SUBMISSION

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Submission on: **Annual Review 2024: Proposed Changes to MPI's Cost Recovery Settings**

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1. Introduction

1. The Animal and Plant Health Association of New Zealand (Animal and Plant Health NZ) welcomes the opportunity to provide feedback on the proposed changes to MPI's cost recovery settings.

2. Our comments focus on the proposed changes to the ACVM fees and levy.

3. We note the significant cost increases proposed in the discussion paper, with an 83% increase in the hourly charge our rate for ACVM staff and a 128% increase in the ACVM levy.

4. We note that ACVM is a monopoly (there is no other provider of this regulatory service) and can charge according to that monopoly unless restricted by legislation (i.e., Regulation 4A and schedule 2 of the ACVM Regulations).

5. APHANZ members acknowledge the importance of the right skills and sustainable capability in ACVMG to service 'core services' as a competent regulatory authority for our members – i.e. the processing of new product registrations and applications. We have supported ACVMG previously to advocate for further resource and have funded previous cost increases for this to enable improved outcomes and efficiency gains.

6. **However, the current cost recovery proposal (as it stands) is not supported, taking stock of the below factors.**

Economic conditions

- Conditions remain challenging for our growers and farmers. There is high potential for these cost increases to translate into further cost passed onto farmers and growers who are already under considerable pressure.

- Conditions remain challenging for our members with the current product registration environment restricting the introduction of new products to the New Zealand market. Many companies are reconsidering and scaling back their investment in New Zealand, including supply of niche products/uses that are critical to support New Zealand primary industry and processes that underpin our trade reputation e.g. animal welfare products.

- The short notice period provided to industry for the significant level of increases proposed for 1 July 2024 is also noted, noting budgets for the 2024/25 year have already been set.

- These economic factors have generated our questions regarding core services/prioritisation, efficiency gains and return-on-investment principles/assurances within this proposal.

Outcomes and return on previous cost increases – are not fully clear

- A major question from our members is what the return on investment is, including from previous cost increases we supported. Answering this question has posed a challenge, as there is currently not a clearly agreed scope of 'core' services (vs user pays) in place and associated performance metrics to report outcomes against.

- Return-on-investment principles, assurance reporting frameworks and funders agreements have enabled the investment levels realised by other regulatory schemes internationally, so we feel this is an opportunity to address this challenge and constructive options proposed below.

Prioritisation and efficiency gains – are not fully clear.

- We support a balance of core funding and leveraging efficiency gains within current processes to support fiscal discipline. We feel this should be thoroughly investigated as part of considering any further investment/resource, given wider case studies/fiscal learnings in the current regulatory landscape.

- We note a broad scope of work is proposed for a regulator already signalling resource is under pressure, without efficiency gains in core regulator services as highlighted in the discussion document.

- 69% of the deficit proposed ($7.71M out of $11.15M) is for future projected expenditure on further staffing increases and a major IT project. It is not clear to our members that additional investment alone will result in performance improvements in core services.

- We support exploring what can be done to define 'core services' and leverage efficiency gains within current processes. We believe there are untapped opportunities to free up ACVM staffing resources from over regulation of some groups of applications which should be considered before investing alone in more staff resources. These opportunities/proposed solutions are discussed further below.

- Detail on the priority ranking and governance oversight of projects and investment areas would also be helpful, notably the digital transformation project for ACVM Online (given wider case studies in this space and the considerable investment digital projects consume).

- Our members also had questions on who the beneficiaries are and what the investment timing is for other work e.g. inhibitors. Return on investment and delivery of final outcomes for these products are highly reliant on a wider part of the regulatory system that is currently signalling significant pressures.

- There is also medium to longer term potential for systems integration and cost savings that should be considered.

7. Based on the above factors, there is need to strike a pragmatic balance of agreed funding for 'core services' while enabling time to better understand other 'non-core' projects for proposed investment.
   To address this our submission proposes a phased approach to the investment, to secure a level of increase to achieve critical short-term outcomes by 1 July 2024, while providing a wider process to support fiscal discipline, and more time, to better understand how to effectively address the wider proposals inherent in the future expenditure plan (future deficit).

Priority Areas and Recommendations

1. Staffing costs

- APHANZ has proactively supported staffing increases to enable ACVM to improve processing of applications over recent years. However, we are concerned there have been declining levels of application processing efficiency as noted in the discussion paper.

- On face value, review of the figures presented within the proposal indicate a decline of approximately 39% in service hours per dollar of expenditure since 2018/19 of which only half can be attributed to inflation. The reason provided for this is high staff turnover post-Covid. We understand how this might have a short-term impact on efficiency levels and thereby on fee levels due to the decline in chargeable hours, but we note that this is also one

of the reasons provided for the increase in the levy.

- It is also unclear why staff turnover is the reason for an increase in both fees and levies. We could not clearly observe any forecast correction to efficiency levels as newly recruited staff in 2022 and 2023 gain experience and efficiency in their work.

- To support better understanding of this area, we feel a more clearly defined scope of service provision with metrics agreed by industry would enable reporting of the value delivered for these services and for changes in efficiency to be measured and included in forecast costs.

- There is a proposed increase in staffing from 1 to 3 FTEs for compliance activity. Because there has been no formal consultation with industry on this area, our members wish to fully understand the costs and benefits of this proposed increase and the driver for tripling staff resources in this area. Further information and consultation would be helpful, as our members also had questions how this investment would be prioritised against other demands (improvements in processing applications and development of guidelines).

2. IT project – ACVM Online

- While APHANZ is in principle supportive of the ACVM Online concept, we are highly aware of other case studies currently in the complexity, fiscal risk and large investment demands with digital transformation projects.
- The current estimates for Phase 1 of the ACVM project to 2024/25 are already substantial ($810,000 in estimated IT costs and associated depreciation) without any formal agreement with industry on costs and milestone progress reporting frameworks.
- Digital projects can easily escalate/blow out over time without careful oversight, fiscal discipline, and reporting mechanisms. A potential solution to address this would be ACVM Online project costs and progress milestone reporting being subject to industry review as part of a Funder's agreement. Further detail would also be helpful and appreciated on
    - Composition of the oversight/steering group for this project (industry, financial, digital expertise represented).
    - Proportion of investment that is attributed to the 'front end' (customer facing portal ACVM online) relative to the 'back end' of the IT system platform (MPI service platform).
    - Any efficiency gains/integration with other parts of MPI's IT system e.g. food safety, biosecurity.

3. Non-industry activities and funding

- It is unclear how ACVM resources are applied to other public services it provides that are outside the scope of cost recovery, and how those other services have been separately funded by the Crown to be assured there is no cross-subsidisation. This is a key concern raised by our members. Further detail and agreed 'core services' would provide a way forward on this point.

4. Timing and impact of the proposed increases

- The estimated increase of $4M (1.6M per annum in fees and $2.4M in fees) comes at a time of significant cost pressures on our industry, farmers, and growers, noting that in the medium-long term these cost increases are likely to be passed on to farmers and growers.

- The size of the fee increase, and its timing relative to company budget cycles, is also a significant concern for our members. There is a very short time period between consultation on cost recovery (commencing end of January 2024 for implementation by July 2024). This

does not provide sufficient notice for significant changes to fees and levies to be incorporated into company budgets.

5. Efficiency improvements

- Current global trends and international regulatory best practice are increasingly shifting to a modern regulator approach, which carefully considers not only the severity of risk, but the probability of risk and other factors for a balanced proportionate approach to policy and implementation.
- It is important that efficiency improvements are considered as part of the cost recovery process to keep cost increases to a minimum and to improve regulatory outcomes. A 2022 KPMG report on ACVMG also recommended several efficiency gains for implementation.
- APHANZ considers there is scope to explore efficiency gains and solutions in the following areas:

    - **Rule of 2 for some companion animal product assessments**
      Our members estimate that companion animal applications may constitute up to 15-20% of ACVMG 'business as usual'. These products have a lower overall number of New Zealand specific considerations compared to production animal products (which also need to consider important residues, trade, and food safety element).
      Beyond what are valid requirements to assess New Zealand species specific efficacy claims for companion animal products, this is an area at possible risk of overregulation. Given resource strains indicated, these products could benefit from adoption of the rule of 2/modern regulator approach (currently proposed in the human health space with immediate registration if at least two larger reputable international regulators with significantly larger risk assessment technical teams have approved these products).
      Safe to follow: Faster access to medicines for Kiwis | The New Zealand Initiative (nzinitiative.org.nz)

    - **Delegating lower risk work to industry self-assessable changes (**as proposed by APHANZ)
      Our members estimate that approximately 80% of ACVMG applications are manufacturing variations. APHANZ has already provided 15 new self-assessable changes as a solution to ACVMG that would reduce this workload (which we are awaiting feedback on).
    - **Removal of pre-screen for C1-C3 applications** (initiated by ACVM)
    - **Improvements to the process for data assessment** (as noted in the KPMG report)

- These efficiency improvements should support reduced workload pressures and a proportionate decrease in costs rather than be applied to do more robust application processing.

- Our members have expressed concern that current application processing requirements are already considered overly rigorous when compared with other overseas regulators. As an example, taking a globally approved product to the New Zealand market regularly requires significant cost and process of undertaking three (or more) separate, rigorous assessment cycles, with separate technical assessors at each step (of different levels and areas of subject matter expertise).

1. *Global dossier registration/approval* - safety, efficacy, chemistry, manufacturing, other data.
2. *Independent NZ data assessment of the above global dossier* - and any supporting NZ data
3. *ACVMG data assessment* – this can be review of the independent data assessor reports (safety, efficacy, chemistry, manufacturing) but may undergo a more detailed cycle of

4. *ACVMG assessment of the independent data assessment and in parallel review the global dossier and supporting NZ data already independently assessed.*

- We would like to have an agreed process for considering these proposals and incorporate them into cost recovery models.

- As part of the scope of the ACVMG Modernisation project, we believe a review of the outcomes and principles to be achieved is also a priority but may not be in the current scope of work proposed.

6. Impact on niche products

- This is an important consideration for ability to access critically needed products/uses for New Zealand primary industry, including for animal welfare.
- This proposal will result in an increase in levies from $2,700 to $6,650 (a $3,950 increase) over the life of a 5-year registration period, which is a significant amount for products that have niche uses and are sold in small volumes. The proposed fee increases will also have an impact on these products.

- Our members have raised concerns that products will be pulled from the NZ market (deregistered) if the annual registration levy increases this much, which will lead to limited options and supply of products for many niche uses.

- By increasing levies, the generics (register product when the registration and IP of a product lapse) will re-consider if it is worth getting and keeping a registration in New Zealand for a niche product. Thereby removing any competitive pricing to growers that may have eventuated. Competition is a means to promote the long-terms interests of growers of niche produce.

7. Removing the ability of the Director-General to reset the levy rate.

- APHANZ does not support this proposal and instead considers the levy rate should be reset with a new maximum level in the ACVM Regulations.

- We note that ACVM is a monopoly (there is no other provider of this regulatory service) and can charge according to that monopoly unless restricted by legislation (i.e., Regulation 4A and schedule 2 of the ACVM Regulations).

- Our view is that the maximum level should be updated and reset in the regulations rather than being subject to ongoing Cabinet consideration which we consider is unnecessary and will create uncertainty for industry.

We note that the discussion document states that *"if the Ministry has not sufficiently justified expected future expenditure it may be appropriate for MPI to:*
- *Change the fees to a level that can currently be justified*
- *Cover the remainder of the costs*
- *Recover the deficit from a future time period after further work has been undertaken*".

Our view is that **the future expenditure component of the fee and levy increases has not been sufficiently justified** and that further work is needed to formalise agreement on these future costs before they can be included in fees and levies.

Recommendations

1. Animal and Plant Health NZ recommends a **5**-phase **plan to cost recovery,** with an initial **Heads of Agreement** to inform a **final Funders agreement**. This is an approach that has been successfully used for other government and industry partnerships/cost sharing arrangements e.g. traceability and biosecurity funding.

2. This is based on a series of agreements as outlined in the table below. This would secure short term funds to achieve critical outcomes and allow time to better understand how to effectively address the proposals inherent in the future deficit, i.e., the proposed deficit component for future expenditure and higher risk projects. A schedule of core services would also allow faster agreement on future cost recovery cycles.

3. In an effort to support the 1 July 2024 time constraints noted in the proposal, APHANZ has also drafted in principle versions of these agreements to support next steps.

5-Phase Plan

Phase I	**Interim Head of Agreement** • Industry funding for 'core services' being secured through an interim Heads of Agreement between MPI and APHANZ. • This would allow the current deficit accrued to date and current year costs to be funded by 1 June 2024 and time to better understand areas of concern before a final Funders Agreement is signed.	By mid-May 2024 to support 1 July funding
Phase II	**Review of Priorities and Efficiency Gains** This would inform the development of a final Funder's Agreement which would consider the remaining proposed future projected expenditure. This review would incorporate: • **Consideration of the Rule of 2 for companion animals:** • **More self-assessable changes:** • **ACVM process efficiency improvements e.g.** C1-C3 applications. • **The ACVM Online Project review/steering group/agreements** • Implementation of a recent KPMG report's efficiency gains	By end July 2024 to inform a Funders agreement by Dec 2024
Phase III	• Following a revised scope of work, the remaining 'user pays' Funding is agreed through a funder's agreement. • An industry approved, co-developed performance reporting framework is implemented and reported into the industry cost recovery group. These priorities inform the principles and outcomes to be achieved in the ACVM Act modernisation work.	Medium term
Phase IV	• The government/industry funder's agreement is reflected into the ACVMG Act with a separate schedule of agreed work reviewed on an annual basis and agreed with public good, core industry and user pay components. • ACVM Act – adopts an approach consistent with modern regulator changes e.g. outcomes and risk-based principles and supporting regulation/codes/risk management practices to align with other 'light touch' implementation approaches like with the Food Act and the Veterinarians Act.	Medium term
Phase V	• Taking a systems view of the current regulatory environment and entities we believe there are options to optimise levy, entity, and policy settings (Biosecurity & Food Safety & Veterinary System alignments). This is a live discussion with the Biosecurity Act review around an integrated centre of excellence for animal health funded through a consolidated levy. Animal health has strong cross overs to ACVM Act components.	Medium-Long term

Specific comments on the discussion document

1. ***4.1.3 "An Industry Liaison Group (ILG) also meets three times a year, offering all stakeholders a forum to discuss operational matters with ACVM staff."***

   The ILG was disestablished last year so this statement is currently incorrect. ACVM staff do engage regularly with industry in wider forums including AVMAC, APHANZ Crop and Animal Health Forum's, the ACVM Workshop, attendance at industry conferences and monthly meetings.

2. ***5.4 "As part of the response to the review findings, an external assessment of the workflow processes for TNP registration was undertaken in 2022. This review found that significant improvements have been implemented and generally processes are working well."***

   This review's purpose was to deliver practical solutions to improve the efficiency and effectiveness of the ACVM approvals process and options to improve resourcing within the process. A finding was that *"significant process improvement has been implemented in recent years and the processes appear to be working well."*

   The review then proposed staffing increases that have largely been implemented and have added to the costs associated with the proposed increase in fees and levies.

   However, the review also made several recommendations for efficiency improvements that have not yet been implemented or included in the cost recovery model - including a review of the data assessment process and efficiencies from implementing the ACVM online project.

   We consider that these are valuable recommendations and efficiency gains should be implemented and allowed for in future cost estimates which should result in a reduced level of increase for the proposed fees and levies.

3. ***6.2.4 "While industry organisations provided caveated support for an increase, they sought greater transparency about the costs before expressing comfort."***

   APHANZ's cost recovery submission last year noted that "*the current arrangements are not sustainable (higher costs for less applications processed within the statutory timeframe) and requested that the regulator consider that the current system is not meeting the principles of the Controller and Audit-General of effectiveness or the current and impending risk to primary industries, importers, exporters, and the public*."

   While APHANZ supports the need for adequate resourcing of ACVM, we were, and remain, opposed to increases in fees and levies that have not fully addressed our questions/concerns about transparency, efficiency, and equity.

4. ***"6.4 Industry has also expressed support for two additional staff to deliver the compliance function."***

   We are not aware that APHANZ/Industry has been formally consulted on the proposal for two additional compliance staff. We have in previous years expressed general support for more work dealing with unregistered products, however this was not linked at the time to the proposed increase in staffing levels. Further detail here would be helpful, as our members had questions on
   - how this investment would be prioritised against other demands (improvements in processing applications and development of guidelines).

- the costs and benefits associated with this proposal.

5. ***"6.4 Responding to industry feedback, MPI has resourced an ongoing work programme to maintain and develop guidance to support industry to engage with the regulatory regime. In October 2023 alone, MPI opened consultation on three guidance documents for Agricultural Chemicals and one for Veterinary Medicines."***

   We note that the three guidance documents consulted on in October 2023, were part of a longstanding process for updating the Agricultural Chemicals Chemistry and Manufacturing Guidelines which was initiated in 2020, a process which has taken over three years to date.

   There are also currently two draft Veterinary Medicine Guidance documents (Veterinary Medicines Labeling and the Chemistry and Manufacturing Guidelines for Immunobiologicals) that APHANZ provided submissions on in 2022. We are still awaiting responses for these, ACVMG have advised this is due to the need to prioritise the processing of applications in the veterinary medicines queue.

   While APHANZ fully understands and supports the need to prioritise the processing of delayed applications given current queue levels, we are concerned with the delays in completing these important guidance documents. Guidance documents provide a very important service to our members as they assist in enabling efficient and effective compliance with ACVM requirements.
   Our view is that investment in development of guidance documents is a higher priority than other proposed work in the discussion document.

Responses to questions in the discussion document

Do you have any general comments on MPI's overall approach to cost recovery? Yes / no. If yes, please explain.

We are in general agreement with MPI's cost recovery principles of Transparency, Justifiability, Efficiency and Equity. We do feel there is opportunity to strengthen the approaches around confirmed priorities, core services and associated performance reporting, to enable strong visibility of outcomes for investment as observed with other regulatory systems.

As noted in MPI's cost recovery principles, costs should also not be recovered unless there's been adequate consultation with affected parties including 'sufficient time and information to make an informed contribution' and that adequate consultation can only happen if MPI has been transparent. An important part of parties' consideration and the overall social licence to operate is ability to demonstrate what value has been realised from previous work/investment.

The level of increase proposed for ACVM fees and levies, at 83% and 128% respectively, is significant, and is well above inflation, reflecting an increase in resourcing and service levels at ACVM.

Our view is that the size of this increase and the reasons for this level of increase could have been forecasted and formally consulted on earlier, to enable industry sufficient time for a better-informed view on the level of service provision associated with these increases.

We note that the discussion document states that *"if the Ministry has not sufficiently justified expected future expenditure it may be appropriate for MPI to:*

- *Change the fees to a level that can currently be justified*

- *Cover the remainder of the costs*
- *Recover the deficit from a future time period after further work has been undertaken*".

Our view is that **the future expenditure component of the fee and levy increases has not been sufficiently justified** and that further work is needed to formalise agreement on these future costs before they can be included in fees and levies.

Therefore, it would be appropriate for MPI to change the current fee increase to a level that can be currently justified (with a strong link to agreed core services) and to establish a process for consulting and formalising agreement on future costs and associated cost recovery.

APHANZ believes that an agreed current fee increase can be swiftly implemented for core services through an interim Heads of Agreement for implementation on 1 July 2024. The proposed future plans for expenditure could then be reviewed and agreed with industry in a Funders agreement by a deadline 31 July for implementation by 20 December 2024. To be supportive, we have prepared draft versions of the above agreements, in anticipation of having these developed and in place as soon as possible.

ACVM Fee update

• Do you agree with the identified problem regarding ACVM fees? Yes / no, please explain.

We do not agree with the problem as currently identified as the forecast costs component of the problem assumes changes to service levels (staffing levels and IT systems) with associated costs that have not been formally consulted and agreed on.

We do agree with the component on the identified problem due to higher-than-expected inflation costs and previously agreed staffing increases in 2020/21 which is when the deficit began to accrue. We also support the findings of the KPMG review on staff levels.

We consider a phased approach will enable us to reach quick agreement on an increase from 1 July 2024 to cover the agreed components of the identified problem, as well as providing a process for reviewing and coming to agreement on those aspects that require further consultation.

• Do you consider that the level of investment in fee services has been necessary? Yes / no, please explain. Can you suggest any other options?

Up to 2023/24 – yes.
Beyond 2023/24 – no.

<u>Staffing increases</u>
APHANZ was supportive of the investment to increase staffing levels in 2020/21 as being necessary and the staffing increases recommended in the KPMG report.
We are also supportive of increased investment in staff costs to ensure employment conditions remain competitive. We are mindful of the significant impacts of staff turnover in recent years on system performance and the importance of retaining experienced staff to provide an efficient and effective service.

However, on face value from the figures presented, we estimate there has been decline of approximately 39% in service hours per dollar of expenditure since 2018/19. Approximately half of this is attributable to cumulative inflation, but the remaining decrease suggests there has been a real decline in chargeable hours per $ of expenditure i.e. fewer hours of charged service provision per dollar spent. The discussion paper notes that a contributing factor may be the higher-than-expected staff turnover post-Covid.

We understand how this might have a short-term impact on efficiency levels and thereby an impact on fees due to the decline in chargeable hours, but this is also one of the reasons provided for the increase in the levy. It is not clear why staff turnover is the reason for an increase in both fees and levies. We also note that there does not appear to be any forecast correction to efficiency levels as newly recruited staff in 2022 and 2023 improve their competency.

To support better understanding of this area, we feel a more clearly defined scope of service provision with metrics agreed by industry would enable reporting of the value delivered for these services and for changes in efficiency to be measured and included in forecast costs.

There is a proposed increase in staffing from 1 to 3 FTEs for compliance activity. We are open to fully understanding the costs and benefits of this proposed increase and the driver for tripling staff resources in this area, but there has been no formal consultation with industry on this area. Further detail and consultation would be helpful, as our members had questions how this investment would be prioritised against other demands (improvements in processing applications and development of guidelines).

IT Project – ACVM online

Per our comments above, while APHANZ is in principle supportive of the ACVM Online concept, we are highly aware of other case studies in the wider environment in the complexity, risk and large investment demands with digital transformation projects.

The current estimates for Phase 1 of the ACVM project to 2024/25 are already substantial ($810,000 in estimated IT costs and associated depreciation) without any formal agreement with industry on costs and milestone progress reporting frameworks.
Digital projects can easily escalate/blow out over time without careful project oversight, fiscal discipline, and reporting mechanisms. A potential solution to address this would be ACVM Online project costs and progress milestone reporting being subject to industry review as part of a Funder's agreement. Further detail would also be helpful and appreciated on

- Composition of the oversight/steering group for this project (industry, financial, digital expertise).
- Proportion of investment attributed to the 'front end' (customer facing portal ACVM online) relative to the 'back end' of the IT system platform (MPI service platform).
- Any efficiency gains/integration with other parts of MPI's IT system.

• Do you consider MPI's assessment of how these services have performed is reasonable?

When we considered performance, there has been significant feedback that the overall registration process experience, compared with Australia, is viewed as less efficient and more burdensome (has been covered in the discussion document).

We appreciate and respect the need for the regulator to assess valid, specific risks to New Zealand, but the sense is the overall approach on balance is heavy-handed side compared with other international regulators/a modern regulator approach.

MPI's assessment also highlights the drop in volume of fee related services relative to expenditure and the reasons why, including high staff turnover, and concluded that cost efficiencies may be possible.

Given the above, we believe there is scope for cost efficiencies to be realised by increasing the opportunities for self-assessment of low-risk variations to registered products through

changes to guidelines proposed by APHANZ. ACVM have also initiated improvements to efficiency through a trial on removing the pre-screen process for C1-C3 applications which is already having had a beneficial effect. The KPMG reports also identified opportunities for efficiency gains through reviewing data assessment and implementation of the ACVM Online Project.

In the medium to long term, APHANZ is proposing changes to the ACVM Act that will enable greater alignment with internation regulators decisions to further improve efficiency.

These initiatives, together with the expected improvements resulting from new staff becoming more proficient suggest that there is significant potential for efficiency gains that have not been factored in. Our expectation would be that these efficiency improvements should result in proportionate decreases in costs rather than be applied to do more robust application processing. As noted in the discussion paper and above, our members have expressed concern that current application processing requirements are already overly rigorous when compared with overseas regulators.

We consider that realising these efficiencies needs to progress swiftly and be included in cost modelling as soon as possible to avoid unnecessary increases in cost recovery and the likely accumulation of surplus should these gains be realised as expected.

• Do you have any other comments on MPI's assessment around the four cost recovery principles?

Yes. As ACVM resources are also used for wider activities in addition to the services provided to our industry, it is important that we understand how ACVM resources are applied to these other services and how those other services have been separately funded to be assured there is no cross-subsidisation.
We understand that this includes a broad scope of work that ACVM does on Ministerial servicing, OIAs, MRL setting, antimicrobial resistance (AMR) and development work for inhibitors.

As part of the consultation process to date, we have received a summary of the public good functions ACVM are performing but, except for the AMR team, no information has been provided on the funding level provided by the Crown for these public good functions.
This makes it extremely challenging to understand how the industry and public good functions of ACVM have been separated for funding purposes.

In line with our earlier comments, we believe a clearly defined scope of core services and associated performance metrics are important.

• Would the proposed base hourly rate cause you / your business / the sector significant concern?

As the discussion paper notes, in the medium to longer term it is likely that these costs will largely be passed onto farmers and growers using products.
The estimated increase of 1.6M per annum or 0.2% of total market value comes at a time when there are a lot of cost pressures on our industry, farmers, and growers.

The size of the fee increase, and its timing relative to company budget cycles, is also a significant concern for our members. There is a very short time between consultation on cost recovery (commencing end of January 2024 for implementation by July 2024).

This does not provide sufficient notice for significant changes to fees and levies to be incorporated into company budgets. Company budgets are often set on calendar years, and expected expenses are often required by Q3 of the preceding year. Any change in cost

recovery that will lead to a substantial increase needs to give companies sufficient time to prepare and budget for the changes – which means as least 8 months' notice, depending on exactly when the fee change would occur.

Therefore, it would be appropriate for MPI to change the current fee increase to a level that can be currently and realistically justified (with a strong link to agreed core services) and to establish a process for consulting and formalising agreement on future costs and associated cost recovery.

• Please provide any additional relevant data/information on the impacts of the proposed base hourly rate to you / your business / the sector.

The discussion paper notes that greater costs may lead to a decrease in the number of agricultural compounds in the market. We agree this is a genuine risk and concern.

Our members have raised concerns that products will be pulled from the NZ market if fees and the levy are increased as proposed. They note that many products are for niche markets and have infrequent demand that is often dependent on the pest/disease incidence. This could lead to limited options and supply of products for many niche uses.

• Are there any other issues you think MPI should be aware of?

In weighing up whether to register a new product in NZ one of the considerations is the cost and time it will take to get regulatory approval and how predictable the registration process is in terms of timing, information requirements and outcomes.

Over recent years, timeframes for approval, increased requirements for information, and less predictable outcomes have made NZ a less attractive market. This impacts products applications within the Environmental Protection Authority and linkages to ACVMG applications.

APHANZ is mindful of the challenges faced by the ACVM team and appreciates the ongoing efforts of ACVM management and staff to engage with industry and to work constructively on improvements and solutions. APHANZ has recommended several changes that we consider would lower the administrative and technical burden on the ACVM team without increasing ACVM risks including:

- Adoption of the rule of 2 for companion animal products
- Trusted Regulator amendments
- Self-assessable changes

We would like consideration of these changes to be given priority as part of the ACVM Modernisation Project, to help rationalise ACVM's workload and to enable ACVM resources to be focused on key areas of risk.

ACVM Levy rate

• Do you agree with the identified problem regarding the ACVM levy? Yes / no, please explain.

No. The problem identified in the discussion document includes a 40% increase in levy expenditure in 2023/24 with inflation currently at 4.7%. We do not agree with this definition of the problem as there is insufficient detail and agreement on the IT and depreciation costs (ACVM Online) which are a major component of this increase.

Increased staffing costs are also a factor behind this increase – with the forecast expenditure includes the cost for two additional compliance staff within ACVM (from 1 to 3 FTEs). Industry has not been formally consulted on this proposal and we would like an opportunity to discuss and agree on this before it is implemented and built into the levy. Consultation would provide greater clarity on understanding the value of a 200% increase in staff resources in this area and level or priority compared to other urgent areas of investment.
The high level of compliance of the industry, with most non-compliances related to unregistered non-compliant ACVM products, would point to less staff resources in this area.

• Do you consider that the level of investment in levied services has been necessary? Yes / no, please explain. Can you suggest any other options?

No, as currently proposed we do not consider the proposed future levels of investment are necessary. We would like to further understand the pros and cons of additional staff to the compliance team (given there was no formal consultation on this to date) and we remain unclear on why there is a significant ongoing expenditure impact due to the high turnover of staff post Covid across both fees and levies. There should be efficiency gains allowed for as these staff progress with their training, and we would expect training costs to return to an agreed normal level based on a long-term estimate of staff turnover rates.

• Do you consider MPI's assessment of how these services have performed is reasonable?

MPI's assessment has not addressed the issue with delays in development of guidance documents. Development of guidance to support industry to engage with the regulatory regime is an important service that ACVM provides under the levy. However, there have been significant delays in getting guidance documents completed over recent years.

The release of a second draft of the chemistry and manufacturing guidance documents for Ag Chemicals in October 2023 was a follow-up to an initial consultation that closed on 14 August 2020. There have also been lengthy delays (>1 year) in progressing updates to veterinary medicines labelling guidance and development of chemistry and manufacturing guidance for biologicals.

We understand that these delays have been due to staffing changes and resources being directed to reducing the backlog of veterinary medicine applications.
Given this situation, we consider that development of new and updated guidance documents should be a top priority for any proposed increase in levy funding.

• Do you have any other comments on MPI's assessment around the four cost recovery principles?

Yes. As ACVM resources are also used for activities in addition to the services provided to our industry it is important that levy payers understand how ACVM resources are applied to these other services and how those other services have been separately funded to be assured there is no cross-subsidisation. We understand that this includes work that ACVM does on Ministerial servicing, OIAs, MRL setting, antimicrobial resistance (AMR) and development work for inhibitors.

As part of the consultation process to date, we have received a summary of the public good functions ACVM are performing but, except for the AMR team, no information has been provided on the funding provided by the Crown for these public good functions. This makes it difficult to see how the industry and public good functions of ACVM have been separated for funding purposes.

- MPI assessment does not recognize that registered agriculture chemicals products have a public good (for domestic gardeners and communities), that is only available due to commercial interests. This is recognized in the Aotearoa Horticulture Action Plan (AHAP), which was developed in partnership by industry, government, Māori, and research providers and released in February 2023. Under Key priority 1.3 acknowledges that '*Without crop protection tools the commercial viability of growing fresh produce is significantly diminished, which puts people's livelihoods and communities at risk and resilience to other factors, such as adverse weather events, is weakened'*.

• Would the proposed levy rate cause you / your business / the sector significant concern. Yes / no, please explain.

Yes. As the discussion paper notes, in the medium to longer term it is likely that these costs will largely be passed onto farmers and growers using products. The estimated increase of 2.4 M per annum or 0.3% of total market value comes at a time when there is a lot of cost pressure on our industry, farmers, and growers.

As with any downturn, farmers and growers reduce costs in agricultural chemicals. The New Zealand Institute of Economic Research (NZIER) 2019 estimated that without access to sufficient, suitable crop protection tools, New Zealand's economy would lose approximately $5 billion per year.

If the manufacturers of crop protection tools do not choose or find it uneconomical to register new tools here, due to costs of registration, protracted approval processes and on-going issues then New Zealand farmers and growers will be further disadvantaged. Disadvantaged in terms of tools as well as cost effective options to choose from.

New Zealand is a small market ($140M/annum) that has limited number of competitors in the crop protection market due to the small market size. Increasing fees, diminishing efficiencies in processing applications has far more to lose than they do
.
As with the fee increase, the size of the levy increase and its timing relative to budget cycles is significant concern for our members (see below). There is a very short period of time between consultation on cost recovery (commencing end of January 2024 for implementation by July 2024). This does not provide sufficient notice for significant changes to fees and levies to be incorporated into company budgets. Company budgets are often set on calendar years, and expected expenses are often required by Q3 of the preceding year. Any change in cost recovery that will lead to a substantial increase needs to give companies sufficient time to prepare and budget for the changes – which means as least 8 months' notice, depending on exactly when the fee change would occur.

• Please provide any additional relevant data/information on the impacts of the proposed levy rate to you / your business / the sector.

The discussion paper notes that greater costs may lead to a decrease in the number of agricultural compounds in the market. We agree this is a concern which particularly applies to the proposed increase in levy costs which are paid annually. The proposal will result in an increase in levies from $2,700 to $6,165 (a $3,465 increase) over the life of a 5-year registration period which is a significant amount for products that have niche uses and are sold in small volumes.

Our members have raised concerns that products will be pulled from the NZ market if the annual registration levy increases by this amount which will lead to limited options and supply of products for many niche uses.

• Are there any other issues you think MPI should be aware of?

We are mindful inhibitors are a priority discussion area for New Zealand currently.

When we take an outcomes focus (the solutions being available and in use on farm), we are highly aware that return on investment and delivery of final outcomes for inhibitor products are reliant on a wider part of the regulatory system that is currently under significant pressure including application timelines. Our members have questions on ACVMG's investment timing for this work in the current cost recovery cycle, considering wider system and timeframe challenges for delivery of outcomes.

Removing the ability of the Director-General to reset the levy rate.

• Do you have any comments on this proposal? Yes/no, please explain.

APHANZ does not agree with this proposal and instead considers the levy rate should be reset with a new maximum level in the ACVM Regulations.

ACVM is a monopoly (there is no other provider of this regulatory service) and can charge according to that monopoly unless restricted by legislation (i.e., Regulation 4A and schedule 2 of the ACVM Regulations currently sets out the levy payable to a maximum of $590).

It is conceivable that the levy would be subject to Section 36 Commerce Amendment Act 2022 that amended laws on the miss use of market power, unless exempt (such as agricultural producer boards).

We agree with the need to update the maximum level in the regulations due to changes in inflation and agreed service levels, and that updating the level should be subject to Cabinet scrutiny as with any regulatory change, particularly given ACVM's monopoly status. However, our view is that the cap should be updated and reset in the regulations rather than being subject to ongoing Cabinet consideration which we consider is unnecessary and creates uncertainty for industry.

APHANZ agrees with the need for consultation with relevant industry organisations and providing sufficient time and information to make an informed contribution, but we do not see a need for Cabinet scrutiny every time there is a change. We note our view is that current proposed increases to fees and levies are an overestimate due to there being no consideration of efficiency gains and it should not be necessary for Cabinet to approve an adjustment to the levy to return a surplus in the future.

About Animal and Plant Health NZ

We are the peak industry association representing more than 85 multinational and New Zealand based companies that manufacture, distribute, and sell crop protection and animal health products that keep our animals healthy and crops thriving. Our mission is to protect and enhance the health of crops, animals, and the environment, through innovation and the responsible use of quality products and services.

Our objectives are to:

- Strive for effective and sustainable animal health and crop protection technology through industry leadership and advocacy.

- Achieve a balanced and science-based regulatory environment that gives members freedom to operate and grow in New Zealand.
- Enable farmers and growers to supply high quality food and fibre into domestic and global markets.
- Create an environment that encourages competition through innovation.
- Promote stewardship and responsible use of products.
- Support the health and wellbeing of pets, livestock, and people.