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Independent Review of Assessment Performance

REPORT

AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

FINAL

22 DECEMBER 2017

BUSINESS PERFORMANCE SPECIALISTS

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EXECUTIVE SUMMARY

Independent Review

Reason Group undertook an independent review of the Australian Pesticides and Veterinary Medicines Authority's (APVMA's) assessment performance. Data was analysed and interviews undertaken with key personnel. The observations and opportunities were determined based on these interviews, research and data analysis from the APVMA's own portal. Recommendations were developed to assist the APVMA improve performance of agricultural and veterinary (agvet) chemical assessment and registration activities.

KPI Reporting

APVMA assessment timeframes are statutory and a target of 100% is expected, however, APVMA has rarely met this target. Public and industry interest in the APVMA's performance is overwhelming, with much commentary surrounding each quarterly report. Since the implementation of reforms in 2014, a number of reports have been commissioned to review specific subsets of APVMA assessment performance and to identify areas for improvement. Internationally, similar agencies are also challenged in meeting their performance targets in an environment of increasing assessment complexity. These agencies have undertaken a variety of reforms.

Reforms to Improve APVMA Performance

Reform of APVMA assessment performance largely depends on changing how the organisation responds to poor quality submissions (notably responses to non-frequent applicants) and changes to assessment processes (which may require regulatory support). There are a number of initiatives underway at the APVMA that will support the improvement of assessment timeframes and make it easier for industry to submit better quality applications. These initiatives have been listed alongside the detailed recommendations developed in this report and include improvement to APVMA guidance documentation as well as the development of ICT systems to better support assessment workflow and reporting.

OBSERVATIONS

- Ability to report timeframe performance to Parliament is at risk due to the manual process undertaken each quarter. Currently the business systems within the APVMA do not support dashboard reporting. Extensive effort is required to undertake specific reports on assessment times and status. Engagement showed APVMA ICT systems lack organisation-wide workload management capability and application status reporting, which could inform priorities and provide better visibility of assessment activities, overdues, client history and other indicators
- The top 38 applicants account for over 50% of the assessments, there are over 800 applicants that make up the remaining assessments. More frequent applicants tend to have their applications assessed within legislated timeframes and are higher quality applications. This results in the Authority assisting industry beyond what legislators anticipated, when timeframes were set. The additional effort contributes to the APVMA's unsustainable operational losses and unmet targets
- The large backlog of overdue or on-hold applications diverts significant resources away from new applications. There is no incentive to complete overdue applications. The APVMA has recently made gains in the assessment time of some items by focussing on backlog reduction and improving resourcing
- Recategorisation occurs when clients submit a product for registration as one item, or assessment level, and then it is recategorised to another. Currently recategorisation of applications occurs late in the evaluation process, resulting in less time being available for the technical assessment. Recategorised assessments contribute significantly to unmet performance targets
- Guidance material and legislation is applied in a very prescriptive manner, rather than applying the objectives of the Act (which would allow for flexibility in the application of the modules). For example, the APVMA required four days to determine whether dog toothpaste should be registered
- Previous decisions and conservative legal advice have resulted in a low appetite for risk across the organisation. The delegation level required to approve and finalise registration has been raised, increasing the time to complete assessments. There are also inconsistencies in how assessors summarise and approve their module assessments, with some delegates having to read the whole report and revise the summary findings, before approving

EXECUTIVE SUMMARY CONTINUED

Analysis of International Regulatory Agencies

It is difficult to directly compare performance of regulatory bodies due to the different regulatory systems, fee structures and levels of scientific rigour in place. While comparison across jurisdictions is difficult, there is evidence to suggest that the performance issues being experienced by the APVMA are also challenging for other international regulatory bodies. No other registration system we reviewed reports its performance as frequently as Australia. The published quarterly performance statistics are a commitment made by the APVMA as part of the Australian Government's Regulator Performance Framework (sections 5.1.a and 5.1.b). These performance metrics are developed through consultation with industry and agreed by the Minister. The Canadian Veterinary Drugs Directorate (VDD) reports average time taken to process applications. This may be a more representative way of reporting regulatory system performance, as it reduces the effect low quality and complex applications have on statistics.

Increasing Assessment Complexity

An increase in assessment complexity over the last five years has been reported by international counterparts and confirmed by APVMA assessors. For example, at the APVMA, the mean Residue Complexity Index (ROCI) almost doubled between 2009 and 2016. This demonstrates that the type of residue assessments now being undertaken by the APVMA, require more time and expertise than they did in 2009. Some regulators charge for actual time taken to process applications, unlike the APVMA's fixed fees which do not allow for increasing complexity and assessment effort. Technical completeness reviews of data prior to the acceptance of the application (when the regulatory clock starts) is also common internationally, however not currently utilised by the APVMA. Australia is also the only registration system we reviewed in which regulatory clocks do not stop, whilst awaiting information from the applicant.

The Use of External Scientific Services

The use of third parties, with peer review and approval by the regulator, has provided efficiencies for international agencies. Efficiencies have also been gained through the acceptance of assessments performed by other regulators and joint initiatives between free trade agreement partners.

RECOMMENDATIONS

Improve the use of regulatory instruments:

- Empower and train APVMA assessors and risk managers in the application of the legislation and regulatory guidelines. Legal officers to provide lessons learned and feedback to staff from overturned decisions
- Encourage quality applications through better use of refusals and requests for information. Refuse poor quality applications through the use of existing provisions of the Act (8S and 8G)
- Develop a more efficient model for using external scientific services
- Provide a list of regulatory consultants to low frequency clients and strongly encourage applicants to use regulatory consultants when submitting applications that require modular assessments
- Strongly recommend Pre-Application Assistance (PAA) for modular items, like item 10 assessments, to reduce recategorisations
- Implement a risk return model for processing of applications where high quality/lower risk applicants are expedited through the assessment process

Build more efficient processes for assessments:

- Restructure resources to address the backlog of overdue assessments
- Allocate resources early in the evaluation planning phase to only focus on new applications and ensure categorisation is accurate
- Link applications with client history so that repetitive non-compliance can be tracked and new applications reviewed using intelligence
- Allow assessors to make approval decisions for module assessments and reduce the time the delegate needs to finalise the report. Assessors to summarise assessments better, for use in the decision document

Modify legislation, regulatory instruments and cost recovery measures

- Simplify legislation to reduce decision making obligations
- Move time frames and fees from the Agricultural and Veterinary Chemicals Code Regulations 1995 to subordinate legislation. Report only annually
- Review and if necessary change fees and levies to reflect the increasing complexity of assessments and the associated additional effort and expertise

Introduction

Why this work?

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INTRODUCTION

Agricultural chemicals, valued at approximately $3 billion, are sold each year in Australia. The National Registration Scheme, which is established under Commonwealth, state and territory legislation regulates the sale and use of these chemicals. Under the scheme, the APVMA is responsible for regulating the supply of agvet chemicals through to the point of sale. The key regulatory activities that are undertaken by the APVMAinclude:

- assessing and registering agvet products
- approving active chemical constituents
- issuing permits and licences
- monitoring compliance with registration, permit and licence conditions
- investigating suspected non-compliance

WHY THIS WORK?

Recent reports demonstrate that the APVMA has experienced unpredictability and volatility in meeting timeframes. Timeframes are statutory and a target of 100% is expected[1], however, the APVMA has rarely met this target[2]. Public and industry interest in the APVMA's performance is overwhelming, with much commentary surrounding each quarterly report. Since the implementation of reforms in 2014, a number of reports have been commissioned to review specific subsets of APVMA assessment performance and to identify areas for improvement. The APVMA has commissioned Reason Group to conduct an independent, comprehensive and evidence-based review of the drivers that influence and impact upon assessment performance and to identify organisation-wide changes that would enable the Authority to better meet its assessment timeframe targets. To do this, Reason Group has undertaken the following activities within the APVMA:

Phase 1: Analysis of APVMA Assessment Performance

- A root cause analysis of the drivers that influence and impact on assessment performance and regulatory functions, including the analysis of data availability, accuracy and integrity.
- Analysis of published assessment performance data (i.e. performance indicators outlined in APVMA Performance Framework[3]) to determine which items have the biggest impact on APVMA operational reporting. Noting that data relating specifically to APVMA assessment measures was the focus of our analysis. Therefore, the only relevant indicator for Phase 1 analysis is the Key Performance Indicator 1.3: Unnecessary impediments to the efficient operation of regulated entities are removed. Performance indicators 2, 4, 5 and 6 were excluded from the analysis as they focused on communication with regulated entities, compliance, transparency and continuous improvement, respectively. Performance indicator 3 was also excluded, as it focuses on ensuring that assessments are proportionate to regulatory risks and this does not impact assessment timeframes directly.

[1] Proof Committee Hansard Senate Rural and Regional Affairs and Transport Legislation Committee Estimates (Public) Tuesday, 24 October 2017 Canberra. [2] APVMA Annual Reports: 2015-16 and 2016-17.
[3] https://apvma.gov.au/sites/default/files/publication/27031-apvma-regulator-performance-framework-2015-16-self-assessment.pdf

INTRODUCTION- CONTINUED

During the data analysis, desktop review and stakeholder engagement activities of Phase 1, a number of opportunities for improvement were identified. These were then translated into three key recommendations during Phase 2.

Phase 2: Development of Future State.

Reason Group has undertaken the following activities within the APVMA during Phase 2 of the review:

- designed a preferred future state of assessment performance
- provided recommendations to address key findings
- engaged key stakeholders to test and refine the three recommendations

Phase 3: Review of Comparable Agencies' Performance (Phase 3). The findings from Phase 3 were used to finalise this report and refine the recommendations.

This report opens with the key comparative criteria and findings from Phase 3 to inform readers that providing timely registration of agvet chemicals, to enable agricultural competitiveness, is a challenge experienced globally.

International comparisons

Findings from the review of comparable agencies' performance (Phase 3)

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INTERNATIONAL COMPARISONS > KEY COMPARITIVE CRITERIA

The following table provides key criteria that should be taken into account when comparing the performance of the Australian agvet registration system to that of other jurisdictions. Due to the very different regulatory systems, fee structures and levels of scientific rigour in place across the various agencies, the use of performance statistics in isolation should be performed with caution.

	Australia APVMA	New Zealand EPA	New Zealand MPI	Canada PMRA	Canada VDD	European Union Plant Protection Products	Japan FAMIC	Brazil
Time frame (min – max)	1-25 calendar months (30-750 days)	10-100 working days	40 working days	80-737 calendar days	2-300 calendar days	2.5 to 3.5 years (912.5-1277 days)	Up to 2 years (up to 730 days)	120 days
Location	Statutory	Statutory	Statutory	Policy	Statutory	Statutory	Statutory	Statutory
Third parties	Regulatory consultants Panel appointed assessors		Registration consultants Accredited Assessors	Grower Requested Own Use (GROU) Committee		Consultants		
Performance target	100%	100%	100%	90%	100%	100%	100%	100%
Recent performance	69% 2016/17	100% 2015/16	55% (approx.) June 2017	Category A 87% Category B 88% Category C 95% 2015/16	Within service delivery standard for 7/9 application types 2015/16	EFSA: 75% (2016) RMS: "delays are commonplace" [1]		Can be up to 6 years[2] Backlog of 6 x those evaluated
Pre-assessment	Administrative		Administrative and	Administrative and				
Reporting requirements	Quarterly	Annual	As required	Annual	Annual			
Reporting mechanism	Parliament	Annual Report	Industry focussed newsletter	Parliament	Parliament			
Statutory clock	Extension of time for requests for information	Clock stops Can request extensions	Clock stops	Clock stops	Clock stops	Clock stops for requests for information	Rejected if issue not addressed within 1 month	
Review period	Risk based			15 year cycle		Risk based not exceeding 15 years		Risk based triggers

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products
[2] Chemlinked, Brazilian Pesticide Regulation Overview, March 13, 2017

It is difficult to directly compare performance of regulatory bodies due to the different regulatory systems, fee structures and levels of scientific rigour in place. While comparison across jurisdictions is difficult, there is evidence to suggest that the performance issues being experienced by the APVMA are also challenging for other international regulatory bodies.

No other registration system we reviewed reports its performance as frequently as Australia. The published quarterly performance statistics are a commitment made by the APVMA as part of the Australian Government's Regulator Performance Framework (sections 5.1.a and 5.1.b). These performance metrics are developed through consultation with industry and agreed by the Minister. The Canadian Veterinary Drugs Directorate (VDD) reports average time taken to process applications. This may be a more representative way of reporting regulatory system performance, as it reduces the effect low quality and complex applications have on statistics.

An increase in assessment complexity over the last five years has been reported by international counterparts and confirmed by APVMA assessors. For example, at the APVMA, the mean Residue Open Complexity Index (ROCI) almost doubled between 2009 and 2016. This demonstrates that the type of residue assessments now being undertaken by the APVMA, require more time and expertise than they did in 2009. Some regulators charge for actual time taken to process applications, unlike the APVMA's fixed fees which do not allow for increasing complexity and assessment effort.

Technical completeness reviews of data prior to the acceptance of the application (when the regulatory clock starts) is also common internationally, however not currently utilised by the APVMA. Australia is also the only registration system we reviewed in which regulatory clocks do not stop, whilst awaiting information from the applicant.

The use of third parties, with peer review and approval by the regulator, has provided efficiencies for international agencies. Efficiencies have also been gained through the acceptance of assessments performed by other regulators and joint initiatives between free trade agreement partners.

The scheduling of re-evaluations is used by Canada and the EU to ensure that products meet updated criteria.

Engagement of the APVMA with international comparative agencies on the following topics will be critical in achieving improved performance:

- Engage with European Union, Canadian and New Zealand regarding their strong regulatory stances/postures
- Investigate the New Zealand Agricultural Compounds and Veterinary Medicines Registration Review Project
- Monitor the outcomes and actions from the 2016/17 audits in the European Union
- Monitor the European Union Pesticide Legislation Review (2017-19)
- Continue to contribute to OECD agvet chemical initiatives

Drivers of Assessment Performance

Identification of drivers of APVMA assessment performance

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DRIVERS > IDENTIFICATION OF DRIVERS IMPACTING THE PERFORMANCE OF APVMA ASSESSMENTS

To identify drivers that are impacting the APVMA's key assessment performance indicators, the following activities were undertaken:

- analysis of assessment volumes and operational data
- desktop review of documentation, including previous audits and reports
- engagement with APVMA staff

We were able to identify the assessment types that represent the largest volume of late assessments and that significantly impact the achievement of KPI 1.3. Further analysis of these item numbers shows that there are also backlogs of assessments for these types. Assessments of new applications were being impeded by the large backlog (especially for items 7 and 8). In addition, we found a cohort of the high volume items were modular and recategorised frequently (items 10, 14 and 21). See the Agvet Code Regulations 1995 for more detailed descriptors of these items.

Engagement showed a lack of organisation-wide workload management and application status reporting which could inform priorities and provide better visibility of assessment activities, overdues and other indicators. It was observed that there was a lack of sophisticated ICT systems to enable workflow, capture client information and simplify reporting. Some assessment modules have better processes and systems for prioritising than others. For example residues use a complexity measure called 'ROCI' to prioritise assessments, support work forecasting and report on team performance. These observations are supported by previous reviews and audits [1,2].

Analysis of clients and number of applications submitted, showed that there are a smaller number of frequent users of APVMA regulatory services and that a long tail of clients, who seldom submit applications, exist. This long tail of clients have longer assessment times due to lower quality submissions and require more engagement with the APVMA. These clients could be differentiated from the frequent users and offered a more tailored service to meet regulatory outcomes. These lower quality applications contribute to the high volumes of incorrectly categorised submissions.

We also observed that the legislation is significantly impacting how assessment processes are undertaken. For example, the assessment clock is not stopped when the client is responding to APVMA notifications and requests. This is a worldwide anomaly and a result of the 2014 legislative reform. If an additional module assessment is required, the additional time is not added on top of the existing timeframe, but is added back in time when payment was made. This results in extended assessment times. The legislation requires the APVMA send a "letter of request" to reject a submission, called an 8S. Justifying a rejection is very time consuming and the client can dispute the rejection, drawing out the assessment time past the legislated timeframe and adding to unrecovered costs.

The three drivers identified as impacting the attainment of assessment KPIs are:

- Assessment backlogs
- Incorrect categorisation of items and module levels by clients (i.e. large numbers of recategorisations)
- Legislation

[1] The Auditor-General ANAO Report N0. 56 (2016-17). Performance Report: Pesticide and Veterinary Medicine Regulatory Reform [2] Registration Process Analysis. Final Report (February 2015). SMS

DRIVERS > ASSESSMENT BACKLOGS

BACKLOG OF HIGH VOLUME ASSESSMENTS

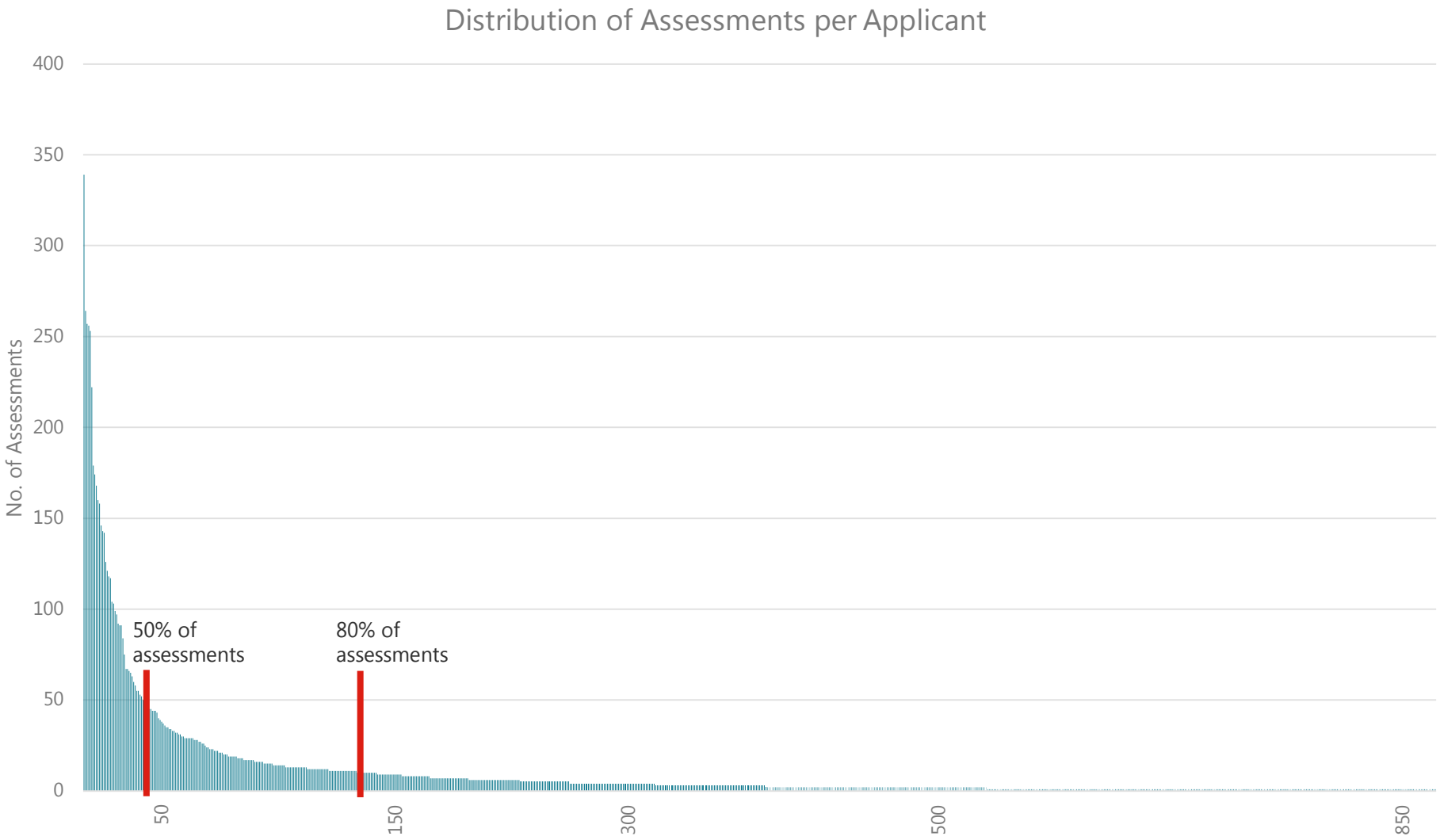
- The term "Backlog" refers to assessments that are either in-progress or overdue. Backlog assessments have been through evaluation planning and are either waiting to be progressed and are in a queue, or are overdue and have passed the legislated timeframe. Resources for high volume assessments (like items 7, 8 and 12) do not require highly qualified staff. New or graduate level staff could be trained quickly to undertake these assessments. Allocation of staff to progress overdue or 'in-progress' assessments, is required to drive backlog reduction across the high volume submissions. Currently analysis is underway as a priority, for defining improvements to the Notifiable Variations (NV) and label change processes and systems. ICT system improvements are required for better managing label changes and to streamline processes for clients and APVMA staff. Currently clients are not notified about assessment delays or provided with an estimated time of completion
- Prioritisation is not managed as well, or as consistently, as it could be across the organisation. The complex dependency of module assessments requires better workflow management across APVMA sections. The lack of tracking and reporting capability by the current ICT systems, does not allow forecasting of resources, technical specialists and external scientific services
- The approach for enlisting external scientists appears to be complex. A general lack of trust for the work undertaken by external scientific services could be mitigated through APVMA developing better guidance material and training
- Large volumes of lower quality submissions from clients who only submit applications occasionally increase recategorisations, backlogs and requests for more information. Note the following two slides showing the submission volume and long client tail

EVIDENCE FROM ENGAGEMENT AND ANALYSIS

- Items 7, 8, 10 and 12 accounted for about 50% of the delayed assessments in 2015-16FY. In particular, there were 196 item 7 and 145 item 8 submissions in 2015-16. Items 7 and 8 are applications for registering new products that contain existing actives and which are not complex or modular. A backlog of items 7 and 8 have resulted in increased processing times as staff are too busy processing the backlog to focus on new assessments
- Chemistry assessment backlog volume is high, as chemistry is the most common module across all assessment items. From a volume perspective, chemistry assessments were the highest number overdue (where the average assessment period for a module was greater than the total legislated period for the application) - at 252 applications (represents 9% of all chemistry assessments). Toxicology assessments have the highest percentage of overdue assessments at 21%, but this represents only 91 applications
- NVs require a significant amount of APVMA staff time and are processed inefficiently due to system and data entry limitations. Currently there is no system for enabling rapid processing of label changes. APVMA staff need to re-verify the correctness of the whole label and not just the change
- The 'Top 20' workshop with industry confirmed that the generic application types (including items 6, 7 and 8) were a high priority for improved guidance
- Around 50% of applications for permits or product registrations are from only 38 clients while the remaining 50% are from over 850 clients [See graphs on following two pages]
- Large variations in the time taken to process applications occur within item numbers and assessment modules. For example, item 17 applications varied from 188 days (for an applicant that had submitted 150 applications) to 69 days (for an applicant that had submitted 57 applications)

DRIVERS > ASSESSMENT BACKLOGS

Eight hundred and eighty seven applicants submitted over 11,000 applications to the APVMA from July 2014 to September 2017. During this time, there were 9677 assessments undertaken by APVMA, with 179 applicants submitting 80% of all assessments and 38 applicants submitting over 50% of the assessments. There is a very long 'tail' of applicants that individually submit a small number of applications infrequently.



DRIVERS > ASSESSMENT BACKLOGS

The graphs below show that there are clients who submit large volumes of assessments and a long tail of clients who submit few assessments each year. The top 4 clients have average assessment durations that are within time frames, particularly for item 10 assessments (Figure A), which are complex and often require multiple modules of assessment. Note that the **orange** line in the graphs below should be on or below the **yellow** line if the assessments are within the legislated timeframes and are meeting the performance target.

Figure A – Item 10 (Modular and Complex Assessment)

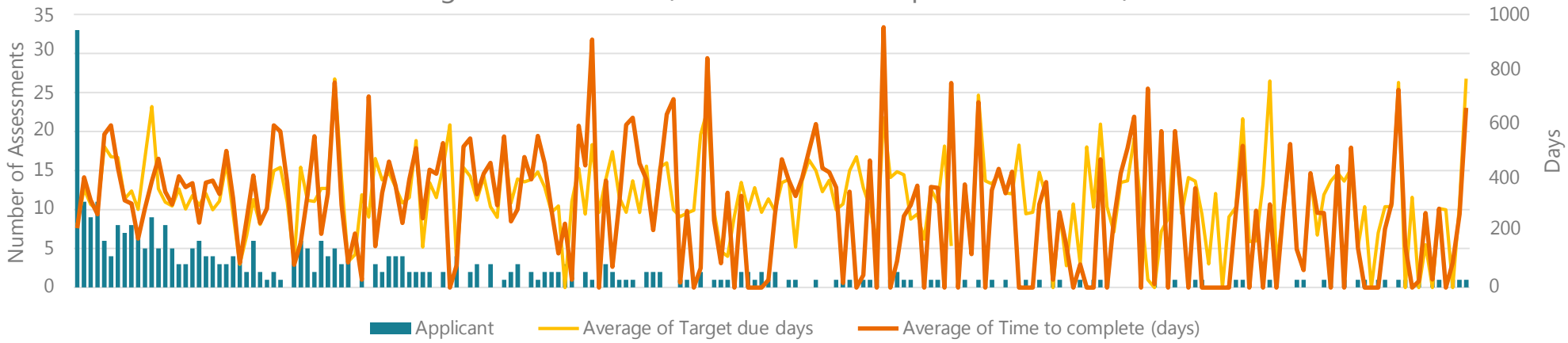
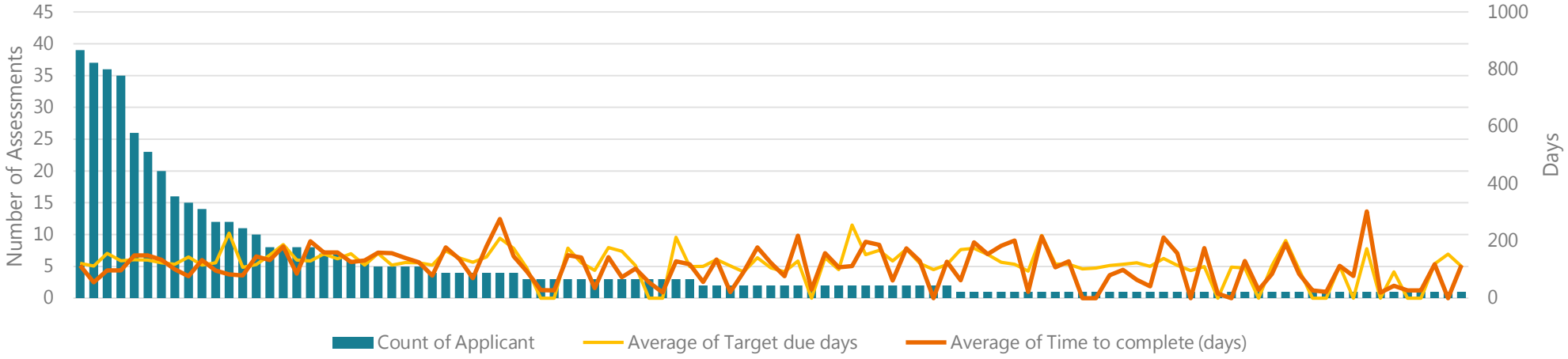


Figure B – Item 8 (Simple Assessment)



DRIVERS > INCORRECT CATEGORISATION

RECATEGORISATIONS

- The recategorisation of some high volume modular applications (like items 10, 14 and 21) is occurring after the evaluation planning phase and often months after the assessment has started. Other internal reviews have discussed similar findings[1]. Rejections do not occur for these applications as the client has provided the data. However, the technical risks and requirements have not been identified early enough to ensure the right assessments have been requested and the correct module levels are applied. This occurs for the following reasons:
  - Online guidance and data directions are not clear and do not enable clients to identify the module level easily leading to more recategorisations. Item 10 assessments are quite complex in nature and the option for clients to use a consultant, or the Pre Application Assistance (PAA) service, to submit applications to the APVMA should be promoted. Expert support prior to the clock starting, should reduce recategorisations
  - Risk assessment staff experience is mixed, this means that module levels and assessment classification are not always correct. In addition, the guidance and data requirement specifications are not adequate for risk assessors to complete their activities effectively, during the evaluation planning phase (within one month after payment and from when the assessment clock starts)
  - Module assessors are not analysing the data early enough to verify the module level accurately. This is due to backlogs (especially in Chemistry) and a lack of prioritisation processes across the assessment teams, particularly for multiple-module assessments like item 10s. There are no dedicated module assessment resources for screening new applications, early in the evaluation planning phase, so that requests for more information, or for recategorisation, can occur promptly

EVIDENCE FROM ENGAGEMENT AND ANALYSIS

- 32% of recategorisations were item 10s, 28.6% were item 14s, 18.5% were item 21s. These three items are modular assessments and represent ¾ of all recategorisations. The recategorisations are mainly happening within an item [i.e. occurring at the level of the module assessments]. For example: a level 3 toxicology assessment is getting recategorised to a level 2. Refer to graphs on next slide
- The median time for recategorisation to occur for item 10s is 2.52 months after the clock starts (over 10 weeks). There has been about a 30% decrease in the mean recategorisation time of item 10s since 2015, but the time to recategorise remains too high to enable the timeframe to be met
- The lateness of item 21 (minor use permits) recategorisation has worsened since 2015. There is a business system change underway to make Efficacy and Safety Level 3 (8.3) automatic as part of this module for all item 21 permits. Module assessments (including Chemistry and Efficacy) have a mean time that is significantly longer than legislated timeframes
- There are issues with safety and efficacy being connected under one module. The safety aspects of an application might indicate a level 3 assessment is required, whereas the efficacy might require a level 2. There are plans to mitigate this confusion, through splitting safety and efficacy
- Applicants believe that the less things they tick in the application, the quicker the assessment will be. Rejection of the application during the evaluation planning phase, early after the clock starts, might help clients to be more diligent in the future, when categorising assessments

[1] The Auditor-General ANAO Report N0. 56 (2016-17). Performance Report: Pesticide and Veterinary Medicine Regulatory Reform

[1] Registration Process Analysis (2015). Final Report [SMS]

DRIVERS > INCORRECT CATEGORISATION

The graphs below show the high volume assessment items (10, 14 and 21). These three items require modular assessments and represent about 30% of all assessments. Item 10 overdues have the highest rates of overdue items (2015-16 data and supported by 2017 data) (Figure A).

Together, items 10, 14 and 21 accounted for over 75% of all recategorisations, since 2015 (Figure B). Item 10 represents the most recategorised item, with the majority of item 10 recategorisations occurring within item 10, requiring an additional module or change to the module level, late in the assessment timeframe (after the 4 weeks evaluation planning phase).

Figure A – % of assessments started and overdue

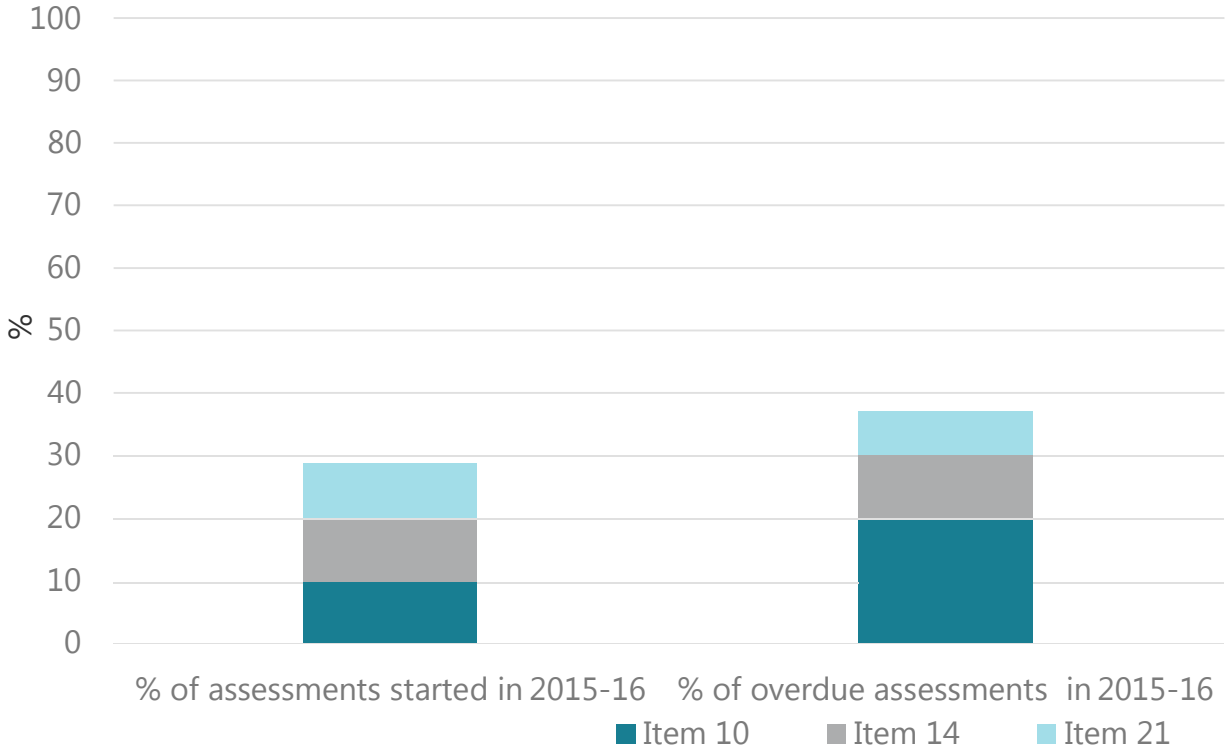
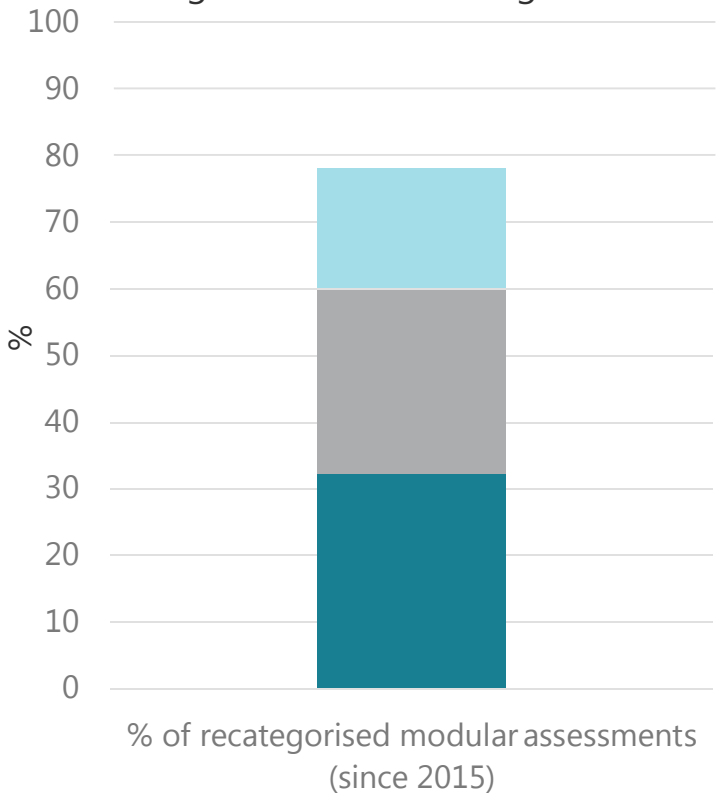


Figure B – % of recategorised



ASSESSMENT TIMINGS, REJECTIONS AND RULES

- The Department of Agriculture and Water Resources amends the policy and regulatory instruments the APVMA administers. Legislative reform has enabled applicants to submit their applications online, since 2014. However, APVMA systems do not support internal workflow. Direct transfer of records and data between assessment staff is not optimal
- The changes to the APVMA legislation in 2014 meant that the assessment clock does not stop when the APVMA is waiting for the client to respond to a notification, or to provide additional data. Changes to remove clock stoppages in 2014, aimed at giving industry more certainty around assessment times, have failed to deliver. Assessment data continues to show large fluctuations in assessment times for simple assessments
- The inclusion of module assessment timings within the legislation does not allow the APVMA to modify timings, as assessment complexity increases, agvet technology modernises and crop coverage increases
- The PAA scheme was developed as part of the legislative reform, but does not include the analysis or review of assessment data (evidence). PAA may need to be extended to include data submission and technical analysis, so that the categorisation of module levels and assessment types is improved
- The appetite within the APVMA to use an 8S notice (proposal to reject) is low, due to the effort required and the potential for extended legal dispute. Previous decisions and conservative legal advice have resulted in a low appetite for risk across the organisation
- The complexity of the agvet rules, guidance and legislation, makes it difficult for assessors to apply the objectives of the Act. This means that the rules are often applied in a very prescriptive manner. For example, the APVMA required four days to determine whether dog toothpaste should be registered

EVIDENCE FROM ENGAGEMENT AND ANALYSIS

- APVMA must send the client an "8S notice" which is more of a 'proposal to refuse' and allows the client to dispute the rejection. Considerable amount of effort is required to develop an 8S - staff are reluctant to initiate this process while the clock continues
- Since 2014, the assessment clock is not stopped when an S159 (request for more information from clients), recategorisation or 8S are with the client. The APVMA does not control the clock and time is lost during disputes, or when the client delays in responding to requests for information. Sample analysis of 16 item 10 assessments that were overdue between 2015 and 2017, showed that several S159's were recorded in the portal as taking six months to process. These would greatly impact APVMA's performance targets. Generally, there was a predominance of S159 activity for item 10s (which represent about 20% of all overdue assessments)
- The additional time required to undertake an additional module assessment (i.e. toxicology) is not added to the quoted assessment time but starts back in time, when the clock was initially started, just after payment. When this additional work is provided to assessment teams there is currently no clear prioritisation process
- A finding from the Phase 3 international analysis showed that the average evaluation time for UK assessments has increased by 70% from 2007 to 2015. This increase is most pronounced in some areas of evaluation such as efficacy, due to the greater number of crops/uses covered in each application and to the increasing complexity of environment fate evaluations[1]. At APVMA, the mean ROCI index used by Residues, almost doubled between 2009 and 2016

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products

Areas for improvement

How can the APVMA meet its targets and improve operational reporting?

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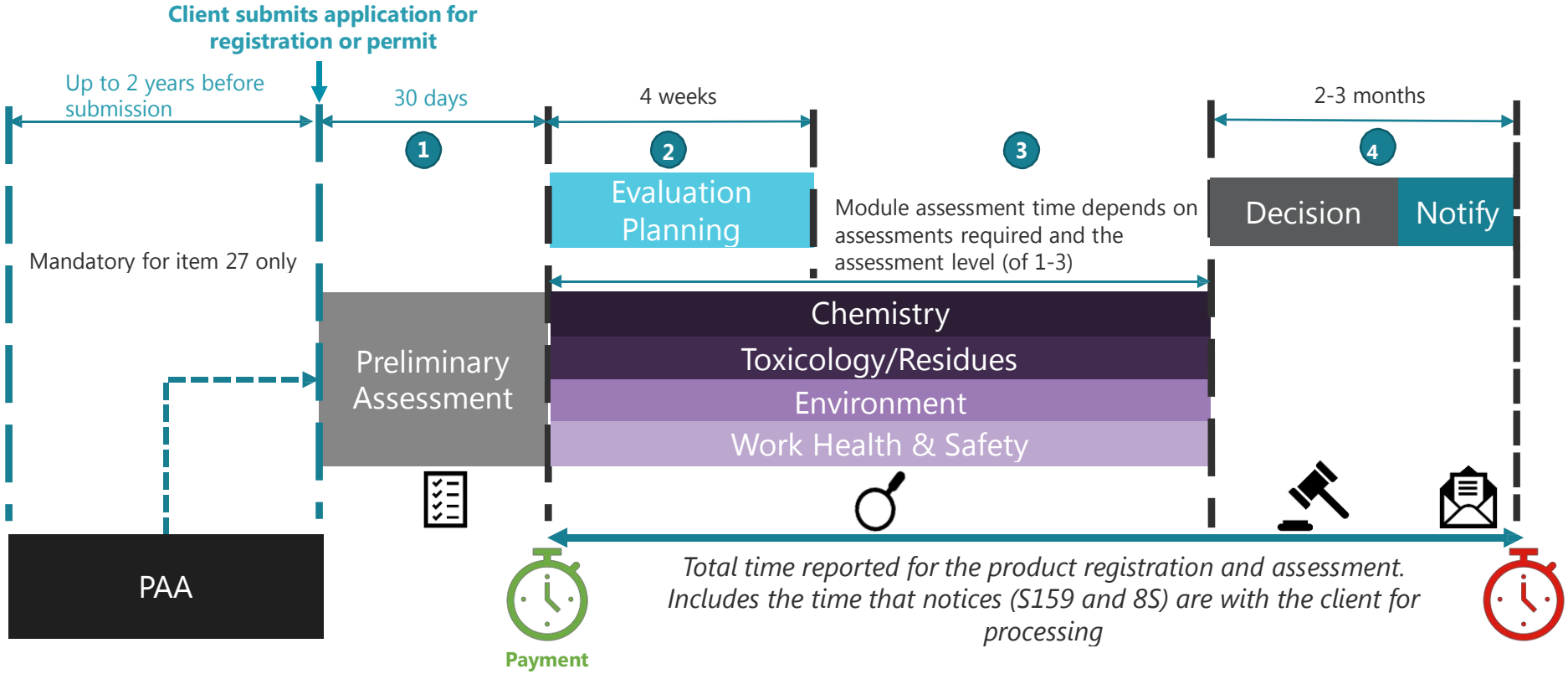
THE CURRENT APVMA ASSESSMENT PROCESS



1. Currently Preliminary Assessments (PA) are administrative only, applications can be rejected during PA using 8G, but because risk assessors do not review data during this time, this is seldom used to reject applications. PA is not currently being used optimally for workload management or prioritisation activities

2. The clock starts and assessments can be rejected in evaluation planning using an 8S, this is time consuming and requires notification of the client. Modular assessments are not currently being categorised correctly by clients and recategorisation is not occurring within the Evaluation Planning phase. Evaluation Planning is often extending past four weeks, there is a lack of prioritisation of submissions and backlogs prevent assessors from reviewing the data of the new applications, early in evaluation (within the four weeks)

3. High level of backlogs for some assessments result in delays for new assessments. In addition, S159 notifications can take six months to be progressed by clients. There is little inter-team management of complex modular assessments during this phase and reporting from the APVMA portal about priority assessments does not occur. Assessments are getting more complex with increases in agvet chemical uses and applications. The APVMA ICT systems do not support efficient workflow management

4. Decisions often require the delegate to revise the summary findings and cut and paste them into the decision document. This is inefficient and time consuming. An electronic form with pre-filled summaries of module assessments would fast-track decision making. There is no Quality Assurance Framework for assessments

OPPORTUNITIES FOR IMPROVING KPI 1.3 ACHIEVEMENT

Opportunities for the APVMA to improve its assessment performance range from improving guidance material and improving risk assessment processes to amending legislation and using more external assessors.

This table frames the opportunities across people, process, technology (which includes data and information) and legislation (Leg). The relevant recommendations are listed at the far right of the table (Rec).

We have harvested these opportunities from engagements and analysis, as outlined in pages 12-19.

These opportunities do not include system improvements already planned such as label changes to fast track notifiable variations, the changes underway to make efficacy and safety level 3 an automatic module for item 21s and the Streamlining Application Processes Project.

[1] The Auditor-General ANAO Report N0. 56 (2016-17). Performance Report: Pesticide and

		Change Impacts On:				
ID	**Opportunity**	**People**	**Process**	**Technology Data/Info**	**Leg**	**Rec**
1.	Prioritise applications based on the value of the product to Australia's agriculture market and use prioritisation tools for module assessments (like ROCI)	✓	✓	✓		**R2.3**
2	Improve the guidance and data requirement descriptions for industry, third parties and for APVMA staff (supported by ANAO Audit[1])	✓	✓		✓	**All**
3.	Require that PAA (level 2) is undertaken for all Item 10s, and/or any modular assessments. This should include data analysis activity. Alternatively, require that these assessments are submitted by regulatory consultants	✓	✓	✓	✓	**R1.3**
4.	Begin evaluation planning at day 7 of pre-assessment (before payment)-when data is available to start checking the categorisation of modules for assessment. Use 8G rejection at pre-assessment, if categorisation by the client is incorrect	✓	✓		✓	**R1.3**
5.	Each assessment team (Chem/Tox/Env etc) should have streamlined processes for screening new assessments so that data can be reviewed early in the assessment time. Dedicated staff should be used to streamline applications and to reduce backlogs. Managers should use the portal to support prioritisation and workload management	✓	✓	✓		**R2.3**
6.	Develop a strategy to define the use of regulatory consultants and external scientific service providers to undertake assessments and reduce backlogs for APVMA. How can the APVMA increase trust in third party assessors? Can APVMA train and certify them?	✓	✓	✓	✓	**R1.2**

Future State Recommendations

How does the APVMA get on track in an increasingly complex operating environment?

REASON GROUP

RECOMMENDATIONS

The APVMA has rarely met its assessment performance indicators (KPIs). The reason for not achieving 100% of legislated assessment timeframes is due to a number of operational factors including, incorrect categorisations, assessment backlogs and legislation changes.

The following recommendations result from the analysis undertaken and are based on the opportunities for improvement. The recommendations are mapped to the three drivers of assessment performance.

Each recommendation describes:

- Recommendation details;
- Key actions required;
- Outcomes of implementing;
- Dependency;
- Impact/Risks
- Feasibility, including complexity and priority
- Estimate timeline

The information within the recommendations is subject to executive considerations and review. They do not replace detailed execution plans. All recommendations require planning and stakeholder engagement prior to key actions.

The implementation of these recommendations may be affected by the relocation of APVMA to Armidale, other reform initiatives and financial constraints.

ID	Recommendations	Outcomes
R-1	**Improve the use of regulatory instruments:** • Provide feedback, lessons learned and training regarding assessment decisions, to improve use of regulatory instruments • Certify frequent users who submit high quality applications in high volumes, so that APVMA can fast track their applications • Develop a more efficient model for using external scientific service providers and regulatory consultants for processing assessments from "low volume" clients • Extend PAA to include a technical completeness check and some evaluation planning for modular assessments	• Reduced number of incorrect categorisations • Reduced number of S159 notices • Reduced rejections • Improved submissions
R-2	**Build more efficient processes for assessments:** • Improve the processes and resourcing for analysing assessment module data early in evaluation planning • Ensure that the appropriate governance bodies are in place for Agvet registrations, compliance and monitoring activities, involving Commonwealth and state/territory participants • Push down delegation and approvals of module assessments to assessment teams	• KPI 1.3 targets are met • Faster assessment times • Reduced number of incorrect categorisations
R-3	**Modify Legislation and Cost Recovery Measures** • Simplify legislation • Move assessment timeframes from the Act to subordinate legislation • Change KPI 1.3 to only report average days to complete an assessment, instead of % completed in legislated time • Change levies and fees to better reflect assessment complexity	• Improved and streamlined decision making for regulators and third party assessors • KPI 1.3 targets are met even with increasing assessment complexity

R-1 > IMPROVE THE USE OF REGULATORY INSTRUMENTS

RISK RETURN	Use current legislation to its full by rejecting poor quality applications early. Certify frequent users who submit high quality applications in high volumes to fast track their applications. Develop a model to promote the use of external scientific providers and regulatory consultants to support low volume clients. Extend PAA to include a technical completeness check and evaluation planning for modular assessments. Train and empower staff to better use legislative instruments and improve assessment processing.
OUTCOMES	• Reduced number of incorrect categorisations (less recategorisations) • Reduced number of S159 notices • Reduced rejections • Improved submissions
KEY ACTIONS	**R1.1:** Train and empower staff to use legislative instruments better, provide feedback and lessons learned **R1.2:** Develop a strategy/model for using external scientific service providers and regulatory consultants more efficiently and affectively, so that low volume clients can obtain support for submitting applications and assessment module backlogs can be progressed more quickly. Include a process for certifying clients who are frequent users of the APVMA and who submit high quality applications. Pilot this with top four clients **R1.3:** Extend the PAA service to include technical check and evaluation planning for modular assessments. Explore using 8G rejections of poor quality submissions early. Mandate the use of PAA for item 10s- incentivise clients to use PAA by promising that no S159s or extension times will be issued for PAA assessed submissions **R1.4:** Engage with industry to confirm appetite for R-1.2 and R-1.3

IMPACT/ RISKS/ CONSIDERATIONS	DEPENDENCIES
Risk: Industry appetite may not be adequate to service low volume clients. Not enough industry participants to undertake this work Consideration: The support from third parties and the expansion of PAA are co-dependent. The APVMA business processes will need to be revised to be able to provide support for the additional PAA related activities Risk: Without clear guidance on module assessment, data requirements and approach to doing assessments third parties will be unable to perform to the standard required by the APVMA. This will result in a lack of trust in external scientific providers	• Tailored guidance material project • The learnings from the Fast Track project • Cost Recovery Arrangements Review • Recommendations: R-2.1, R-2.2, R-2.3, R3.2 • APVMA accelerated regulatory science training program • UNE Regulatory science course

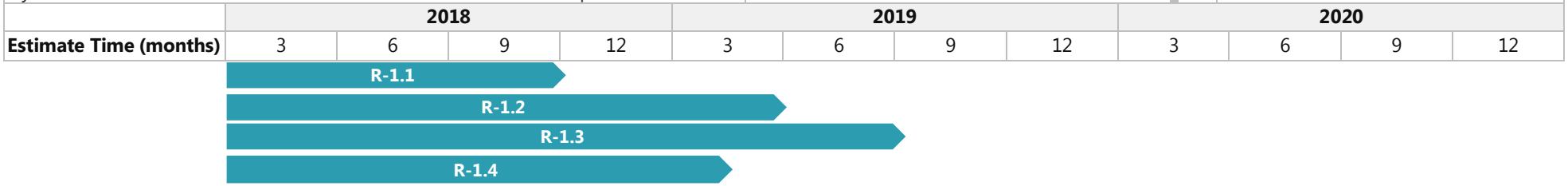
FEASIBILITY

COMPLEXITY

1	Limited additional work. No integration or collaboration across APVMA
2	Some additional work. Limited integration and collaboration across APVMA
3	Some additional work. Some integration and collaboration across APVMA and external stakeholders
4	Significant additional work. Some integration and collaboration across APVMA and external stakeholders
5	Significant additional work. Significant integration and collaboration across APVMA and external stakeholders

PRIORITY

1	Somewhat important and not urgent
2	Somewhat important and somewhat urgent
3	Important and urgent
4	Very important and urgent
5	Very important and very urgent



R-2 > BUILD MORE EFFICIENT AND EFFECTIVE PROCESSES FOR ASSESSMENTS

EFFICIENT ASSESMENTS	Improve processes and resourcing for analysing assessment data earlier in evaluation planning. Push down decision making to assessment teams. Use third parties to reduce backlogs. Implement an Authority wide Quality Assurance (QA) Framework which includes compliance and monitoring undertaken by states and territories.
OUTCOMES	• Reduced number of incorrect categorisations • Faster assessment times • KPI 1.3 target is met
KEY ACTIONS	**R2.1:** Increase resourcing for managing backlogs **R2.2:** Ensure that the appropriate governance bodies are in place for Agvet registered products, compliance and monitoring activities, involving Commonwealth and state/territory participants. Implement an Authority wide QA Framework that assures the work of assessors and delegates, internal and external providers **R2.3:** Design assessment processes that are more efficient by: • using dedicated assessors to review assessment data early in evaluation planning and increase resources for backlog processing. Develop prioritisation tools across all assessment modules. Push sign off decisions down to assessment teams for module components • develop systems and processes to link applications with client history so that repetitive non-compliance can be tracked and new applications reviewed using intelligence from client history. Use portal data and dashboard reporting to help better prioritise assessments

IMPACT/ RISKS/ CONSIDERATIONS	DEPENDENCIES
• Consideration: The compliance activity undertaken by state and territory governments may need to be improved. It will be important to be able to share data about non-compliance and incursions regarding the use of agvet chemicals and products. Also, ICT improvements are needed to develop a reporting dashboard for management of operations. Agreement on what is reported on the dashboard is essential. Resourcing and funding should also be considered in planning for this work, along with the APVMA's move to Armidale • Risk: The change in approach to assessments will require a cultural change at the APVMA which may take a lot of time to achieve	• Current and future state process mapping • Cost Recovery Arrangements Review • Efforts underway to develop reporting capability using business intelligence systems. • Adverse Experience Reporting Program • Recommendations 1.2, 3.2 • Labelling project for NVs • Tailored guidance material project

FEASIBILITY

COMPLEXITY

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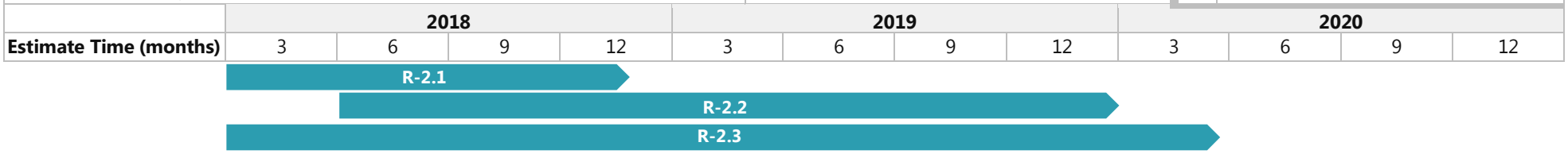

R-3 > MODIFY LEGISLATION, REPORTING AND COST RECOVERY MEASURES

LEGISLATION	Modify the legislation and rules (guidelines) for agvet products so that they are simpler to use and apply. Remove assessment timeframes from the Legislation and put them into policy documents, so that they can be easily changed when assessment complexity and approach changes with technology and science improvements (i.e. future-proof assessment time frames). Report less frequently.
OUTCOMES	• Improved and streamlined decision making for regulators and third party assessors • KPI 1.3 targets are met even with increasing assessment complexity
KEY ACTIONS	**R3.1:** Move timeframes in Schedule 6 of the Agvet regulations to subordinate legislation and change reporting of KPIs to annual reporting, instead of quarterly. Change KPI 1.3 to only report average days to complete an assessment, instead of % completed in legislated time **R3.2:** Simplify the Legislation and decision requirements to enable more timely decision making on product registrations **R3.3:** Review and modify the current cost recovery measures, including fees and levies, to better reflect the increase in effort and expertise associated with rising assessment complexity

IMPACT/ RISKS/ CONSIDERATIONS	**DEPENDENCIES**
• Risk: Industry may resist the removal of timeframes from the legislation as they require certainty • Impact: Assessment timeframes may change in policy from year to year. An agreed change process, including industry consultation, will be required • Consideration: Stakeholder engagement with industry will be key to these actions	• Cabinet approval of legislation changes • Industry engagement and agreement to the approach for legislated changes • Cost Recovery Arrangements Review

FEASIBILITY

COMPLEXITY	
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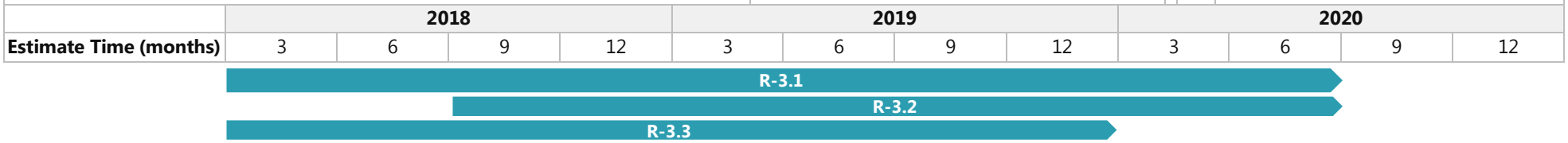
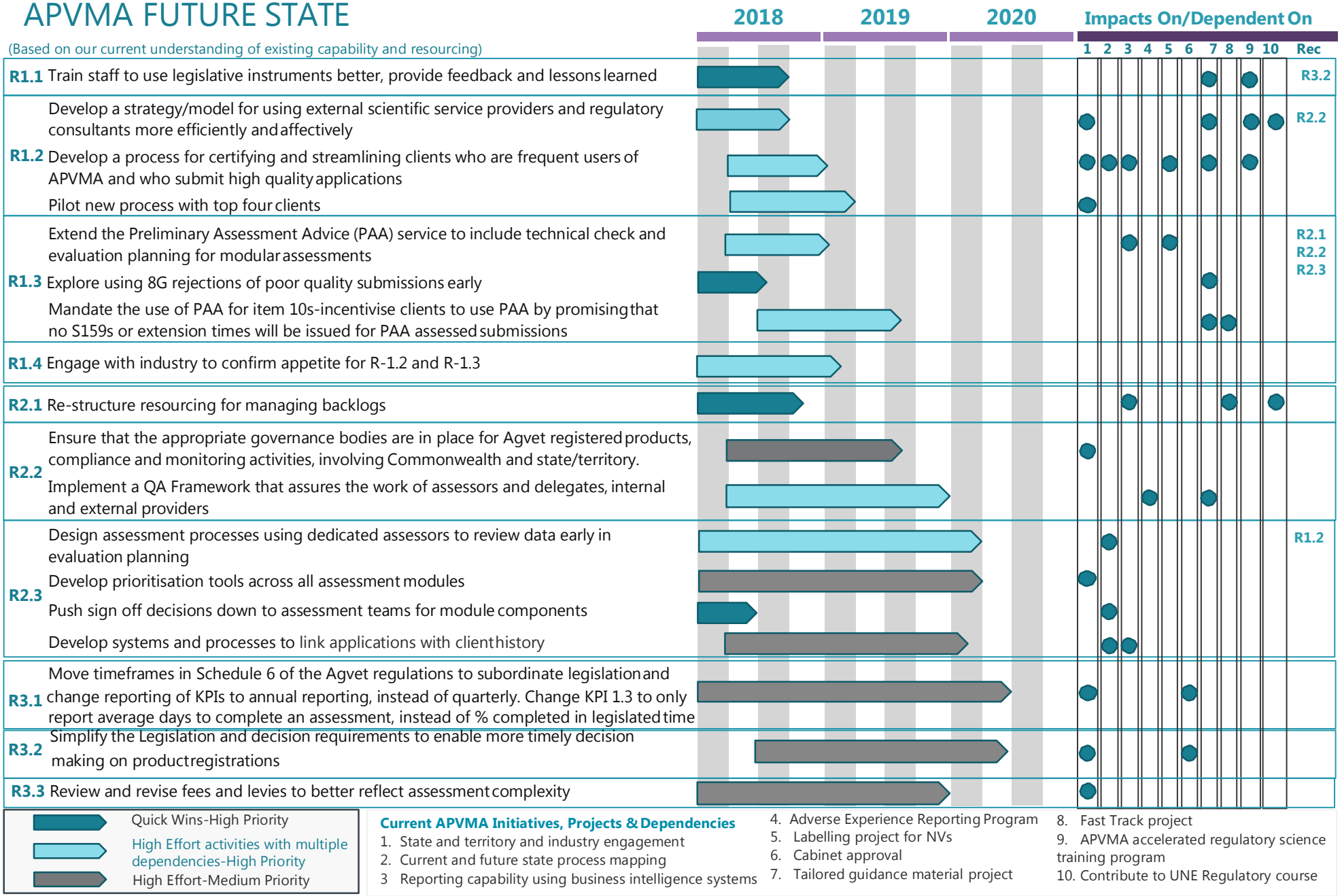


APVMA FUTURE STATE

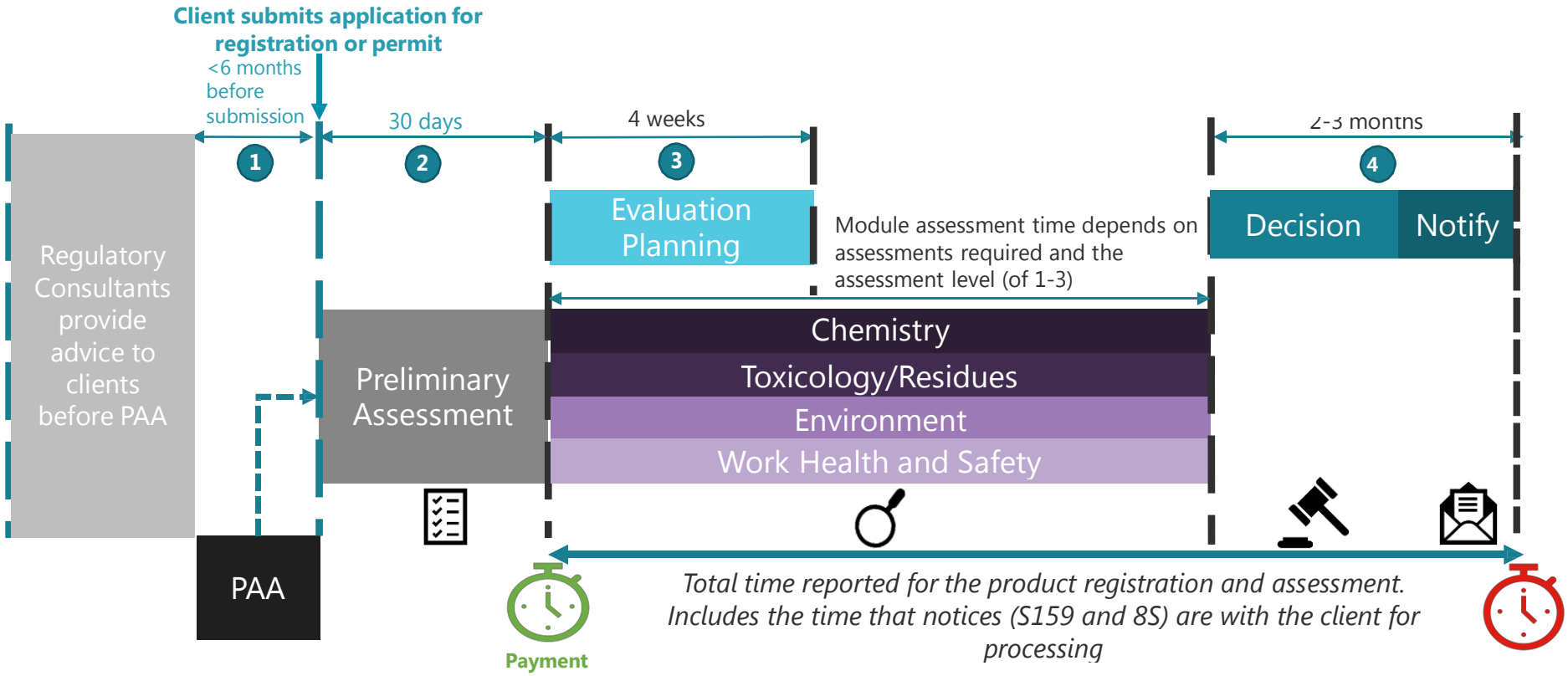
(Based on our current understanding of existing capability and resourcing)



Current APVMA Initiatives, Projects & Dependencies

1. State and territory and industry engagement
2. Current and future state process mapping
3. Reporting capability using business intelligence systems
4. Adverse Experience Reporting Program
5. Labelling project for NVs
6. Cabinet approval
7. Tailored guidance material project
8. Fast Track project
9. APVMA accelerated regulatory science training program
10. Contribute to UNE Regulatory course

THE FUTURE STATE APVMA ASSESSMENT PROCESS



1. Pre-Application Assistance (PAA) is mandated for low volume clients who submit applications requiring modular assessments. PAA includes a technical check, just prior to submission to ensure classification is correct and all data is provided. Requests for additional information (S159s) and extensions will be greatly reduced for PAA-assessed submissions. This will be the main incentive to adopt the PAA service. A list of regulatory consultants is available to low volume clients for use when submitting applications
2. Preliminary Assessment (PA) is used to review applications using client-history information, focusing on non-compliance history, ensuring that clients with repeat non-compliance have their application progressed for initial technical assessment to a suitable risk assessor. 8G rejection of poor quality submissions are activated in PA for repeat offenders and those who have submitted a poor quality modular application (like an item 10), without using PAA. PA is also used to prioritise assessments for evaluation planning and for managing the workload of module assessments, including the tentative booking of external (third party) assessors
3. Dedicated assessors are available during Evaluation Planning to review data, check categorisation and prioritise assessments using tailored prioritisation tools for each module assessment (like the ROCI tool for residues). Systems link assessments across modules and workflow assessments to assessment teams, producing tailored reports of real time status and showing the time that assessments are with assessment staff, clients or external assessors. Increased resources support business as usual (BAU) and external assessors support assessment efforts and backlog reduction effectively. A Quality Assurance (QA) Framework supports decision making
4. Decision makers receive approvals, recommendations and summaries from each module assessment team and do not have to summarise assessment findings. The module components are approved already and the Delegate can easily complete the report, trusting the assessment from module delegations

Attachment A

REASON GROUP

REASON GROUP

original thinking | lasting impact

Independent review of assessment performance

Review of comparable agencies' performance (Phase 3)

AUSTRALIAN PESTICIDES VETERINARY MEDICINES AUTHORITY (APVMA)

V1.0 | DRAFT

15 DECEMBER 2017

COMMERCIAL-IN-CONFIDENCE

BUSINESS PERFORMANCE SPECIALISTS

Sponsorship

Dr Chris Parker	Chief Executive Officer, APVMA
Amy Fox	Deputy Chief Executive Officer, APVMA

Reason Group Project Team

Aleksander Vranesevic	Principal Consultant
Peter Boyle	Senior Manager
Dr Darren Krause	Manager
Amanda Phillips	Senior Consultant

Related Documents

Independent review of assessment performance (Phase 1): Review of existing metrics and supporting processes	15 December 2017
Independent review of assessment performance (Phase 2): Development of future state	15 December 2017

TABLE OF CONTENTS

Introduction

Background

Summary

Key comparative criteria

INTRODUCTION > BACKGROUND

This report details the findings from Phase 3 of the Independent Review of Assessment Performance APVMA undertaken by Reason Group in late 2017.

The Australian Pesticides Veterinary Medicines Authority (APVMA) is responsible for the registration of all agricultural and veterinary chemical products into the Australian marketplace.

- The APVMA regularly reports on assessment performance, providing insight into the activities and operations of the organisation and publicly released reports on performance indicators on a quarterly basis
- Recent reports demonstrate that the organisation has experienced a degree of unpredictability and volatility with its timeframe performance, particularly as it relates to the finalisation/completion rate of applications
- Timeframe performance provides insight into a portion of the picture that is the process of reviewing, analysing, assessing and approving applications for new products, permits and chemicals for use within Australia
- Since the implementation of reforms in 2014, a number of reports have been commissioned to review specific subsets of operational performance

The APVMA has commissioned an independent, broad ranging and comprehensive, evidence-based review of the drivers that both influence and impact upon the assessment performance.

This report forms part of the independent review and undertakes a comparative analysis of APVMA performance reporting against (chemical) regulators internationally (Phase 3). This is achieved through:

- Reviewing other regulators against similar performance metrics
- Analysis of publicly available information on transformations which similar agencies have undertaken to improve their performance

INTRODUCTION > SUMMARY

It is difficult to directly compare performance of regulatory bodies due to the very different regulatory systems, fee structures and levels of scientific rigour in place. Therefore use of performance statistics in isolation should be performed with caution. However, there is evidence to suggest that the performance issues being experienced by the APVMA are also challenging for other international regulatory bodies. Provided below is a summary of the review of other comparable agencies performance.

AUSTRALIA

69% of applications completed within statutory timeframe

- Quarterly performance reporting
- Variability in quality of applications accepted
- Clock extended not stopped when awaiting response/s from applicant

CANADA

Performance target of 90% with actual results of:
87% (Cat A), 88% (Cat B) and 95% (Cat C)

- Times and target set in policy not legislation
- Review times are generally longer than those set in Australia
- Review times do not include finalisation after decision
- Clock stops when awaiting response/s from applicant
- PMRA may re-negotiate review timeline with applicant
- Completeness check includes format, data and fee requirements

BRAZIL

- The time required for registration can be up to 6 years[2] as opposed to the targeted 120 days
- Applications pending review is almost 6 times the number evaluated

NEW ZEALAND

100% (Hazardous Substances and New Organisms Act) and approximately 55% (Health and Safety at Work Act) applications within statutory timeframe

- Example of the use of independent third party data assessors enabling much shorter legislative time frames (40 days)
- Strong stance/posture with regard to application quality
- Application completeness check (including data review) prior to acceptance
- Registration Review Project may have lessons learnt applicable to the APVMA
- Fees cost recovered based on actual work undertaken

EUROPEAN UNION

European Commission & European Food Safety Authority: 75% (2016) and Rapporteur Member States: "delays are commonplace"[1]

- Strong stance/posture with regard to application quality
- Progress of EU Pesticide Legislation Review (2017-19) will be of interest
- Actions resulting from the audits carried out in EU Member States in 2016 and 2017 will be of interest
- The UK has demonstrated the increasing complexity of assessments

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products
[2] Chemlinked, Brazilian Pesticide Regulation Overview, March 13, 2017

INTERNATIONAL COMPARISONS > KEY COMPARITIVE CRITERIA

The following table provides key criteria that should be taken into account when comparing the performance of the Australian agvet registration system to that of other jurisdictions. Due to the very different regulatory systems, fee structures and levels of scientific rigour in place across the various agencies, the use of performance statistics in isolation should be performed with caution.

	Australia APVMA	New Zealand EPA	New Zealand MPI	Canada PMRA	Canada VDD	European Union Plant Protection Products	Japan FAMIC	Brazil
Time frame (min – max)	1-25 calendar months (30-750 days)	10-100 working days	40 working days	80-737 calendar days	2-300 calendar days	2.5 to 3.5 years (912.5-1277 days)	Up to 2 years (up to 730 days)	120 days
Location	Statutory	Statutory	Statutory	Policy	Statutory	Statutory	Statutory	Statutory
Third parties	Regulatory consultants Panel appointed assessors		Registration consultants Accredited Assessors	Grower Requested Own Use (GROU) Committee		Consultants		
Performance target	100%	100%	100%	90%	100%	100%	100%	100%
Recent performance	69% 2016/17	100% 2015/16	55% (approx.) June 2017	Category A 87% Category B 88% Category C 95% 2015/16	Within service delivery standard for 7/9 application types 2015/16	EFSA: 75% (2016) RMS: "delays are commonplace" [1]		Can be up to 6 years[2] Backlog of 6 x those evaluated
Pre-assessment	Administrative		Administrative and technical	Administrative and technical				
Reporting requirements	Quarterly	Annual	As required	Annual	Annual			
Reporting mechanism	Parliament	Annual Report	Industry focussed newsletter	Parliament	Parliament			
Statutory clock	Extension of time for requests for information	Clock stops Can request extensions	Clock stops	Clock stops	Clock stops	Clock stops for requests for information	Rejected if issue not addressed within 1 month	
Review period	Risk based			15 year cycle		Risk based not exceeding 15 years		Risk based triggers

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products

[2] Chemlinked, Brazilian Pesticide Regulation Overview, March 13, 2017

New Zealand

NZ Environmental Protection Authority (NZEPA)

Ministry for Primary Industries (MPI)

REASON GROUP

NEW ZEALAND > NZ ENVIRONMENTAL PROTECTION AUTHORITY (NZEPA)

OVERVIEW

- Approval under HSNO Act 1996 administered by NZEPA is required before product consideration under Agricultural Compounds and Veterinary Medicines Act 1997 administered by the Ministry for Primary Industries (MPI)
- NZEPA make pre-assessment consultations available
- On 1 December 2017 the rules for managing hazardous substances in the workplace are moving from the Hazardous Substances and New Organisms Act 1996 (HSNO) to the Health and Safety at Work Act (HSWA). Many of the existing requirements will continue. However, there are some changes to improve the management of these substances at work

Approval under HSNO Act is a prerequisite for ACVM Act

TIMEFRAMES

- Decision times set in legislation [1]
- HSNO rapid application process: 10 days statutory decision time
- HSNO full release application process (no public notification): 60 days statutory decision time with clock stoppage
- HSNO full release application process (public notification): 100 days statutory decision time with clock stoppage

PERFORMANCE MEASURES & REPORTING [2]

Number of hazardous substance decisions and advice – Parts 5 and 6a

APPLICATION TYPE	Actual 2015/16	Actual 2014/15	% met all statutory time frames 2015/16	% met all statutory time frames 2014/15	% met all statutory time frames 2013/14
IMPORT OR MANUFACTURE FOR RELEASE					
Notified	5	6	100	100	100
Non-notified	54	53	100	100	100
Rapid	53	27	100	100	100
IMPORT OR MANUFACTURE IN CONTAINMENT					
Non-notified	12	12	100	100	100
EMERGENCY USE APPLICATIONS					
Special emergency	0	0			NA
TRANSHIPMENT					
Transhipment of hazardous substance	4	12	100	100	100
REASSESSMENTS					
Grounds	5	5	100	100	NA
Modified	4	2	100	100	100
Full	2	0	100	-	100
GROUP STANDARDS					
Externally generated	0	0	-	-	NA
Internally generated	0	0	-	-	NA
Amendments	1	1	NA	NA	NA
OTHER					
Amendment of existing approval	25	8	NA	NA	NA
Statutory determination on a substance	0	0	-	-	NA
TOTAL	**165**	**126**	100	100	
Non-statutory advice - Status of substances	428	254	NA	NA	NA
Non-statutory advice - Product labelling	2	5	NA	NA	NA
TOTAL NON STATUTORY ADVICE	**430**	**257**	-	-	-

1 Hazardous Substances and New Organisms Act 1996
2 NZ Environmental Protection Authority Annual Reports 2015/16, 2014/15 & 2013/14

NEW ZEALAND > MINISTRY FOR PRIMARY INDUSTRIES (MPI) > ACVM ACT

OVERVIEW

- Agricultural Compounds and Veterinary Medicines Act 1997
- Because of the tight statutory timeframe for making decisions on applications to register (or to vary registration of) trade name products and the limited technical resources, the ACVM Group of MPI is unable to carry out all the necessary data assessment required for the technical appraisal of registration applications[1]
- Third party data assessors must be independent and the MPI provides a list of approved 'Full' and 'Provisional' Data Assessors
- It is not mandatory for persons completing data assessment reports to be listed. However, MPI expects that data assessment reports completed by non-listed persons will be subject to greater scrutiny and may require peer review[1]
- As a regulatory body MPI cannot provide consultation through the registration process. Third party consultants assist applicants unsure of the registration process
- Pre-screen of applications submitted to the MPI includes both administrative and technical screens (NZ$540.00 exc GST) before being formally accepted and the regulatory clock starting[2]
- The fee for application processing is $155.00/hour (exc. GST). Estimates of time are given as a range, as time for individual applications vary depending on technical input required[2]

TRANSFORMATIONS TO ADDRESS PERFORMANCE

- Registration Review Project launched in December 2015

REVIEW TIMEFRAMES

- Timeframes set in policy not legislation
- Assessment period of 40 days
- Extensions of time may be requested by MPI and approved by applicant which results in the regulatory clock being paused

See next page for further information on the Registration Review Project

1 Becoming a Data Assessor for ACVM Products
2 ACVM (Fees, Charges, and Levies) Regulations 2015

NEW ZEALAND > MINISTRY FOR PRIMARY INDUSTRIES (MPI) > REGISTRATION REVIEW

REGISTRATION REVIEW PROJECT OVERVIEW[1]

In December 2015 the MPI established an ACVM registration review project team of three staff. This project comprised an end-to-end review of the entire registration process.

The objective of the review was to streamline internal processes, enabling consistent and timely processing of applications. This work was to support the MPI's business objectives of meeting both statutory timeframes and key performance indicators as agreed with industry. Process mapping had already been completed and the team had commenced the first round of internal workshops.

In conjunction with the review, the MPI continued to look at assessment activity that could be carried out by the Operations Team to reduce multiple handling and allow the Technical Team to focus on more complex assessments ensuring the overall robustness of the process. The MPI also explored various pathways, as utilised by other international regulatory agencies, to manage minor variation applications.

DECEMBER 2016 PROJECT UPDATE[2]

Registration renewal process Review of the registration renewal process completed and a recommendation to change the default registration expiry period from 3 years to 5 years was made.

Paperless process initiative The Kaikoura earthquake reaffirmed the need for a paperless registration process that could be run remotely by MPI staff. ACVM staff had been trialling a digital process flow. Issues identified during the trial were being worked through.

Product and manufacturing specs Work on how product and manufacturing specifications are defined and captured as part of the registration process was ongoing. The MPI are proposing to strengthen the product identity, manufacturing and quality characteristics that define a trade name product. Better information in the product and manufacturing specifications will act as a more effective point of reference when variations are made, and for purposes of auditing and compliance. Importantly, this will also inform the development of guidance to applicants and pathways for the management of applications for specifications changes to registrations.

Screening of applications The MPI is proposing to be more rigorous in the screening of applications prior to official receipt. Efficiency of the registration process to date had been negatively impacted by acceptance of applications that are found later to be inadequate or insufficient.

Transparency The MPI is still looking at cost effective ways to improve transparency around applications received, as well as applications approved. The intent is to provide more information for interested and affected parties while preserving protection of commercially sensitive information.

1 ACVM News and Views – December 2015
2 ACVM News and Views – December 2016

NEW ZEALAND > MINISTRY FOR PRIMARY INDUSTRIES (MPI) > PERFORMANCE

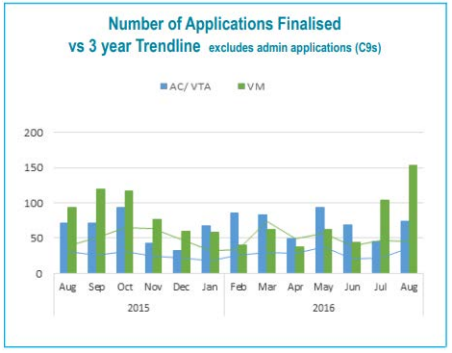
PERFORMANCE - NOVEMBER 2015[1]

Regulated time frames		
Application type	**Percentage complete**	**Time (working days)**
A	95%	40
B	95%	30
C*	80%	20
Notifications, renewals	95%	7-10
* working towards 95% in 15 working days and transfer of minor amendments.		

Key work streams and services (nonregulated)	
Label changes	20 working days
Deviations	30 - 40 working days
Data assessments	As agreed with applicant – Target 40 days
Provisional approvals	20 - 30 working days
Research approvals	20 - 30 working days
Acknowledge enquiries	5 working days
Confirmation app. received	5 working days
Operating plans	As agreed with applicant – Target 40 days
GMP audit reports	60 working days
Quality of assessments	< 5% decisions appealed
Adverse event report	Annually
Antimicrobial sales report	Annually

Performance indicators were set to enable the MPI to set clear objectives for the registration review project.

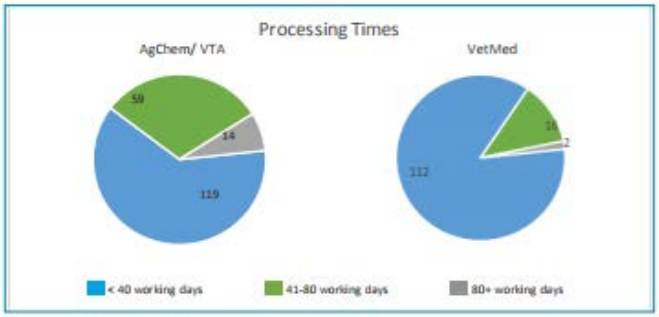
PERFORMANCE - OCTOBER 2016[2]



42% applications processed within timeframe after a slump to 24%

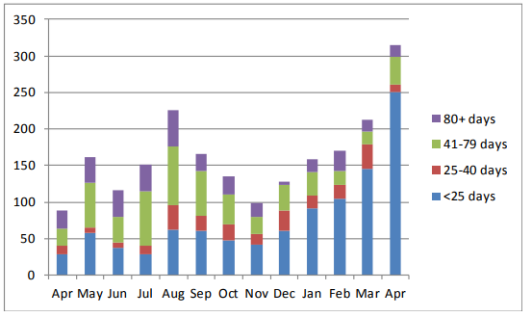
Due to a consistent backlog over the 12 months to August 2016, numbers of applications being finalised were well above the 3 year average

PERFORMANCE - MARCH 2016[3]



3 ACVM News and Views – March 2016 4 SAAM News and Views – June 2017

PERFORMANCE - JUNE 2017[4]



1 ACVM News and Views – December 2015
2 ACVM News and Views – October 2016

61% on time for AgChem/VTA

86% on time for VetMed

ACVM registration applications from April 2016- April 2017. The columns indicate processing times of applications from passing pre-screen to issuing registration

Canada

Pest Management and Regulatory Agency (PMRA)

Veterinary Drug Directorate (VDD)

REASON GROUP

PEST MANAGEMENT AND REGULATORY AGENCY (PMRA)

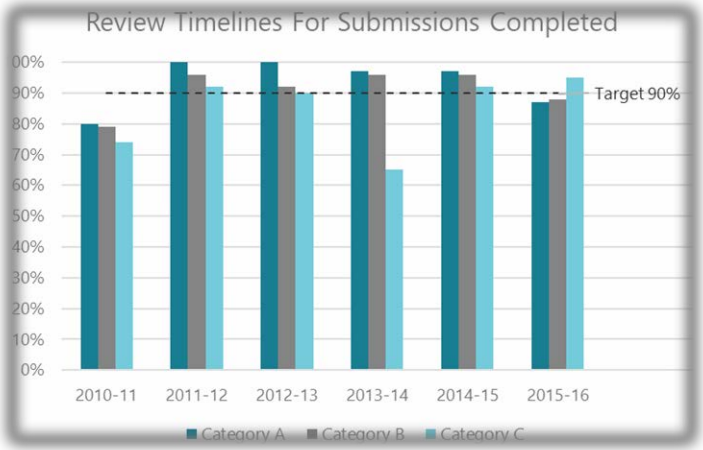
The Health Canada Pest Management Regulatory Agency (PMRA) is responsible for pesticide regulation in Canada

OVERVIEW

- Pest Control Products Act is reviewed every 7 years[1]
- 15 year evaluation cycle ensures products meet latest health and environmental risk assessment standards[1]
- Mobile app released for labels in 2015/16
- Grower Requested Own Use (GROU) program allows growers to import and use foreign versions of Canadian registered products
- Related submissions my be grouped and tailgate submission process
- Minor clarifications allowed with responses required within 10 days
- Use of data from OECD member countries
- Allows expedition for lower risk products
- Activities (excluding pre-assessment consultations) are financed through cost recovery

PERFORMANCE MEASURES & REPORTING

- Annual reporting to parliament through PMRA Annual Report



TIMEFRAMES

- Times set in policy not legislation[2]
- Performance target set at 90% completed within review time
- Review times are generally longer than those set in Australia
- Review times do not include finalisation after decision
- Clock stops when awaiting response/s from applicant
- PMRA may re-negotiate review timeline with applicant
- 37 day completeness check includes format, data and fee requirements before being accepted for review
- 45 day public consultation period (not included in timeframes)

Category [2]	Days (months) [2]
Pre-submission	80
Category A New active ingredients, new Maximum Residue Limits (MRLs) and major new use registration	285-737 (9.5-24)
Category B New formulations, changes in current formulations, new hosts and/or pests added to existing products, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application	158-425 (5-14)
Category C Changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, administrative changes or re-instatements	180-240 (6-8)

[1] Pest Control Products Act 2002 (last updated Sept 21, 2017)
[2] Regulatory Directive DIR2017-01, Management of Submissions Policy (MOSP)
[3] PMRA Annual reports

VETERINARY DRUGS DIRECTORATE (VDD)

OVERVIEW

- Submissions may be placed on hold at various points (clock stops)
- Pre-submission meeting
- Screening within 45 days of submission

PERFORMANCE MEASURES & REPORTING

In 2015-2016, HPFB's actual performance for submissions was:

	Time in Calendar Days
New Drug Submission	335
Abbreviated New Drug Submission	364
Supplemental New Drug Submission	246
Supplemental Abbreviated New Drug Submission	187
Administrative	19
DIN (including changes to DINs)	125
Notifiable Change	86
Experimental Studies Certificate	55
Emergency Drug Release	1.5

The target for achieving VPD timeframes is the average time to reach first decision on a submission within an individual fee line.

TIMEFRAMES[1]

Commitment to service delivery standards to reach first decision outlined as time in calendar days in the following table:

	Time in Calendar Days
New Drug Submission	300
Abbreviated New Drug Submission	300
Supplemental New Drug Submission	240
Supplemental Abbreviated New Drug Submission	240
Administrative	90
DIN (including changes to DINs)	120
Notifiable Change	90
Experimental Studies Certificate	60
Emergency Drug Release	2

Evaluates and monitors the safety, quality and effectiveness, sets standards, and promotes the prudent use of veterinary drugs administered to food-producing and companion animals

[1] https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/service-standards-high-volume-regulatory-authorizations/service-standards-veterinary-drug-submission-evaluations-under-food-drug-regulations.html

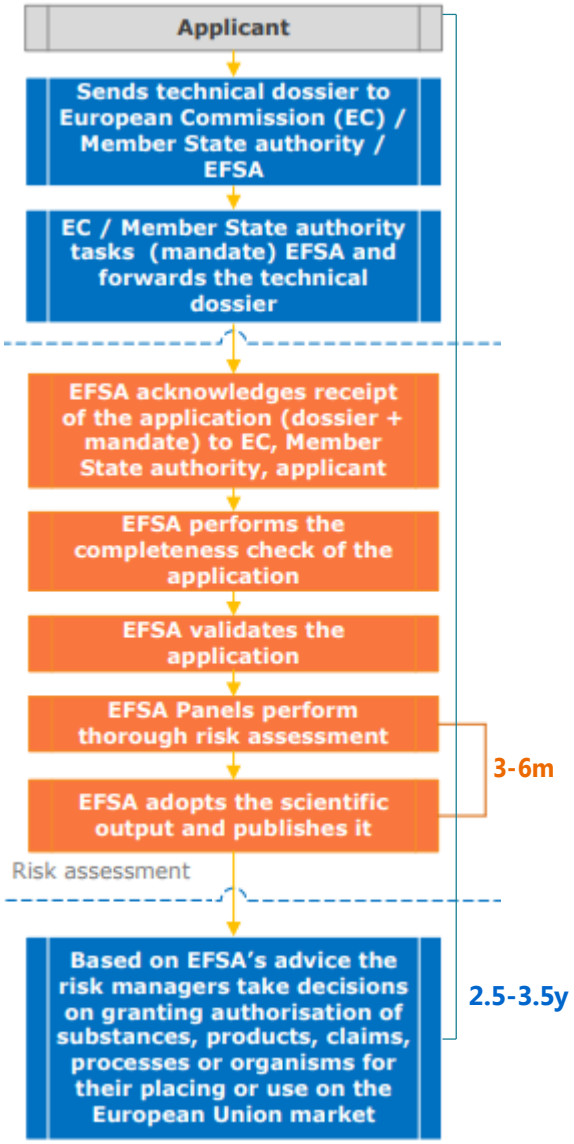
Europe

European Commission & European Food Safety Authority (EFSA)

Rapporteur Member States (RMS)

REASON GROUP

EUROPEAN UNION > EUROPEAN COMMISSION & EFSA



OVERVIEW

- Regulation (EC) No 1107/2009 is the legislation concerning the placing of plant protection products (PPPs) on the market in the European Union
- EU countries authorise plant protection products on their territory and ensure compliance with EU rules
- Before an active substance can be used within a plant protection product in the EU, it must be approved by the EC
- The controls of the use and placing on the market of PPPs are performed by Member States
- The EU is divided into 3 zones: North, Central and South. Member States assess applications on behalf of other countries in their zone and sometimes on behalf of all zones
- Member states can cost recover through fees and charges
- Periods are extended when additional information (stop the clock events) and consultation with experts are considered necessary

TIMEFRAMES

It takes 2.5 to 3.5 years from the date of admissibility of a new active application to the publication of a Regulation approving a new active substance. This time varies greatly depending on how complex and complete the dossier is.

Under EU rules, it takes up to 1.5 years from the date of application to the granting, amendment or withdrawal of an authorisation for a Plant Protection Product (PPP). This time varies depending on how complex and complete the application is and the type of application.

Review periods are based on risk and are not to exceed 15 years

EU PESTICIDE LEGISLATION REVIEW (2017-19)

The European Commission is carrying out a REFIT evaluation of the EU pesticide legislation in order to assess if the regulations meet the needs of citizens, businesses and public institutions in an efficient manner. REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose'; that regulatory burdens are minimised and that all simplification options are identified and applied. The evaluation is foreseen to be finalised in the first half of 2019.

The main evaluation criteria to be addressed in relation to this REFIT Evaluation are:

- Effectiveness of the intervention
- Efficiency in relation to resources used
- Relevance in relation to identified needs and problems
- Coherence with other interventions with common objective
- EU added value compared to what could have been achieved by Member State or international action

OVERVIEW REPORT - AUTHORISATION OF PLANT PROTECTION PRODUCTS[1]

This overview report provides a summary on the outcome of audits to Member States carried out in 2016 and 2017 by the Health and Food Safety Directorate General of the European Commission to evaluate the systems in place for the authorisation of plant protection products. Key statistics and information from this report are presented in the following pages.

EFSA KEY PERFORMANCE INDICATORS[2]

Table 15: Key performance indicators for Activity 2

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Ensure effective delivery of work programme	Number of scientific outputs adopted	306	265	259[a]
	Number of technical reports finalised[b]	-	47	62[c]
	Number of closed scientific questions[d]		413	382[e]
	Reduction of backlog of reasoned opinions on MRLs (backlog elimination by end of 2019)		Planned to be reduced to 237	Reduced to 221
Improve the timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	84%	90%	75%[e]
	Proportion of scientific questions adopted within deadline		90%	75%[e]
Ensure full compliance with EFSA's Policy on Independence	Proportion of experts with approved annual DoI (aDoI) before first meeting invitation	100%	100%	100%
	Proportion of experts with approved specific DoIs (sDoI) before participation in an EFSA meeting	100%	100%	100%
Ensure effective use of financial resources	Proportion of original budget for Activity 2 committed/paid at year end[g]	99.9% 91.8%	100% 90%	100.8% 89.5%

[1] https://ec.europa.eu/food/plant/pesticides/refit_en

[2] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products

EUROPEAN UNION > RAPPORTEUR MEMBER STATES (RMS)

INCREASE IN EVALUATION COMPLEXITY[1]

The UK compiled data on the resource requirements for each step in the evaluation process. The data showed that the average evaluation time has increased by 70% from 2007 to 2015. This increase is most pronounced in some areas of evaluation such as efficacy, due to the greater number of crops/uses covered in each application, and to the increasing complexity of environment fate evaluations (see chart No 1).

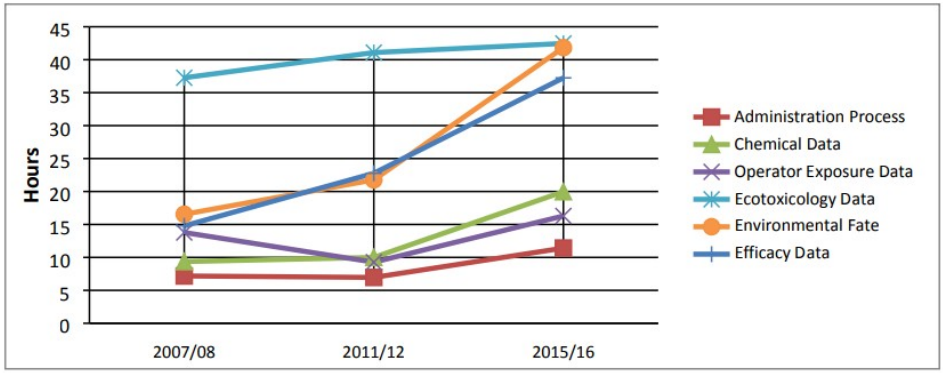


Chart 1 Time required for different evaluation areas of the PPP authorisation process. (Source UK).

UK - BREXIT[2]

- Until the withdrawal date, the UK remains a member of the European Union therefore the UK can still be act as RMS under the renewal procedure
- The European Commission services have started discussing with all Member States in order to re-allocate some substances to a new RMS or co-RMS

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products
[2] Questions and Answers Related to the United Kingdom's Withdrawal from the European Union with Regard to Plant Protection Products and Pesticides Residues

AUTHORISATION AS ZONAL RAPPORTEUR MEMBER STATE (zCMA)[1]

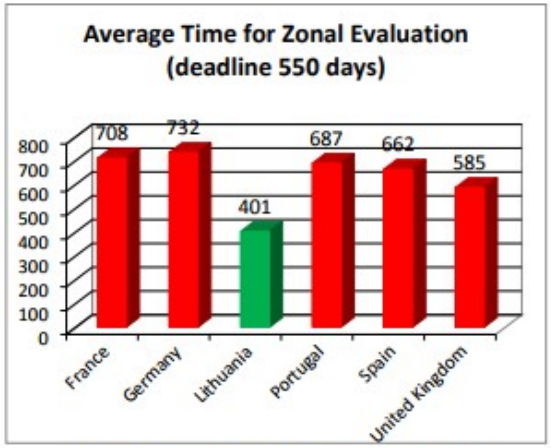


Chart 7 Average time for zonal evaluation

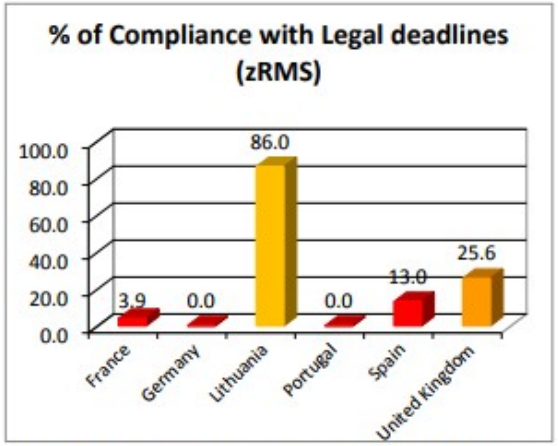


Chart 6 Percentage of compliance with legal deadlines (zRMS)

Although the UK complies with deadlines for only 26% of the applications, it received a high number of applications and was still able to take a decision on almost 70 % of the cases with an average of just one month above the deadline.

AUTHORISATION AS CONCERNED MEMBER STATE (cMS)[1]

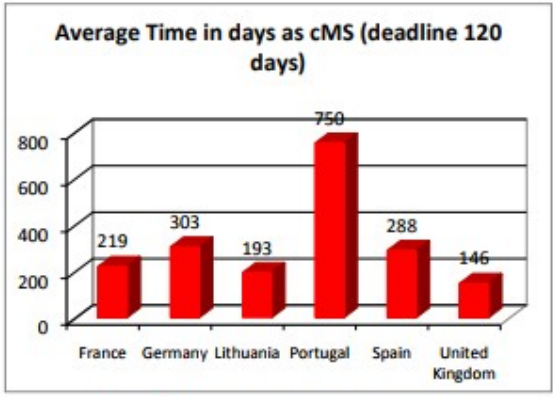


Chart 8 Average time (in days) as cMS

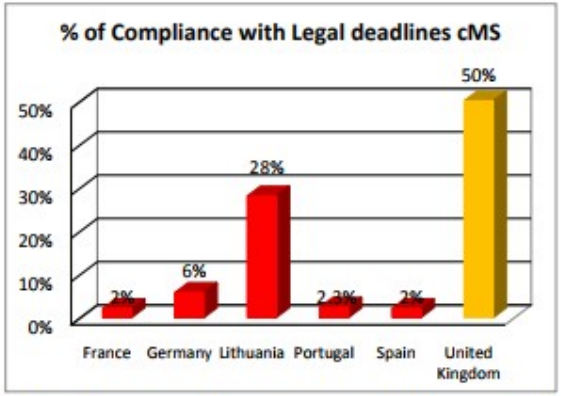


Chart 9 Percentage of compliance with deadlines as cMS

Based on the final registration report including the copy of the PPP authorisation of the zRMS, each cMS shall decide on their corresponding PPP applications within 120 days.

When acting as cMS, the average time for processing these applications exceeds the 120 day deadline. This highlights a lost opportunity for MS to process applications based on the work done by the zRMS.

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products

EUROPEAN UNION > RAPPORTEUR MEMBER STATES (RMS)

RE-REGISTRATION OF PLANT PROTECTION PRODUCTS[1]

Significant delays were commonplace for the re-registration of PPPs. Examples of delays were seen ranging from eight months to five years.

AUTHORISATION BY MUTUAL RECOGNITION[1]

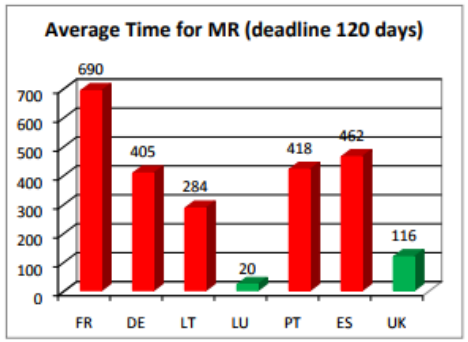


Chart 10 Average time for MR applications

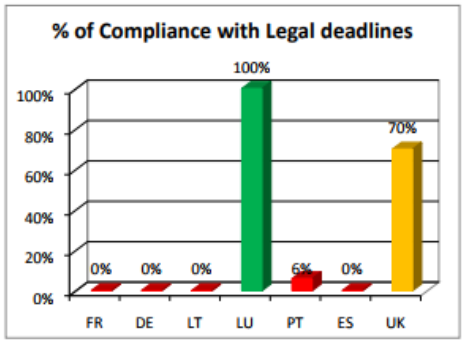


Chart 11 Percentage of compliance with deadlines (MR)

AUTHORISATION OF "GENERIC" PRODUCTS[1]

The audit series revealed differences in how Member States evaluate applications for authorisation of PPPs equivalent to existing authorised PPPs, resulting in significant variation in the number of generic PPPs on the market across Member States.

PARALLEL TRADE PERMITS[1]

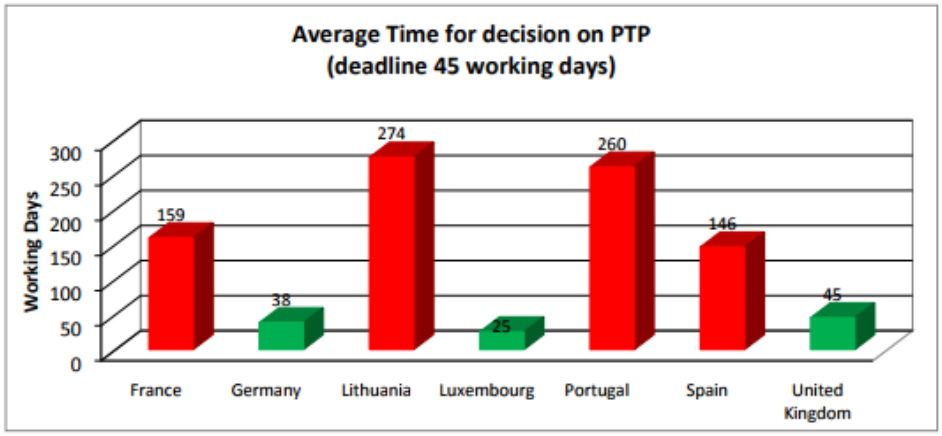


Chart 15 Average time for decisions on PTP applications

EMERGENCY AUTHORISATIONS[1]

Delays in granting regular authorisation, especially for minor uses, lead to an increased number of emergency authorisation applications. The majority of the Member States are taking steps to address the lack of authorised PPPs for minor uses, where profitability for applicants is limited due to the limited demand for such products. To the extent that these efforts facilitate authorisations of PPPs for minor uses, this has a positive effect in reducing the number of emergency authorisations.

[1] Overview Report on a Series of Audits Carried Out In EU Member States in 2016 and 2017 in Order to Evaluate the Systems in Place for the Authorisation of Plant Protection Products

Brazil

Ministry of Agriculture, Livestock and Supply (MAPA)

National Health Surveillance Agency (ANVISA) under the Ministry of Health (MS)

Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA)

REASON GROUP

BRAZIL > MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY (MAPA); NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA); BRAZILIAN INSTITUTE OF THE ENVIRONMENT AND RENEWABLE NATURAL RESOURCES (IBAMA)

OVERVIEW[1]

- Brazil's current pesticide legislative framework (under Law 780) regulates the research, experimentation, production, packaging, labelling, transportation, storage, marketing, commercial-advertising, utilisation, import, export, waste and package disposal, registration, classification, control of pesticide, components and similar products
- Three federal ministries are involved in the registration management of pesticides. This includes the Ministry of Agriculture, Livestock and Supply (MAPA), the National Health Surveillance Agency (ANVISA) under the Ministry of Health (MS) and the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA) under the Ministry of Environment (MMA)
- Validity of a product registration is unlimited. However, this can be canceled due to a negative result during a periodic reevaluation, violation of government imposed enterprise sanctions or breach of operating scope
- Holders of a registration pay yearly fees to the government, even when there are not active sales

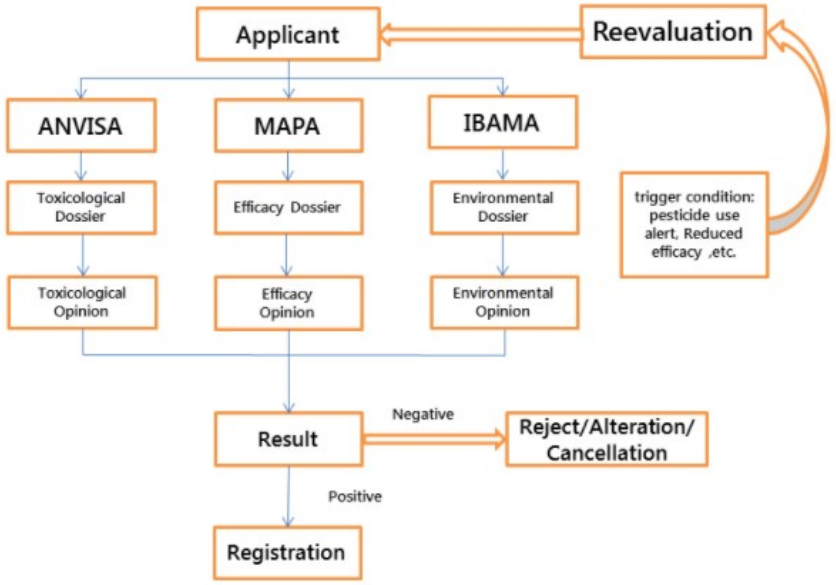
TIMEFRAMES[1]

- According to federal regulation, the three agencies mentioned above should evaluate registration submissions within 120 days of receipt. In reality, registrations can take up to 6 years to be evaluated
- Statistics from ANVISA show the number of registration applications pending review is almost 6 times the number of applications evaluated

REGISTRATION PROCESS [1]

The Brazil National Commission on Chemical Safety (CONSAQ) is responsible for pesticide regulation in Brazil

- Applications and dossiers are submitted to the federal authorities of agriculture (MAPA), health (ANVISA) and environment (IBAMA)
- It is proposed that a new organisation, the National Technical Commission of Plant Protection, be established to replace the administrative authority of these three entities.
- Authority currently conferred to IBAMA, ANVISA and MAPA will be transferred to, and centralised with this Commission
- A new system of evaluation and registration similar to that implemented in the United States and Canada is expected to be implemented in Brazil



[1] Chemlinked, Brazilian Pesticide Regulation Overview, March 13, 2017

JAPAN

Food and Agriculture Inspection Centre (FAMIC)

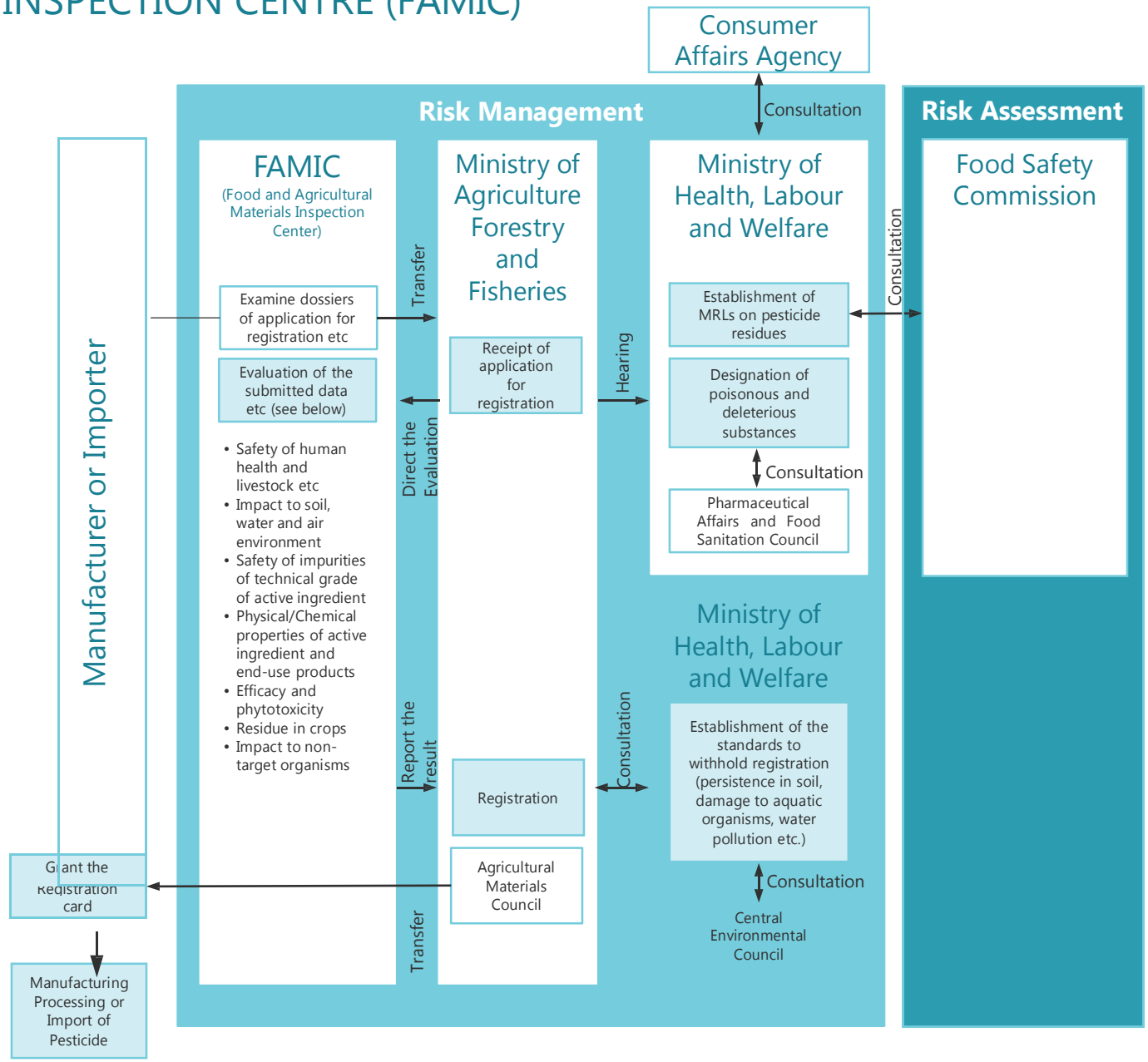
REASON GROUP

FOOD AND AGRICULTURE INSPECTION CENTRE (FAMIC)

OVERVIEW

The Food and Agriculture Inspection Centre (FAMIC) is responsible for pesticide regulation in Japan.

- Timeframes up to two years
- Manufacturing, importing, selling and utilising agricultural chemicals is regulated through Agricultural Chemicals Regulation Law
- FAMIC conducts evaluations on applicant test results on efficacy, toxicity, and crop and soil residual properties, and then reports the results to the Ministry of Agriculture, Forestry and Fisheries
- Applicants pay a fee prescribed by government ordinance on the basis of the actual expenses incurred
- After the inspection/examination, the inspection report is reported to the Minister of Agriculture Fisheries and Forestry.
- No performance targets are stipulated.
- To implement a system for the prompt supply of safe and high quality agricultural chemicals Japan is reviewing the agricultural chemicals registration system
- Dossiers are presented in the OECD Dossier form
- OECD Good Laboratory Practices ensure data provided is reliable



Attachment B

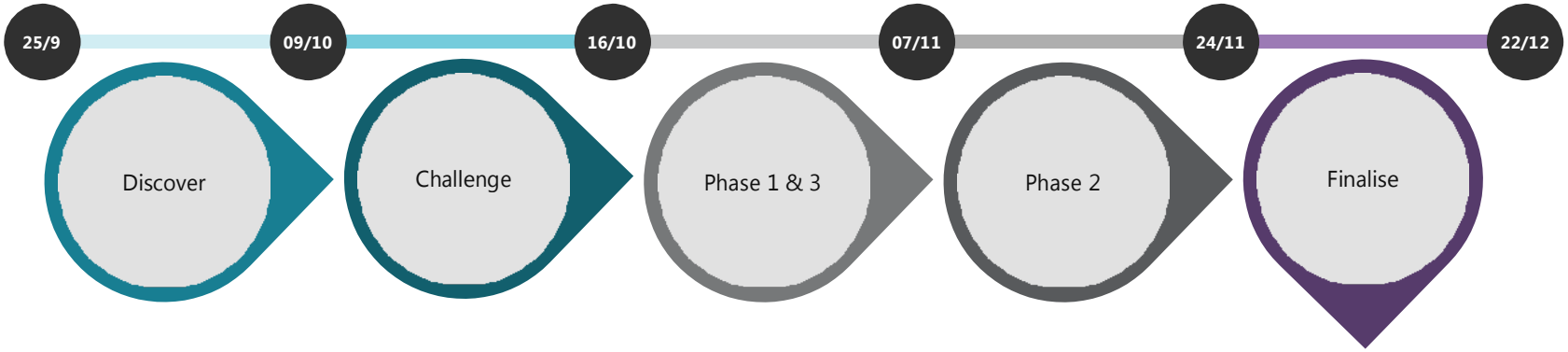
Deliverables and Phasing

Stakeholder Engagement Details

REASON GROUP

DELIVERABLES AND PHASING

The following diagram describes the overall approach to undertaking the independent review of APVMA performance



PURPOSE	**Confirm the approach, context and focus**	**Initial review of data**	**Analyse data and identify issues**	**Define future state reporting**	**Finalise the report**
	Meetings with senior members to finalise the scope and approach	Identify metrics used in public reporting	Prioritise key data	Determine policy, people, technology and data requirements	Review draft future state report with stakeholders
	Clarify the deliverables	Conduct meetings and interviews with stakeholders	Analyse data and data management processes	Review legislative and performance framework obligations	Identify risks, dependencies, finance, skills and other enablers
	Identify existing materials and key internal stakeholders	Identify processes, administrative and ICT systems	Review other international agencies	Define opportunities for improvement	Finalise recommendations
	Undertake desktop research	Define the impacts, dependencies and top 3-5 priority changes	Identify assessment reporting changes	Draft future state report	Submit the report for Executive review
DELIVERABLES	**Engagement Plan**	**Initial Observations**	**Phase 1 and 3 performance report**	**Phase 2 future state draft report**	**Phase 2 future state final report**

STAKEHOLDER ENGAGEMENT DETAILS

All stakeholder engagement was with internal stakeholders. All engagements were as directed by the Deputy CEO and the Director of Innovation and Implementation (Alyssa Hicks). Weekly meetings were held with the Deputy CEO to discuss deliverables. In addition, regular update meetings were held with the Executive Director of Registration Management and the Executive Director of Evaluation and Scientific Assessment and Chemical Review.

Division	Stakeholder	Topics for discussion	Format	Date
Agency	CEO – Chris Parker Deputy CEO, Business Operations and Reform – Amy Fox	• Challenges, issues and concerns over the next five years • Top priority initiatives, regulations and changes • What data, documentation and other evidence is available? • Previous review and audit findings and recommendations	Meeting and Desktop research	21 September 2017
Registration Management and Evaluation	Executive Director – Alan Norden	• APVMA Independent review scope and activities • Reporting and assessment issues, risks and concerns over the next five years • Opportunities for streamlining assessments • Opportunities for improving reporting	Meeting	27 September 2017
	Quality Oversight and Reporting – David Perry	• Assessment items that have large volumes and which do not meet legislated timeframes • Reporting and assessment issues, risks and concerns • Opportunities for improving assessment times	Meeting and Desktop research	9 October 2017
	Minor Use – Bronwyn Battison	• Assessment items that have large volumes and which do not meet legislated timeframes • Reporting and assessment issues, risks and concerns • Opportunities for improving assessment times	Meeting and Desktop research	9 October 2017
	Quality Oversight and Reporting -Simeon Turk	• Assessment items that have large volumes and which do not meet legislated timeframes. How are these tracked in the APVMA portal? • Reporting and assessment processes, recategorisation, issues, risks and concerns • Opportunities for improving assessment reporting and modelling	Meeting and Desktop research	11 October 2017

STAKEHOLDER ENGAGEMENT DETAILS (CONTINUED)

Division	Stakeholder	Topics for discussion	Format	Date
Scientific Assessment and Chemical Review	Acting Executive Director – Dr Jason Lutze	• APVMA Independent review scope and activities • Reporting and assessment issues, risks and concerns over the next five years • Opportunities for streamlining assessments • Opportunities for improving reporting	Meeting	27 September 2017
	Efficacy Assessment Coordinator – Michelle Wooster	• Contestability trial for efficacy related assessments	Meeting	11 October 2017
Corporate Services	Information Management and Technology – Lisa Reaney	• Use of Portal to analyse data	Meeting	9 October 2017
Audit Committee	Peter Hoeffer	• APVMA independent review scope and activities • Reporting and assessment issues, risks and concerns over the next five years • Opportunities for streamlining assessments • Opportunities for improving reporting	Meeting	30 October 2017
Office of the Chief Scientist	Chief Scientist – Professor Phil Reeves	• Risk-based analysis of assessment • Issues with assessments • Certification and training of scientists • Opportunities for improvement of assessments	Meeting	30 October 2017
Across the APVMA	Portfolio Officers across the Authority	• Risk-based analysis of assessment • Issues with assessments • Delegation and approval processes • Opportunities for improvement of assessments	Several Meetings	November 2017
Legal	Deputy Senior Counsel – Dwayne Currie Senior Director – Helen Stokes Michael Wright Paul Grutt	• Legislation • Issues with undertaking assessments that relate to legislation • Opportunities for improvements	Meeting	16 November 2017

STAKEHOLDER ENGAGEMENT DETAILS (CONTINUED)

Division	Stakeholder	Topics for discussion	Format	Date
Across the APVMA	Chris Schyvens (Tox) Janine Knight (Env) Sarah Sunderland (Case Management and Administration Unit) Lauren Hay (Case Management and Administration Unit)	• The use of external scientific reviewers: the processes for assessments (issues and opportunities)	Several Meetings	December 2017

Attachment C

Abbreviations and Terms

REASON GROUP

ABBREVIATIONS AND TERMS

Term/Acronym	Definition
8G	Section 8 of the code.[1] Notice of rejection of an application that can be sent by APVMA during Preliminary Assessment
8S	Section 8 of the code.[1] Notice of intention to reject an application that can be sent by APVMA after Preliminary Assessment
agvet	agricultural and veterinary
ANAO	Australian National Audit Office
ANVISA	National Health Surveillance Agency (Brazil)
APVMA	Australian Pesticides and Veterinary Medicines Authority
EFSA	European Food Safety Authority
EMA	European Medicines Agency
FAMIC	Food and Agriculture Inspection Centre (Japan)
GROU	Growers Requested Own Use
HSNO	Hazardous Substances and New Organisms Act (NZ)
HSWO	Health and Safety at Work Act (NZ)
IBAMA	Brazilian Institute of the Environment and Renewable Natural Resources
ICT	Information and Communication Technology
Items 7 and 8[2]	Agvet products submitted for registration that contain an approved active ingredient and require specific module assessments. Fixed timeframes for assessment
Item 10[2]	Agvet products that contain an approved active ingredient and require multiple module assessments for registration by APVMA. Variable timeframes for assessment, depending on the modules required

Term/Acronym	Definition
KPI	Key Performance Indicator
MAPA	Ministry of Agriculture, Livestock and Supply (Brazil)
MPI	Ministry for Primary Industries (NZ)
NZEPA	New Zealand Environmental Protection Authority
OECD	The Organisation for Economic Cooperation and Development
PMRA	Pest Management and Regulatory Agency (Canada)
Recategorisation	When an agvet product is submitted to the APVMA as one item or module level and then is categorised as another item number or module level. This occurs often after the risk assessor or module assessor determines the product needs to be assessed differently, due to technical factors, risks and safety concerns
RMS	Rapporteur Member States
ROCI	Residue Open Complexity Index
S159	Section 159 of the code[1]. Request Notice for more information. Sent from APVMA to the client
VDD	Veterinary Drug Directorate (Canada)
PA	Preliminary Assessment
PAA	Pre-Application Assistance

[1] Agricultural and Veterinary Code Regulations (1995). Statutory Rules No. 27. [2]Agricultural and Veterinary Code Regulations (1995): Schedule 6

ACKNOWLEDGEMENT

Reason Group wishes to thank the staff of the Australian Pesticide and Veterinary Medicines Authority for their time, effort and cooperation during the review and in the preparation of this report.

DISCLAIMER

The recommendations within this report should be reviewed and endorsed by the executive before implementation.

The materials presented in this report reflect Reason Group's best judgement in light of the available information at the time of preparation.

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