

Submission on the Agricultural and Horticultural products regulatory review

To the Ministry for Regulation 6 September 2024

Submitter details

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The Parliamentary Commissioner for the Environment

The Parliamentary Commissioner for the Environment was established under the Environment Act 1986. As an independent Officer of Parliament, the Commissioner has broad powers to investigate environmental concerns and is wholly independent of the government of the day. The current Parliamentary Commissioner for the Environment is Simon Upton.

Introduction

Thank you for the opportunity to provide feedback on the Ministry for Regulation's agricultural and horticultural products regulatory review.

In 2022 I released a report titled *Knowing what's out there: Regulating the environmental fate of chemicals* (the chemicals report).¹ That report examined whether New Zealand's chemical regulatory system asks sufficient questions to give us confidence that we are appropriately managing the environmental fate of chemicals. Specifically, the report asked two questions about New Zealand's chemical regulatory system:

- Are regulators consistently in possession of adequate information about the likely environmental fate of the chemicals they regulate; and
- Are the questions that are asked about the environmental impact of chemicals asked in a consistent way.

My conclusion was that we cannot be confident of that. The report describes a complex and disjointed system that fails to deliver key information on chemicals used throughout the country, and their subsequent release into the environment.

The report addresses many issues pertinent to the regulation of agricultural and horticultural products that interfaces within the regulation of hazardous substances regime.

¹ PCE, 2022. Knowing what's out there: Regulating the environmental fate of chemicals. https://pce.parliament.nz/publications/regulating-the-environmental-fate-of-chemicals.



My report forms part of my submission. I think it is required reading to help inform your review.

I have organised my submission into four sections. First, I provide some feedback following my review of your Agricultural and Horticultural Products Regulatory Review Economic Analysis Issues Paper, secondly I offer some comments on public versus private benefits, thirdly I recapitulate some key points from the chemicals report, and fourth I conclude with some general comments.

Agricultural and Horticultural Products Regulatory Review Economic Analysis Issues Paper

Overall, this is a very high level and simplistic analysis of the issues at play. It asks submitters to give opinions on what the economic issues are rather than setting out the Ministry's thoughts and getting submitters to respond to those. I have provided some thoughts below, but in general in the future I would expect to see greater thought being put into this section that reflects the issues faced by the sector in question.

Given the issues in this sector, the key one to understand will be risks. The Productivity Commission's 2014 review of regulatory institutions and practices² stated:

"To be successful, regulators need to have an approach to regulatory practice that is based on a sophisticated understanding of the nature of the risk, the nature of regulated parties and changes in the regulated environment..."

The necessity to provide the regulator with the means to analyse risk was central to my work on the chemicals report. The related issues are discussed in this submission and the chemicals report. As such I will make a few brief comments here.

Risks are diverse and best assessed at the product or chemical level. I used the following twoprong approach in my chemicals report:

- 1. creating a framework to help focus regulation and monitoring on the most important environmental contamination risks
- 2. using case studies to explore how the various risks created by different chemicals work through the system.

I recommend using a similar approach to help guide your thinking here. This could involve developing a schema of the different issues posed by different chemicals so they can be prioritised. This would help simplify thinking about the appropriate regulatory responses that are required.

Market failures, costs and benefits might also better be considered as a subset of risks. Regulation is largely about managing risk, so I would suggest the framework integrates these other issues under different risks rather than trying to artificially isolate them. Here are some examples that illustrates these points:

• One key risk to consider (and one that wasn't considered in my report) is the potential impact on New Zealand export markets. We have a trusted reputation in global markets

² https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-rip-final-report-regulatory-institutionsand-practices-v2.pdf



as a source of high-quality goods, especially protein. Consumers and supply chains globally are increasingly vigilant of issues like environmental degradation, chemical residues, pollution and animal welfare. Given our dependence on the primary sector, this is the risk that is likely to carry a large potential cost for New Zealand – as evidenced by the issues in the past with melamine and use of dicyandiamide (DCDs). In terms of market failure this is largely an example of asymmetric information.

• Other risks include those posed to human health and the environment by the use of these chemicals. This is the lens through which I developed the risk framework that I used for the chemicals report. The potential cost of each risk will vary depending on the characteristics of the chemical including how it spreads (as opposed to staying localised), whether it accumulates (as opposed to breaking down) and the details of how that risk can translate into harm. In some rare circumstances the potential cost could be very high – such as the risk of toxicity of neonicotinoid use on pollinators (which are critical to a well-functioning primary sector). In terms of market failure these are more classic externalities.

The suggested approaches to managing risks used in the economic issues paper are rather reductive and focused on ex ante approaches. For example, there is no mention of adaptive management, a possible regulatory approach. Adaptive management would require better information on chemical sales and use, something that is not currently available and is generating substantial pushback from industry.

The Policy Options section contains a table of tools which is as far as it goes, but many other regulatory approaches are missed. This thinking needs to be integrated with the approaches to managing risk (on page 3) and broadened to include the other regulatory options that are in the toolkit (many are mentioned in the Productivity Commission review). Bringing all this together would provide a useful framework for the Ministry.

Therefore, as a general point I would like to see the Ministry develop a more integrated and nuanced taxonomy of regulatory approaches and the circumstances in which they should be used. One example would be to provide some consistent criteria to assist the decision on when it is appropriate to apply the 'trusted regulator' approach.

Finally, I note that there is no mention of regulatory failure or regulatory overlap within the framework that is provided. Given that two overlapping Acts (the Hazardous Substances and New Organisms (HSNO) and the Agricultural Compounds and Veterinary Medicines (ACVM) Acts) are being assessed here, and that there are several regulatory approaches at the Crown's disposal, this is an important area to explore. The Productivity Commission's inquiry highlighted the importance of clarity of role and mandate for effective regulation.

Cost Recovery: Public versus private benefits

The Productivity Commission's 2014 review of regulatory institutions and practices³ stated:

"If regulation delivers significant positive spillovers to the wider community as well as those in the market being regulated, it may be appropriate to fund part of the administration of the regulation from general taxation revenue. Where such spill-overs are small or absent, recovering the costs of administering regulation through fees or

³ https://www.treasury.govt.nz/sites/default/files/2024-05/pc-inq-rip-final-report-regulatory-institutionsand-practices-v2.pdf



levies can improve efficiency, although factors that may affect the size of the efficiency gains need to be considered [...] In general, there is a strong case for regulators to recover the administrative costs of regulation, so that an industry's costs reflect the full costs of production."

Collectively, New Zealanders benefit from having appropriate regulation so that health and the environment are protected. We also benefit from increases in productivity of the primary sector. However, I would argue that the vast majority of the benefits of the chemical assessment programme lie with both the chemical industry and agricultural and horticultural producers. While the Productivity Commission points out a number of risks with cost recovery, none of those appear to be relevant in this case.

The benefits accruing to industry include the financial benefits from the ability to use these chemicals in the first place, as well as insurance against the reputational risk of these chemicals creating unexpected side effects. From a purely financial perspective, the producers and users of these products are clearly the main beneficiaries. Simply put, their respective business models rely upon these products. Assessments are crucial to maintaining the social license of both the chemical industry and agricultural and horticultural producers. The economic impact of chemical residues in food for our export markets for example would pale in comparison to the localised impacts of chemical use. Even where there are localised impacts on health and the environment from chemical use, the "polluter pays" principle suggests that the producers and users should bear the majority of the cost.

Despite producers and users receiving the majority of benefits, rates of cost recovery are lower in New Zealand than overseas (in other words the rates of taxpayer subsidy are higher than overseas). In the 2021/22 financial year, the Environmental Protection Authority (EPA) only recovered 14% of the cost of assessments from applicants (through application fees). In contrast, Australia's two main chemical regulators recovered between 89% and 127% through fees and levies in the 2021/2022 financial year.⁴ By international comparison, industry in New Zealand is paying very little, with the taxpayer subsidising the rest. While there is a case for a limited public subsidy, the reasoning for this level of subsidy is not clear to me.

Resourcing to certain aspects of the regulatory system, for example for ecotoxicology modelling capabilities for the EPA should be increased (discussed further in a section below). However, this resourcing does not only have to come from the Government and taxpayer, as a properly resourced EPA would give the chemical industry greater certainty around the timing of assessment processes and controls that are reliably proportionate to the risks. Alongside cost recovery the Productivity Commission report recommended putting in place relevant performance measures for the EPA so that industry can hold them to account.

I recommend that the current fee structure is reviewed to more accurately reflect the private benefits that accrue to many applicants, reduce the burden currently placed on New Zealand taxpayers, and bring New Zealand more in line with our international counterparts, a sentiment echoed within the Sapere report.⁵ The public at large would benefit from a regulatory system

⁴ Sapere, 2023. The EPA's role and performance in assessing hazardous substances: A summary of the current state and performance against international benchmarks. https://www.epa.govt.nz/assets/RecordsAPI/Briefing-to-the-Incoming-Minister-for-the-Environment-

December-2023-The-EPAs-role-and-performance-in-assessing-hazardous-substances.pdf



that is robust and manages environmental and health risks at an acceptable cost both to commercial applicants and to taxpayers.

Key observations from PCE's chemicals report

As noted in the introduction, my 2022 a report titled *Knowing what's out there: Regulating the environmental fate of chemicals* (the chemicals report) took an in-depth look at the regulation of chemicals in New Zealand.⁶ The analysis and recommendations of that report are highly relevant to your review. This section provides a brief summary. It is not a substitute for reading and considering the report as a whole.

Overview of the report relevant to this review

We have developed a very complex system for approving and managing chemicals, spanning multiple government agencies and different pieces of guidance and legislation. It is a mosaic of approval, guidance, consenting and monitoring that poorly captures the environmental fate of some contaminants and in other cases misses them entirely.

There is considerable overlap in the types of products covered by the HSNO and the ACVM Acts. Chapter 3 of my chemicals report describes in detail the New Zealand chemicals regulatory system of which agricultural and horticultural chemicals are a subset. It looks at how the HSNO, ACVM and health regulatory systems overlap and interact and helps illustrate how the regulations you are concerned with fit into the wider picture.

Chapter 5 is also important reading. To give a sense of how this regulatory framework works in practice, four chemical substances were selected and followed through the lifecycle of their use and disposal. The case studies illustrate the way the regulatory system intervenes – or does not – to limit the impact of these chemicals on the environment. The four chemicals chosen are: the neonicotinoid class of insecticides, the tetracycline antibiotics, the herbicide terbuthylazine and the metal zinc.

Each of the four chemicals poses some hazard to the environment. But in most respects, they are very different, representing different use patterns (agricultural, industrial and household), different likely receiving environments (surface water, soils, groundwater and coastal environments) and different degrees of knowledge about the impacts of the chemical. Each case study highlights different approaches to the management and level of monitoring of each substance. They provide illustrative examples of the different ways the environmental fate of chemicals is managed by New Zealand's regulatory system.

We do not have the information to appropriately manage the risks of chemicals used in our environment

To more efficiently and effectively manage and regulate chemicals in New Zealand we need better information on the amount of chemicals that are used and therefore potentially released into the environment.

We cannot know if regulation is working if we don't know broadly where the weight of its use is concentrated. If we are going to impose controls on use, we need to know where that use is

⁶ PCE, 2022. Knowing what's out there: Regulating the environmental fate of chemicals. https://pce.parliament.nz/publications/regulating-the-environmental-fate-of-chemicals.



occurring so that we can assure ourselves that the controls are working, i.e. that we're detecting the sorts of levels we approved as being safe.

Keeping track of the quantities of chemicals imported, manufactured, or sold would provide this information. New Zealand's regulatory system has only recently been changed to provide quantity data on certain priority chemicals imported into or manufactured in New Zealand.⁷ This can only provide a national level view. However, that still leaves a large information gap on where those chemicals are being used at a more granular scale, such as regions and sub-regions.

Just last year, health officials in France alerted the public that a majority of drinking water samples tested by the government contained the presence of the highly toxic fungicide chlorothalonil.⁸ EU member states banned the substance in 2019, due to concerns over water contamination and elevated cancer risk associated with the metabolites of chlorothalonil, however they are still understanding and attempting to address the lingering effects of its use.⁹ Chlorothalonil is approved for use in New Zealand (by professionals only),¹⁰ however to my knowledge the EPA does not track where, or how much of it is released into the environment. This means we can't even begin to understand whether this sort of contamination might be a problem in New Zealand, even though another jurisdiction is concerned about it.

This information could be gleaned by using regional sales data as a proxy for use. In the United Kingdom, data on the usage of pesticides have been collated for 50 years and enable publication of data on pesticide use by area and weight. Its database includes the ability to break down pesticide use by region.¹¹

If we knew what was being used and the regional distribution of that use, we could organise our environmental monitoring efforts more efficiently to match those use patterns. In the United States, regionally specific pesticide-use data enable the prediction of where pesticide contamination is most likely to occur, which can be verified by concentrations detected in monitoring. Monitoring results are also able to be interpreted against risk-based guideline values to provide an assessment of potential toxicity to organisms. Overall, the combined value of these data provides a comprehensive picture of pesticide distribution, presence, and potential risk in the United States.¹²

It is disappointing to see that there appears to be no plan by either the Ministry for the Environment (MfE) or the EPA to undertake the necessary policy work to give the EPA the power to collect sales information that would enable us to have a regional or sub-regional understanding of where chemicals are used.

⁷ https://www.epa.govt.nz/public-consultations/decided/proposal-importers-and-manufacturersnotice/

⁸ https://www.lemonde.fr/en/france/article/2023/04/10/drinking-water-in-france-extensively-pollutedby-banned-pesticide_6022353_7.html

⁹ https://www.theguardian.com/environment/2019/mar/29/eu-bans-widely-used-pesticide-over-safetyconcerns and https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5126

¹⁰ https://www.epa.govt.nz/news-and-alerts/alerts/vtas/

¹¹ The programme of pesticide usage surveys is commissioned by the independent expert committee on pesticides and funded by the chemicals regulation directorate.

¹² Stackpoole, S.M., Shoda, M.E., Medalie, L. and Stone, W.W., 2021. Pesticides in US Rivers: Regional differences in use, occurrence, and environmental toxicity, 2013 to 2017. Science of the Total Environment 787: 147147.



Something like a pollution release and transfer register (PRTR) would provide additional information on the quantities of chemicals released into the environment. A PRTR is a national platform for collecting data on known discharges to the environment. They enable countries to join the dots between permitted discharges of potentially harmful substances to the environment and environmental monitoring that picks up traces of contaminants. Every developed country except New Zealand has a PRTR.¹³

Clearly, we don't need a PRTR for every single substance. Rather, we need it for the things that are most widely used in the New Zealand economy and whose use we may wish to monitor because the scale of their use and the potential for harm means we want to keep an eye on them.

Efficient and effective regulation requires good information. More adequate granular information and targeted monitoring would allow for more appropriate and tailored controls and risk management. I recommend that this gap be filled by requiring the collection of chemical sales data.

New Zealand lacks a cohesive framework to understand and prioritise chemicals' risk

While not all of the chemicals present in New Zealand will present a high level of concern, there are many unknowns, and our current regulatory system does not adequately address these.

With respect to environmental risks, our chemical management system needs to be able to target its regulatory effort to those contaminants and uses that raise the most serious issues. However, it currently lacks a framework to make sure that happens. For that reason, my principal recommendation in the chemicals report was that all the agencies dealing with chemicals need to develop a common framework to prioritise their efforts to consider, and manage, the environmental impacts of chemical use. The design of any such framework should involve Māori. That framework needs to be based on the intersection of three factors:

- the scale on which a chemical is being used
- the potential environmental harm that it could cause
- the extent to which the contaminant's presence is being detected in the environment.

The following figure summarises the way information about each of these factors can help regulators ask the right questions about the most important risks.

¹³ In Australia, Canada and the European Union, pesticide information is collected directly from product registrants, is required annually, and is typically based on sales information as a proxy for use.





Figure 1: A framework to help focus regulation and monitoring on the most important environmental contamination risks.

It would clearly make sense for the greatest focus to be on chemicals that fall within the centre of the figure: those that are used on a large scale, which are known to cause harm, and whose presence is detected in the environment. But beyond that, the existence of two of the three factors (scale, harm and presence) can indicate the need for taking a focused interest.

For instance, things that are widely used and not believed to be particularly harmful may still merit monitoring. Good quality information enables us to see if their environmental contamination and impact is as predicted. Furthermore, if new information comes to hand about emerging risks, we have a baseline to start from. Similarly, if something known to be harmful is used on a small scale within specified limits, monitoring the ongoing scale of use will be vital to ensure that the level of environmental risk remains at a manageable level. And if concerns arise, we know where to start looking.

Having a common framework would streamline prioritisation systems to be more efficient across regulatory agencies, which would allow the regulatory system as a whole to be more strategic in how it manages risk.

Many chemicals in use have not been properly assessed

New Zealand, on average, takes a relatively 'hands-off' approach to the regulation and monitoring of chemicals used domestically, especially when it comes to the risks of these chemicals to receiving environments.

There are roughly 150,000 substances approved for use in New Zealand, made up of an estimated 30,000 chemicals. The vast majority of these have been the subject of some scrutiny by regulators in other large economies, so we do not start with a blank sheet. But the particular features of our environment and the particular use we make of certain substances means that we cannot simply adopt the judgements of other countries without further assessment. Similarly, regulators in different countries work by balancing risk through different cultural filters in different cultural contexts, such that the outcomes of risk assessments have some



specificity and, as a result, it may not always be appropriate to generalise from one national context to another.

Despite the complex system we have created for the regulation of chemicals in New Zealand, as of 2022 only about 3,500 substances have ever been the subject of individual approvals, and only a few hundred have been fully reassessed. This is the legacy of a mass transfer of chemicals to the system created by the HSNO Act that took place in 2005. The reasons for this are explained in Chapter 3 of the report. It has left some enduring consequences in its wake.

Firstly, the bulk of substances present in New Zealand are managed under group standards. These are a very 'hands-off' form of regulation because they delegate responsibility to assign approval status to an importer or manufacturer. While records of this assignment must be kept, the EPA as the national regulator does not typically receive this information unless a compliance issue arises, so it provides little oversight.

Secondly, at the time of transfer there was no formal risk assessment weighing up the risks, costs and benefits and effectiveness of individual substances because of the sheer size of the task. While group standards and transfer notices provided new controls, evidence of the risks, costs and benefits of individual substances were not evaluated and won't be unless the chemicals are formally reassessed as approval for substances under the HSNO Act do not expire. The EPA has been undertaking a programme of reassessments to address this situation. However, it is a costly business, and the EPA has never had anywhere near the resources to conduct more than a handful of reassessments per year.

We do not appropriately manage the environmental risks of substances equally

Monitoring and managing the environmental effects of agrichemicals used in agriculture, horticulture and forestry is particularly complex because of the range of chemicals used, their toxicity and their use in close proximity to receiving environments. Chemicals used include pesticides (both applied directly to plants and land or as part of treated seed) and a range of veterinary medicine treatments.

Controls are imposed through national-level processes under the EPA and Ministry for Primary Industries' (MPI) remit covering the different risk profiles of agrichemicals. However, national controls and conditions do not typically require monitoring (except in a small number of cases, such as the use of 1080). Further, the level of monitoring and control of agrichemical use at a regional level is limited due to the diffuse nature of the discharges and their release being a permitted activity under many regional plans.

The EPA performs environmental risk assessments for some substances during initial approval or during a reassessment. For agrichemicals, this process may entail quantitative modelling to estimate exposure. The risk assessments often result in tailored controls (e.g. a maximum application rate) based on the assumptions relied upon, in addition to the standard suite of controls that follow from a given hazard classification and use pattern.

By contrast, a lower level of national scrutiny is applied to many other substances. While veterinary medicines are assessed for efficacy and animal health risks under the ACVM Act, the environmental risks have generally not been specifically assessed by the EPA because in most cases they are covered by group standard approvals or were approved by transfer at the



initiation of the HSNO Act.¹⁴ The controls that apply to these group standards are often based on hazard and use patterns that have been set with little scrutiny of the environmental fate of the contaminants within individual substances.

As a result, even where environmental risk from agrichemicals has been assessed, it has been done only at a high level based on multiple assumptions, not real-world on farm usage.

The suite of chemicals used, how they are used and in what quantities varies depending on land use, different management practices and different geographies. Some chemical users keep good records of what chemicals they use, where, in what quantities and when. Others do not. Even when records are kept, these tend to be for internal farm management purposes rather than regulatory purposes, although record keeping is sometimes required for certain chemicals (such as Hi-Cane for kiwifruit) either under the HSNO controls set by the EPA, by an industry body or the local regional council.

In a regulatory sense, we are managing the environmental effects of diffuse rural chemical use in a near vacuum. Only limited monitoring and testing of farm soils for chemical accumulation occurs. In certain scenarios, the acceptable annual loading of approved substances has been high enough to noticeably increase the natural levels of metal content in soils, and in adjacent ecosystems.¹⁵ There is also a lack of consideration for the long-term accumulation of such compounds that may result in toxicity threshold exceedances.

Some of the risks arising from the regulatory gaps and 'hands-off' approach to regulation of some agrichemicals can be illustrated through the example of animal wastes. Group standards for veterinary medicines do not control contaminants that remain in animal wastes. Many veterinary medicines can be self-allocated by industry to group standards and have therefore not been subject to EPA risk assessment, with the result that few tailored controls relating to specific environmental risks of individual substances apply. The pathway of potential environmental exposure through manure is not considered under these group standards, which cover finished-dose or non-dispersive applications.

In view of the lack of regulatory guidance for the management of manure on productive land, some industries have taken a proactive approach to its handling and recycling (e.g. the Poultry Industry Association of New Zealand and DairyNZ). However, there does not seem to be adequate consideration within industry guidelines of the variable timeframes over which veterinary products degrade in manure and different types of soil. For example, the degradation of antibiotics in animal waste will depend on their exposure to ultraviolet light, temperatures and microorganisms and can range from less than two days to more than 180 days.¹⁶

¹⁴ Veterinary medicines that are 'finished dose' (e.g. a flea tablet in a blister pack) or 'closed-system application' (such as an oral drench applied with a drench-gun) are typically covered by group standards and do not require assessment as relatively little environmental exposure is anticipated.

¹⁵ Robinson, B., Greven, M., Green, S., Sivakumaran, S., Davidson, P. and Clothier, B., 2006. Leaching of copper, chromium and arsenic from treated vineyard posts in Marlborough, New Zealand. Science of the Total Environment 364(1–3): 113–123; Vermeulen, V. and Kim, N.D., 2016. Imprint and risks of anthropogenic zinc in soils and freshwater ecosystems of the Waikato region. Wellington: Massey University.

¹⁶ Degradation variability is wide across antibiotics. For example, persistence of macrolides in liquid manure can range from two days to 130 days; persistence of sulphonamides range from eight days in broiler faeces to 90 days in laying hen faeces; and persistence of tiamulin in liquid manure can last for



Some of the chemicals we use, including some pesticides are endocrine disrupting chemicals (EDCs). Over the course of my chemicals investigation I noted the lack of knowledge and information about EDCs in Aotearoa New Zealand and their potential impact on living things. As a result, I later commissioned Cawthron Institute to review endocrine disrupting chemicals and what is known about their potential impact on our natural environment.

EDCs can interfere with endocrine systems leading to adverse health effects, such as interference with sexual development, reproduction, metabolism, immune response and behaviour in both exposed humans and wildlife. In the absence of robust evidence to the contrary, there should be on-going scrutiny over the potential endocrine disputing activities of chemicals registered and used in New Zealand and more stringent assessments of the potential for chemicals to affect the endocrine system should be included as part of the national chemical registration process.¹⁷

Overall, controls are not always appropriately tailored for the risks posed, in part because individual substance assessments happen infrequently or are not undertaken at all because substances are covered under group standards.

The EPA does not have the tools nor the resources to adequately manage the risk of chemicals, including AgHort chemicals, used in New Zealand

Ecotoxicological models are a fundamental tool used in risk assessments and are used by all chemical regulatory agencies to assess the environmental risk and determine effective controls (where applicable) of a particular substance. As part of its risk assessment, the EPA quantifies the risks posed by substances using ecotoxicology models to help predict the environmental concentrations that a certain chemical might have. The models used need to give accurate information for New Zealand contexts to ensure that appropriate controls and measures can be in place when chemicals are introduced or reassessed.

The modelling of predicted environmental concentrations of chemicals is only as accurate as the data that go into a model and the way a model uses them.

The chemicals report identified some key limitations of the current modelling used in risk assessments by the EPA.

- Limitations in terms of the parameters that can be included.
- Limited ability to include New Zealand specific scenarios.
- The inability to directly incorporate metabolites which can be as, or sometimes more, persistent and toxic than the parent compound.
- Several of the models used by the EPA have been superseded in their original jurisdictions.

Trying to model risks without proper tools can lead to the under or over-estimation of risks or excessive risk aversion.

more than 180 days (Boxall, A.B.A., Kay, P., Blackwell, P.A. and Fogg, L.A., 2008. Fate of Veterinary Medicines Applied to Soils. In: K. Kümmerer (ed). Pharmaceuticals in the Environment. Berlin: Springer: 165–180).

¹⁷ Cawthron Institute, 2023. Endocrine disrupting chemicals in Aotearoa New Zealand.

https://pce.parliament.nz/publications/endocrine-disrupting-chemicals-in-aotearoa-new-zealand/



I would recommend that you read Chapter 5 of the report, where examples of differences in modelling are discussed more in depth.¹⁸

To support applications for assessments and reassessments it is not unusual for applicants to generate their own environmental risk assessments. These risk assessments may contain outputs from models or parameters that cannot be routinely assessed by the EPA using its current modelling capabilities. To understand these, the EPA must expend technical resources. In contrast, if the EPA had updated models, this would allow applicants to utilize these EPA-approved models to generate their own quantitative environmental risk assessments. This would more efficiently use both applicant and EPA resources and orient discussion between the EPA and applicants to the selection of inputs into models rather than the merit of certain models used. This highlights the fact that updated modelling capabilities would increase efficiency and outcomes for both industry and the EPA alike.

To my knowledge, the EPA has tried for the past two years to specifically fund new modelling capabilities, in line with recommendation 3 of my report, however, thus far this work has not been funded. Without specific, dedicated funding to upgrade these models, the EPA would have to compromise its existing activities to fund any upgrades. As such, I recommend that the Government prioritise funding this work.

Other Comments Relevant to the Review

New Zealand's unique context

New Zealand has a unique environment. Our flora and fauna have evolved in near isolation from the rest of the world, and the country spans two biomes, temperate and subtropical with large mountain chains. This results in New Zealand having very complex, distinct climatic and hydrological patterns.

These differences not only affect how we do or should use chemicals, but also affects how the chemicals themselves can interact with our specific environment (both biotic and abiotic). A few examples of some crucial factors are soil types, slope, water table depth, rainfall, temperature, and these can change significantly in different areas of the country.

There are lessons to be learned from models that have inadequately incorporated New Zealand specific variations. For example, in 2018 I reviewed Overseer,¹⁹ a model used for calculating nutrient losses in New Zealand. The report identified that Overseer had an inability to represent farm systems in particular regions. This was primarily due to its calibration of nitrogen losses being from the Waikato and Southland regions, covering a limited range of soil types, a limited band of rainfall (between 600 and 1200 millimetres), and a limited range of management

¹⁸ For example, Terbuthylazine (pages 107-114). Specifically, Box 5.2 (page 110), which illustrates how terbuthylazine groundwater concentrations are predicted by models and the advantages of models that can directly incorporate metabolites. PCE, 2022. Knowing what's out there: Regulating the environmental fate of chemicals. https://pce.parliament.nz/publications/regulating-theenvironmental-fate-of-chemicals

¹⁹ PCE, 2018. Overseer and regulatory oversight: Models, uncertainty and cleaning up our waterways. https://pce.parliament.nz/publications/overseer-and-regulatory-oversight-models-uncertainty-andcleaning-up-our-waterways/



practices. This meant that any sites with high rainfall (>1400 millimetres) as well as those on shallow, free-draining soils (which are common in Canterbury) were not well represented within the model and therefore results for those regions had significantly higher uncertainties.

These biotic and abiotic differences across different regions of New Zealand, and when comparing New Zealand to other countries, need to be appropriately considered in ecotoxicology modelling to ensure appropriate regulatory controls are given.

This uniqueness of New Zealand's biotic and abiotic environment also means that taking decisions from 'trusted regulators' overseas needs to be done with care. Though the 'trusted regulator' approach improves the EPA's ability to use international information in its assessments and modified reassessments, it is not a panacea. It is not always appropriate to take an overseas approval 'on face value'. The EPA still needs to consider New Zealand-specific information and scenarios before approving a product to determine whether our specific environment, cultural factors, and use cases/patterns will alter the risk associated with a certain chemical compared to overseas. Overseer has taught us that one must be careful when and under what circumstances one generalises.

New chemicals are not always better

A lot of discussion is had about the fact that our regulatory system is slowing the approval of newer chemicals with newer, 'greener' chemistries. However, I would note that just because a chemical is new, it does not necessarily mean it is less environmentally harmful (my office avoids the term 'green' or 'greener'). While this is an understandable claim to be making and is likely true in some cases, claims such as these should be treated with caution. Firstly, it is important to consider whether industry and users would stop using older chemistries if new ones became available, especially considering that approvals do not expire.

History is also littered with 'new and improved' products that have ended up being worse or riskier than their 'original' counterparts. Given that all the same risks exist with new products, it is important that these products still undergo the normal assessment process. Industry would be making themselves liable for any wrongdoing if these products were not subject to the normal regulatory pathway.

Scope of review does not include funding of regulators

I do not see how you can comment on regulator behaviour without taking account of resourcing. One undoubtedly affects the other – if a regulator is not properly resourced, its ability to provide appropriate answers to a specific problem will be curtailed.

Specifically, you need to understand the level of resources available for work on the regulation of agricultural and horticultural products under the HSNO Act carried out by the EPA (e.g. including but not limited to assessments and reassessments), and under the ACVM Act, carried out by the MPI.

Without such an understanding, your capacity to make judgments about many aspects of the regulatory system will be limited. For example, the review intends to compare domestic regulators with their international counterparts. This makes sense but the relative resourcing of these agencies cannot be overlooked and there is a risk of faulty comparisons that do not appropriately compare similar entities.



For example, a report commissioned by the EPA from Sapere, showed that New Zealand is an outlier internationally in that we expect our EPA to operate far faster and with fewer resources than many comparable jurisdictions.²⁰ Comparing New Zealand with Australia in the 2021/22 financial year, New Zealand spent (on a GDP-adjusted basis) 45% of what Australia did on assessing hazardous substances.

This sort of comparison of funding will greatly inform what are appropriate expectations of various agencies. We cannot expect an agency that is not sufficiently funded to perform as well as a fully resourced one. Lack of sufficient funding and resources creates a whole host of flow on effects. These include, the use of out-of-date models, poor information collection, and limiting the number, speed and efficiency of assessments and reassessments.

The Terms of Reference overplays industry as a stakeholder and underplays stakeholders with other concerns such as public health and the environment

The Terms of Reference establish the industry as the primary stakeholder in this review. The review includes the formation of a specific industry sector reference group and a list of organisations which are invited to be part of this group. Though it mentions other stakeholder interests and indicates "targeted engagement with some selected stakeholders", there is a lack of detail on who will be consulted, when, and how frequently.

Regulations in respect of agricultural and animal products exist, in part, to provide some assurance that environmental and public health risks are being appropriately and transparently managed. Stakeholders representing these interests are just as important. As specialists in regulation, the Ministry will be well aware of the risks of regulatory capture by special interests. It is doubly important that a Ministry responsible for regulatory review avoids any such possibility.

You must ensure balanced sources of information in undertaking your review.

You could do this in one of two ways. You could establish another reference group that incorporates environmental, public health, Māori, and scientific expertise to inform the review including involvement in testing analysis and potential solutions in the same way that the industry sector reference group will. Alternatively, if the additional cost of a parallel group is judged to be too expensive, you could broaden the remit and membership of the single reference group to include the suggested expertise.

There is a huge risk of ignoring the costs to the environment when looking primarily at private interests who gain the benefits of but see the costs of regulation.

Conclusion

My chemicals report *Knowing what's out there* provides you with a basis for asking hard questions about prioritising regulatory effort within a highly complex regime. It also draws attention to some of the tools and data regulators need so they can respond in an agile way both to innovation in the chemical industry and to emerging environmental risks.

²⁰ Sapere, 2023. The EPA's role and performance in assessing hazardous substances: A summary of the current state and performance against international benchmarks.

https://www.epa.govt.nz/assets/RecordsAPI/Briefing-to-the-Incoming-Minister-for-the-Environment-December-2023-The-EPAs-role-and-performance-in-assessing-hazardous-substances.pdf



Though there are no doubt efficiencies to be made within the current regulatory system, we already have a system that is permissive, and that takes a largely 'hands-off' approach to regulation. It will be up to the Government and Ministers to decide whether they view the current scheme as too prohibitive, however, I wish to illustrate to you how little we know about the chemicals used in New Zealand, where they are used, and the effect these have. These chemicals are not environmentally benign. Using them comes with potentially significant risks.

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