SUBMISSION

+64 (0)4 499 4225 I PO Box 5069, Wellington 6140 New Zealand I **www.aphanz.co.nz**

To:	costrecovery@mpi.govt.nz
Submission on:	Annual review: Proposed 2023 changes to MPI's Cost Recovery
Date:	**27 April 2023** **(Extension of time from 24 April 2022 provided by Bruce Arnold, MPI)**
Submitter:	Mark Ross Chief Executive Animal and Plant Health Association of New Zealand Email: mark.ross@aphanz.co.nz

1 Introduction

1.1 The Animal and Plant Health Association of New Zealand (Aphanz) welcomes the opportunity to provide feedback on the MPI discussion paper *Annual review: Proposed 2023 changes to MPI's Cost Recovery*..

1.2 Aphanz response relates to agricultural compounds and veterinary medicines (ACVM) levy (currently $540 by user) proposed to increase to $1,176 levy by user from 1 July 2023 and thereafter increasing annually by $354 (to $1530 by user in 2024/25) and $391(to $1921 by user in 2025/26) based on unverified accounts (preferred option of the regulator Ministry for Primary Industries (MPI)). That is an initial increase of 117% followed by an annual increase of 25.5% (2024/25) and 37.5 % (2025/26) totaling 180% over a period of 3 years.

2 Animal and Plant Health NZ Submits:

2.1 Aphanz has a current position of supporting regulatory cost recovery where that cost is fairly allocated to the regulatory task, is based on performance to meet statutory requirements, is accompanied by a transparent process of delivery and that the regulator maintains an effective performance delivering the service.

2.2 It is important to our members, chemical and veterinary medicine manufacturers, and importers, that benefits occur from any increases in fees. The premise of the discussion paper is that expenditure is surpassing the levy charged, hence an increase is required. There is no corresponding undertaking presented in the discussion paper to lift performance, improve resourcing, provide efficiencies, or provide a continually improving system of application processing.

2.3 Aphanz submits that the statutory turnaround of applications has fluctuated at ACVM. A Review [1] of the ACVM service (2020- 2021) has seen a deterioration of processing timeframes for new product use of 46.75% processed on time, chemical and manufacturing alterations processing of 71.45% processed on time. Acknowledging that COVID had a part to play in the performance and that administration variations reached a commendable 98.76% processed on time. In comparison, similar regulators (Australian equivalent of ACVM) have a 94% plus rating for processing on time.

2.4 Aphanz submits that there is insufficient detail (transparency or justification) to support a decision on the preferred option (listed in section 1.2 of this document) or other options as proposed in the discussion paper.

2.4.1 As an association representing members using the ACVM services, Aphanz expects a more thorough breakdown of the proposed 117-180% levy increase, to include, scope of the deficit, pre-application screening fee, total assessment time per application with hourly rates, type of application, administrative / document handling fees, publication fees and so on. There is no comprehensive time-recording data presented that accurately captures the activities and services associated with processing applications. Therefore, no transparency has been provided on the content of the deficit making it impossible to determine whether other ACVM activities outside of applications have been included in the deficit calculation. Not having access to, and consideration of this level of data, raises concerns about the ability of the regulator to accurately resource and meet statutory performance targets in future years.

2.4.2 Aphanz acknowledges that those companies applying for new ACVM services (i.e., inhibitors) are testing the ACVM system with a product that is a world first (compounds and application process) and that the process will take time and incur significant costs. Under cost recovery principles it is anticipated that each application is costed according to the time taken to approve, and the applicant pays full cost recovery. The deficit includes the gearing up of ACVM (for the inhibitor process) as noted in section 5.3.2.2 of the discussion paper, when the companies applying for inhibitor approval are not necessarily previous applicants of normal ACVM services. Insufficient detail has been provided to determine whether the costs associated with inhibitor applications would be fully cost recovered or if the costs associated with processing inhibitors would be subsidised (through deficits) by those applicants that are not associated with inhibitor applications.

[1] Agricultural Compounds & Veterinary Medicines Act 1997 – A regulatory System Review (the Review)

2.5 The regulators assumption is that *charging beneficiaries encourages them to demand and use the quantity and quality of services they value highly enough. It helps ensure that the quantity and the quality of service is not higher than what is required* (Section 3.2.1 of the discussion paper). In a contested service market this would be true, however, the service ACVM provides is a monopoly (there is no other provider of this regulatory service). Therefore, ACVM customers (operating in a competitive international market) may demand improved service, but as a monopoly ACVM has no commercial impetus to provide the resources to meet the demand and is able to charge according to that monopoly unless restricted by legislation (i.e., Regulation 4A and schedule 2 of the ACVM Regulations sets out the levy payable to a maximum of $590).

2.6 Aphanz does not support deficits (from previous applicants) being apportioned to future applicants. This would contravene Regulation 4A and schedule 2 of the ACVM Regulations that sets out the maximum levy payable is based on future fiscal years. In addition, the deficit data presented does not provide sufficient information to ascertain that the public good functions (that are separate to applicants) undertaken by ACVM are not part of the deficit.

2.7 Aphanz members are supportive of reform that enables innovation and balances economic viability and sustainable environmental management, but there is too much change (increased fees from (Environmental Protection Authority (EPA) as well as MPI) at once and it is happening too quickly for stakeholders to respond or adjust economic forecasts and pricing. This will cause significant pressure on a small compliant industry that is struggling to get applications approved (ACVM and EPA) to respond to pest and disease risk for land-based industries or to accommodate biosecurity requirements at the border (for import and exports) where all (chemical companies, land based, importers, exporters, general industry) are experiencing economic hardship due to adverse events, climate change, supply chain issues, labor shortages and offshore economic challenges. With this in mind, we propose that the implementation of any significant changes to cost recovery be delayed until early 2024.

2.8 Aphanz submits that imposing a significantly higher levy structure without demonstrating how this will lead to process improvement acts as a disincentive for applicants to propose safer or more environmentally sustainable chemicals for consideration due to the high-cost implications of delays to processing applications. From the information provided the cost recovery process itself is not resourced, therefore there is no forward planning and hence inconsistencies in performance from year to year.

2.9 Aphanz, submits that the current arrangements are not sustainable (higher costs for less applications processed within the statutory timeframe[2]) and request that the regulator consider that the current system is not meeting the principles of the Controller and Audit-General of effectiveness [3] or the current and impending risk to primary industries, importers, exporters, and the public.

2.10 Aphanz submits that the scope of approvals (for example, assessment of animal medicines not classed as veterinary drugs overseas, assessment of chemistries already approved overseas, requiring resubmissions for any minor change in chemistry) is duplicating effort. Sometimes effort is duplicated between EPA and ACVM causing confusion.

2.11 Aphanz submits that MPI need to engage with industry to ensure that applications are processed within statutory time frames, there is certainty within the process for applicants and that planning enables future inconsistencies with application processing to be annulled.

2.12 Aphanz acknowledges and supports ACVM's important role in managing risks under the ACVM Act and the part it plays in the logistics chain for agricultural compounds needed to manage risk in a land-based economy. Aphanz submits that MPI/ACVM progress and action the efficiency findings of the Agricultural Compounds & Veterinary Medicines Act 1997 – A Regulatory System Review (the Review) as well as the findings of the Auditor General, and KPMG Processing and Resourcing Review (report requested but not available to be reviewed) to consistently deliver timely and expeditious service to applicants consistently with cost modeling that fairly represents application processing costs.

3 Clarification of the MPI Discussion Paper

3.1 We understand that MPI seeks feedback on the proposed options to recover costs, but the submission time is short (the discussion paper period for response is 4 weeks or 20 working days) compared to the usual consultation period which is 30 working days. The shortened time over a holiday period (Easter) reduces the ability to provide quality submissions in a timely fashion.

3.2 Section 5.2.5 of the discussion paper states that various industry representatives indicated that cost recovery for trade name product registrations and applications works well based on based on a Review. The Review[3] referred to actually noted that whilst industry are appreciative of the personnel that work within ACVM , the review found there were concerns raised about some elements in the way the system operates; some industry stakeholders commented on the time it can take to register new ACVM products or new uses, alignment of regulatory practice with common international practice, level of communication about the status of registration applications, and the lack of an online registration portal.

3.2.1.1 The Review also noted that no forward-based thinking had been adopted resulting in an accumulation of funds (in some years) and no investment in the process (technology, process streamlining, resourcing). The review further noted that suitable personnel were in short supply with constant vacancies.

3.3 The performance measures priorities (as noted in Section 3.1) state '*once Transparency and Justification principles have been met, the Efficiency and Equity principles provide that the beneficiaries of a service should generally pay for that service*. The discussion paper uses the term 'efficiency" as to how the service being provided manages a regulation. Industry is interested in productive efficiency (maximizing outputs) to meet the statutory turnaround for an application.

3.4 There does not seem to be any cost modelling to estimate future levies. A formula is mentioned in section 5.3.2.3 but there is no detail of what this could be. Previously the levy increased after consultation and is an estimate (of the maximum levy able to be charged under the ACVM regulations). However, there is no mention in the discussion paper as to what the maximum levy amount would be and no mention of any further consultation regarding a formula.

3.5 It is noted that the MPI Cost Recovery Policy Guidance (by which the discussion paper is guided) provides the principles (transparency, justification etc.) but does not provide a way of attributing costs equitably (between benefiters/public benefit) with adequate resourcing providing an ongoing acceptable service.

3.6 There is a disconnect in interpretation of cost recovery principles with other regulators and how to manage cost recovery. For example Treasury Guidelines were relied on by the EPA when consulting on cost recovery, where detail of the cost allocation and a plan of monitoring and review is provided. The details of the actual time taken to process an application is not provided in the discussion paper and this is key to the cost recovery process (per Treasury Guidelines)

3.7 A review of ACVM Cost Recovery was conducted in 2015 and the submission from Aphanz noted that Aphanz was realistic about ACVMs need to cost recover, but where full cost recovery was not achieved it was MPI's responsibility to manage any shortfall. Aphanz submits that this is still our member's position. Noting the levy applies to future fiscal years and does not accommodate past deficits.

Cost Comparisons

3. 8 The regulator is presenting an extreme levy increase (117% increase) without breaking down the makeup of the deficit (as relevant to applications submitted) which the proposed levy suggestion is based on. If the deficit is quantified, then future levy payers will be subsidizing the deficit (there is no write off mentioned of the current

[3] Agricultural Compounds & Veterinary Medicines Act 1997 – A regulatory System Review (the Review)

deficit) as well as any future efficiencies (updated application system) with no guarantee of an improvement in application turnaround that meets the statutory requirements of 40 days.

3.8.1 The Consumer Price Index (CPI) for the year 2015 to 2022 is 23.1%[4]. A disparity between the cost increases requested from the regulator (117%) initially provides an overall cost increase differential of 94% above the CPI.

3.8.2 There is insufficient detail to determine if ACVM (service for applications and the ACVM role that is a public good) is differentiated.

3.8.3 The cost of not managing risk, caused by delays, is that the benefits to all parties (applicants, public and industry) dissipate. Over ten years the impact of a one-year delay (of an application) could be a loss of between $7- $70 Million in contribution to New Zealand's GDP[1.]

3.8.4 Applicants to ACVM services operate in an international market, of which New Zealand is a very small market (.06% of the global market). To invest in the New Zealand agricultural compound market requires efficiencies (regulation efficiency, importation/manufacture, potential sales). With an inefficient regulatory service (first action to research/import/manufacture) then there is little incentive for applicants to pursue approval of agricultural compounds in New Zealand.

Economic impact of the industry

3.9 The crop protection industry and veterinary medicines alone services land based agricultural industries that provide a combined ($22.92B (8% of NZ's GDP of $284B (2018))[5], whilst the industry itself contributes $142M to NZ's GDP through exports. The data provided in the discussion paper (section 4.2) of $350M of the total size using 2019 data does not recognize the direct contribution that both veterinary medicines and crop protection exports contributes to the economy and underestimated the contribution of crop protection provides. Factors such as preserving biodiversity and managing increasing challenges from climate change are not factored into the economic analysis.

3.10 In addition, the ability to import and export goods relates to the ability of NZ inc. to treat (apply chemicals) on arrival to various imports to preserve NZ's biosecurity/land-based economy or meet the importing country phytosanitary requirements (ICPR) for NZ exports. A review of this area shows that $26B6 of imported goods rely on chemical treatment to preserve biosecurity at the border, and some $3B/annum rely on a chemical treatment to meet ICPR requirements.

3.11 Over ten years the impact of a one-year delay (of an application) could be a loss of between $7- $70 Million in contribution to New Zealand's GDP1. This loss impacts land-based farming (GDP will reduce from 10%) and the overall GDP of the industry itself to the NZ economy (currently .01% of GDP). In addition, imports and exports are affected as restrictions on the key chemical treatment (methyl bromide) is being phased out over the next 13 years. This requires the industry to look at innovative, greener chemistries to manage a wide range of issues.

Suggestions

3.12 Aphanz notes that there are reviews and process analysis of the costings available to improve the performance of the service (Agriculture Compounds and Veterinary Medicines Advisory Council for the Inspector General Review, Auditor General Reports and KPMG Processing and Resourcing Review (undertaken by MPI but not released).

3.13 Aphanz contends that the reviews undertaken may provide guidance as to how to maintain a fair and equitable. system of cost recovery whilst building the regulatory efficiencies that growers and industry seek.

---

[4] Reserve Bank of New Zealand inflation-calculator

[5] NZIER Report & KPMG Report

[6] https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203660/97838963f6/APP203660_Response-from-MPI-to-EPA-re.Methyl-bromide-information.pdf

4 Questions for Submitters

Q1, Do you have any thoughts on MPI's overall approach to cost recovery? Yes/No. if yes, please explain.
This point is covered in section 2.1-3.12 of this document. In addition:

i. A 180% increase of fees without addressing the cause of the deficit or providing details of the deficit, plus without including new efficiencies (transparent processing, faster turnaround, increased resources) with more pending costs (new processing technology) on the way does not inspire confidence in the cost recovery process.

ii. The cost recovery process has not worked consistently (a deficit continually occurs; the service is not efficient and able to always meet statutory requirements) and investment in a continual improvement process and service provision has been slow to materialise.

iii. Despite reviews of the ACVM service, recommendations have not been enacted.

Q2 Is MPI's understanding of related economic impacts on the areas under review like you're understanding and experience? Yes/No. Please provide a reason(s) for your response.

This point is covered in section 3.9 to 3.11 of this document and show that the economic impacts noted in the discussion document are significantly underestimated.

Q3 How do you think the current financial and economic climate will impact the proposed changes?

iv. Costs associated with approval of crop protection and veterinary medicines will be passed to growers/farmers, which are already struggling in the financial and economic climate as well as coping with recent adverse events. The ability of growers/farmers to keep on top of pests and diseases will be compromised as growers under financial duress opt not to manage certain pests and disease which will affect production targets and export markets .

v. NZ is a modest animal health market. Increased compliance costs are going to disincentivise bringing new products to New Zealand (contrary to the comments made in the submission discussion paper) as the cost: benefit ratio has deteriorated substantially with the slow regulatory processing of applications. In addition, assistance through guidelines for applications (i.e., updated Chemistry and Manufacturing Guidelines or Guidelines for Veterinary Biologics) is delayed. Any harmonisation (reliance on other regulators offshore) mentioned by ACVM at various forums is delayed.

Q4 Is there any additional relevant data/information MPI should be aware of to help consideration in this area? Yes/No. Please explain.

i. There is no update as to what the maximum levy will be replaced with (under ACVM Regulation). Will applicants be asked to fund the regulation change ? Currently the levy is set at a maximum of $590 with a proposal to lift the levy to cover past deficits and a new application system.

ii. The lack of options on the market for growers has necessitated the use of old chemistries which are harder on the environment and are becoming restricted, prohibited, or ineffective overseas and in New Zealand. With reduced ability to get greener products on the market, growers' ability to export to markets that demand a 'greener' footprint will be compromised.

5 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.

6 References

1. Inspector General Regulatory Systems, June 2022, *Kaitiro Matua Punaha Waiture Agricultural Compounds and Veterinary Medicines Act 1997*

2. New Zealand Institute of Economic Research, July 2019, *The Importance of Crop Protection Products for The New Zealand Economy.*

3. Klynveld Peat Marwick Goerdeler KPMG , 2021, *Assessing the value of the Animal Health Industry to New Zealand*, 2021,

4. MPI, July 2019, *Information on the biosecurity use of methyl bromide in New Zealand*, Response from MPI to EPA re Methyl bromide information

5. NZ Treasury, 2017, *Guidelines for setting Charges in the Public Sector*

6. Reserve Bank of New Zealand Inflation calculator