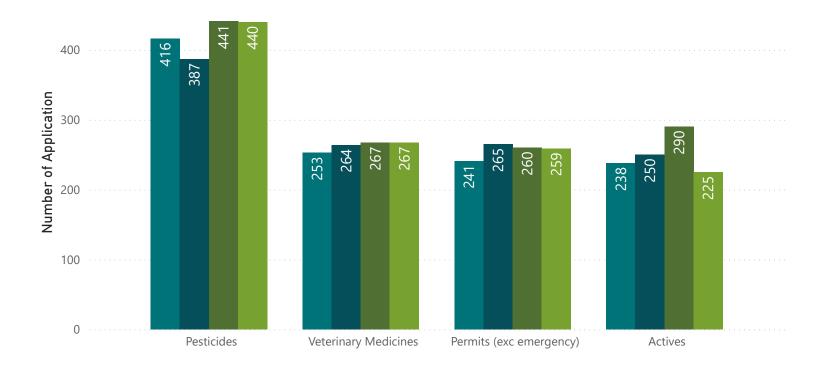


Major vs Non-Technical Performance



Work in Process

● 2023 - 24 Q3 ● 2023 - 24 Q4 ● 2024 - 25 Q1 ● 2024 - 25 Q2



Application by item number

All applications

Table 9: All applications by Item Number (1 Oct - 31 Dec 2024)

Тур	e of application	Received	In Progress	Processed	Processed on time (%)
	Products	358	707	359	90.5%
	1	1	1	1	100.0%
	2	3	25	3	33.3%
	3	0	0	0	N/A
	4	0	0	0	N/A
	5	6	22	4	100.0%
	6	1	8	4	75.0%
	7	79	104	70	91.4%
	8	28	23	33	97.0%
	9	0	0	0	N/A
	10	28	159	29	75.9%
	10A	13	13	4	100.0%
	11	2	3	1	0.0%
	12	78	119	90	95.6%
	13	2	6	7	100.0%
	13A	62	27	50	100.0%
	14	55	161	61	80.3%
	27	0	35	2	100.0%
	27V	0	1	0	N/A
	Actives	80	225	145	91.7%
	1	1	1	1	100.0%
	2	3	25	3	33.3%
	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	2	0	N/A
	16	0	1	0	N/A
	17	52	139	99	93.9%
	18	3	8	5	100.0%
	24	13	24	25	88.0%
	24V	8	8	11	90.9%
	27	0	17	1	100.0%
	27V	0	0	0	N/A
	Permits	135	271	140	84.6%
	19	1	1	10	100.0%
	20	67	86	58	86.2%
	21	34	140	37	78.4%
	22	19	12	23	N/A
	23	14	30	12	83.3%
	112A	0	2	0	N/A
	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	573	1203	644	89.7%

Pesticide applications

Table 10: Pesticide applications by item number (1 Oct - 31 Dec 2024)

Type of application	Commenced	In Progress	Finalised	Processed on time (%)
□ Products	187	440	188	93.6%
1	0	1	0	N/A
2	1	8	1	0.0%
3	0	0	0	N/A
4	0	0	0	N/A
5	5	16	4	100.0%
6	1	6	4	75.0%
7	47	59	47	100.0%
8	19	14	27	100.0%
9	0	0	0	N/A
10	20	124	17	82.4%
10A	4	4	4	100.0%
11	2	3	1	0.0%
12	47	77	51	98.0%
13	2	6	7	100.0%
13A	0	0	0	N/A
14	39	109	24	79.2%
27	0	12	1	100.0%
27V	0	1	0	N/A
Permits	98	214	110	84.5%
19	0	0	10	100.0%
20	51	63	52	86.5%
21	27	120	30	76.7%
22	13	10	13	N/A
23	7	19	5	80.0%
112A	0	2	0	N/A
Other	0	0	0	N/A
24	0	0	0	N/A
Total	285	654	298	90.5%

Veterinary medicines applications

Table 11: Veterinary medicines applications by item number ($\frac{1}{2}$ Oct - $\frac{1}{2}$ Dec $\frac{2024}{2}$)

Type of application	Commenced	In Progress	Finalised	Processed on time (%)
☐ Products	171	267	171	87.1%
1	1	0	1	100.0%
2	2	17	2	50.0%
3	0	0	0	N/A
4	0	0	0	N/A
5	1	6	0	N/A
6	0	2	0	N/A
7	32	45	23	73.9%
8	9	9	6	83.3%
9	0	0	0	N/A
10	8	35	12	66.7%
10A	9	9	0	N/A
11	0	0	0	N/A
12	31	42	39	92.3%
13	0	0	0	N/A
13A	62	27	50	100.0%
14	16	52	37	81.1%
27	0	23	1	100.0%
27V	0	0	0	N/A
Permits	37	57	30	85.0%
19	1	1	0	N/A
20	16	23	6	83.3%
21	7	20	7	85.7%
22	6	2	10	N/A
23	7	11	7	85.7%
112A	0	0	0	N/A
Other	0	0	0	N/A
24	0	0	0	N/A
Total	208	324	201	86.9%

Average decision time

All applications

Table 12: All applications by Item Number (1 Oct - 31 Dec 2024)

	Standard			Extended			
Type of Application	Finalised	Average	Assessment	Finalised	Average	Assessment	
		Duration	Period		Duration	Period	
□ Products	275	3.2		84	10.9		
 1	1	N/A	18	0	N/A	25	
2	1	0.3	5.9	2	22.6	20.0	
3	0	N/A	18	0	N/A	25	
4	0	N/A	18	0	N/A	25	
5	0	N/A	8	4	11.9	12	
6	1	7.8	8	3	20.2	12	
7	58	2.9	3	12	5.5	5	
8	32	2.6	3	1	5.0	5	
9	0	N/A	2	0	N/A	4	
10	11	4.3	4.4	18	12.4	11.4	
10A	4	1.9	2.0	0	N/A	~	
11	0	N/A	10	1	22.7	14	
12	82	2.9	3	8	4.7	5	
13	7	2.4	3	0	N/A	5	
13A	50	0.7	1	0	N/A	2	
14	28	10.3	10.3	33	11.5	9.5	
27	0	N/A	N/A	2	25.2	25.3	
27V	0	N/A	~	0	N/A	~	
Actives ■ Actives	99	6.1		46	9.6		
<u> </u>	1	N/A	18	0	N/A	25	
2	2	13.0	14.5	1	19.3	17.1	
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	64	6.3	7	35	9.4	10	
18	4	5.5	7	1	N/A	10	
24	17	3.6	4.3	8	9.6	9.3	
24V	10	3.7	0.0	1	6.2	0.0	
27	1	37.6	37.7	0	N/A	N/A	
27V	0	N/A	~	0	N/A	~	
─ Permits	115	3.4		25	7.7		
	10	2.9	3	0	N/A	5	
20	53	3.1	3	5	6.6	5	
21	25	5.4	5.4	12	9.2	12.6	
22	18	1.2	N/A	5	6.5	N/A	
23	9	4.8	5.2	3	4.4	6.0	
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	~	
		N/A		0	N/A		
28	0	N/A	~	0	N/A	~	
29	0	N/A	~	0	N/A	~	
Total	489	3.8		155	10.0		

 $[\]sim$ = 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.

Pesticide product applications

Table 13: Pesticide product applications by Item Number (1 Oct - 31 Dec 2024)

		<u>'</u>	,	,		
	Standard			Extended		
Type of Application	Finalised	Average Duration	Assessment Period	Finalised	Average Duration	Assessment Period
□ Products	152	3.0		36	14.6	
1	0	N/A	18	0	N/A	25
2	0	N/A	~	1	19.3	17.1
3	0	N/A	18	0	N/A	25
4	0	N/A	18	0	N/A	25
5	0	N/A	8	4	11.9	12
6	1	7.8	8	3	20.2	12
7	46	2.8	3	1	2.7	5
8	27	2.5	3	0	N/A	5
9	0	N/A	2	0	N/A	4
10	6	3.4	3.5	11	13.9	12.4
10A	4	1.9	2.0	0	N/A	~
11	0	N/A	10	1	22.7	14
12	51	2.8	3	0	N/A	5
13	7	2.4	3	0	N/A	5
13A	0	N/A	1	0	N/A	2
14	10	7.6	6.9	14	13.0	10.7
27	0	N/A	N/A	1	37.5	37.6
27V	0	N/A	~	0	N/A	~
□ Permits	96	3.5		14	6.7	
19	10	2.9	3	0	N/A	5
20	49	3.1	3	3	8.4	5
21	23	5.5	5.5	7	7.6	11.3
22	11	1.0	N/A	2	4.3	N/A
23	3	8.2	5.5	2	3.3	4.0
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	248	3.2		50	12.2	

 $[\]sim$ = 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.

Veterinary medicine product applications

Table 14: Veterinary medicine product applications by Item Number (1 Oct - 31 Dec 2024)

Table 11. Vetermary medicine product apprearions by				1	C. (<u>1 Occ</u>	<u> </u>	
	Standard			Extended			
Type of Application	Number	Average	Assessment	Number	Average	Assessment	
	processed	duration	period	processed	duration	period	
□ Products	123	3.3		48	8.8		
1	1	N/A	18	0	N/A	25	
2	1	0.3	5.9	1	25.8	23.0	
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	12	3.2	3	11	5.7	5	
8	5	3.1	3	1	5.0	5	
9	0	N/A	2	0	N/A	4	
10	5	5.3	5.2	7	10.6	10.3	
10A	0	N/A	~	0	N/A	~	
11	0	N/A	10	0	N/A	14	
12	31	2.9	3	8	4.7	5	
13	0	N/A	3	0	N/A	5	
13A	50	0.7	1	0	N/A	2	
14	18	11.2	11.5	19	10.6	8.8	
27	0	N/A	N/A	1	12.9	13.0	
27V	0	N/A	~	0	N/A	~	
□ Permits	19	2.4		11	8.9		
19	0	N/A	3	0	N/A	5	
20	4	3.1	3	2	4.8	5	
21	2	4.3	5.0	5	11.1	14.0	
22	7	1.4	N/A	3	8.6	N/A	
23	6	2.6	5.0	1	6.6	10.1	
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	142	3.2		59	8.8		

 $[\]sim$ = 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 Agyet 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.

Glossary of term

Table 15: Glossary 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 a pesticide 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.
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 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.
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 pesticide or veterinary medicine or for an off-label use of a registered pesticide 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.
Processed	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.
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.