# The EPA's role and performance in assessing hazardous substances

A summary of the current state and performance against international benchmarks

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## Appendices

# Executive summary

This paper benchmarks the funding and performance of the Environmental Protection Authority (EPA) in assessing hazardous substances against comparable regulators in Australia, Canada, the United Kingdom, the United States and the European Union.

**New Zealand spends considerably less on hazardous substances functions than benchmarked countries**

New Zealand invested approximately $3.9m in 2022/23 to assess applications to manufacture or import hazardous substances and to reassess the safety of already approved chemicals. This level of funding is considerably less than the countries we benchmarked against, even after adjusting for population, GDP, and key sectors. For example, New Zealand spends only 7 per cent of what Australia does on assessing hazardous substances, 37 per cent of what Australia spends on a per capita basis, and 45 per cent on a GDP-adjusted basis.

It is reasonable to assume there should be a degree of correlation between a country's expenditure on hazardous substances assessments and the size of its primary and manufacturing sectors, as these sectors play a key role in determining demand for assessment activity (as well as efforts to lift productivity by introducing newer chemicals). Even after making such an adjustment, it is apparent that New Zealand is well below international benchmarks – in such a scenario we spend a quarter of what Australia and the United Kingdom do on hazardous substances assessments and 70 per cent of what is spent in each of Canada and the United States.

**The impact of the lack of funding is materialising through lengthening assessment timeframes, low decision volumes, and a reliance on outdated models**

*Applicants are facing increasing timeframes for assessments*

The EPA's cost per application is efficient compared to other similar regulators and, once it begins actively working on an application, it completes that assessment work within a timeframe that is comparable to overseas regulators.

However, the EPA is not funded to process the volume of applications it receives in a timely manner. Since February 2020 the EPA has received an average of ten assessment applications each month but has averaged only eight assessment decisions, meaning a growing number of applications have been added to a 'pre-application' queue. This trend extends all the way back to at least 2013. Applicants are now facing large – and increasing – wait times and uncertainty about when their application will be assessed.

Currently, the median time 'release' applications are being held in the 'pre-application' queue is 336 days. This figure is the time elapsed before the applications are formally received and the statutory assessment begins.[1] This varies considerably across pathways, meaning that while in 2023 the EPA

[1] Median time from application being lodged to being formally received by the EPA, for decisions made in 2023. 'Release' applications refers to an application to import or manufacture a hazardous substance for release under s28A or s29 of the HSNO Act

completed its 'rapid assessments' of chemicals in a median time of 13 days, applicants in the pathway were actually facing a median end-to-end wait time of 340 days. These delays have increased markedly compared to a decade ago. For example, the median end-to-end time that applicants now wait for an assessment and decision on the most complex applications (Category C) has increased from 402 days (during 2013-2015, 14 applications) to 1,048 days (during 2021-2023, 8 applications) with less applications of this type decided.

As of September 2023, there are 106 unprocessed applications in the pre-application queue. Based on the number of assessments completed since 2020, we estimate that if the EPA was to drop all its current assessments and stop accepting any new applications it would take between two to four years of work simply to clear the applications in this queue.

*The EPA is relying on outdated ecotoxicity models*

A lack of funding means the EPA has been unable to invest in upgrading the ecotoxicity models that it uses to assess applications. Several of these models are now over 20 years old and are no longer fit-for-purpose. Reliance on the outdated models is contributing to increased costs borne by the EPA in making decisions, longer decision-making timeframes, and are likely to result in increasingly conservative outputs as the EPA cannot validate the modelling provided by applicants.

Unlike overseas regulators, the EPA's models cannot be used by applicants in advance of making an application because of their age and the inability to access them – meaning that additional costs and resourcing commitments are borne by the EPA rather than applicants.

*New Zealand is not reassessing already-approved chemicals where new information is available*

There are chemicals in use in New Zealand that have been subject to bans or new controls by overseas regulators in response to emerging evidence of risk. While the EPA has appropriately prioritised which chemicals to reassess, it is severely constrained in its ability to act promptly or to process the volume of chemicals where there are new indications of risk.

The EPA has prioritised 43 chemicals as needing reassessment. In 2022 the EPA completed two reassessments covering five already-approved chemicals, well below the 16 reassessments completed in Canada and the 39 reassessments completed in Australia.[2]

*The EPA should review its fees, with a view to better recovering assessment costs from applicants*

The EPA recovers 16 per cent of its assessment costs from applicants. A comparison with international hazardous substances regulators demonstrates its fees are artificially low – both the absolute fees and the proportion of total costs that it recovers from applicants.

Increasing applicant fees will not solve the immediate resourcing pressures the EPA faces, nor is it the panacea for all problems impacting the EPA's ability to process applications. But over time, increased

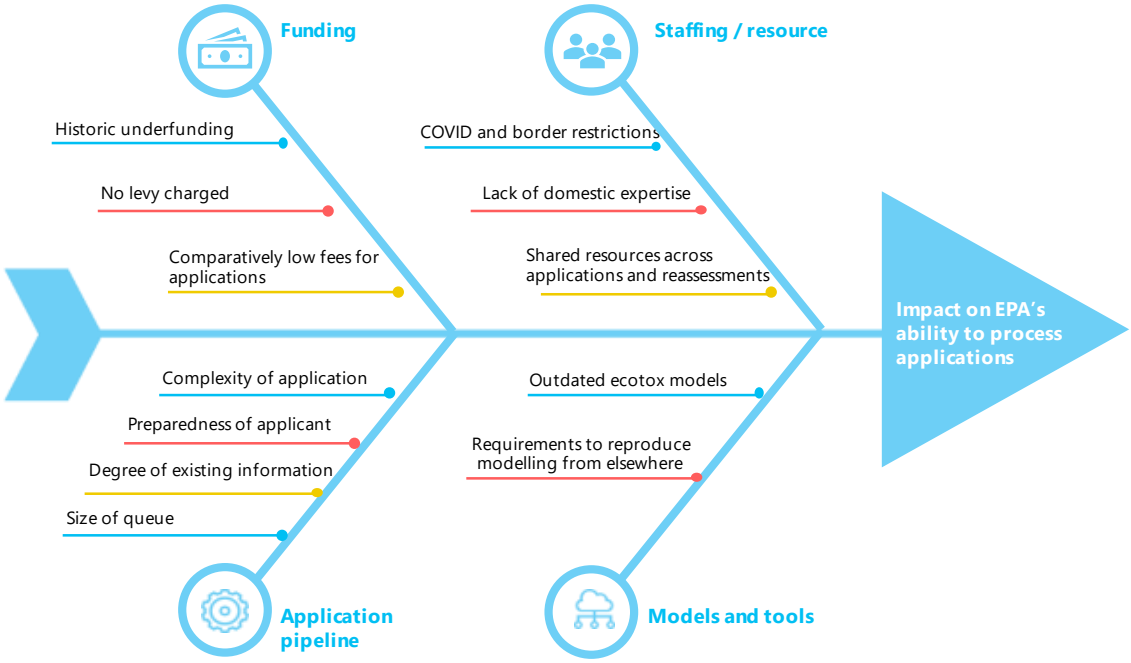
[2] As a caveat it is difficult to know exactly what the scope, complexity, and processes are for different jurisdictions when it comes to reassessments or evaluations of already-approved hazardous substances. It is possible some of these comparator jurisdictions are doing less-intensive and/or administrative reassessments of hazardous substances compared to the New Zealand EPA's targeted reassessments programme that is focusing on high-priority chemicals.

fee revenue would enable the EPA to scale up its HSNO activities. We recommend the EPA review its fee structure for hazardous substances assessments, with a view to increasing its fees to better cover the costs it incurs and to reflect the private benefits that will accrue to many applicants.

**There are potential health, environmental and economic gains from increased investment**

There are a number of factors that impact the EPA's ability to assess hazardous substances in a timely manner, some of which we have depicted in Figure 1.

Figure 1: Factors impacting on the EPA's hazardous substances processing timeframes[3]




There is no single solution to addressing the increasing wait times faced by applicants. However, what is clear is that our benchmarking has demonstrated there is a compelling case for urgent additional funding for the EPA's hazardous substances activities. New Zealand is investing considerably less (even after adjustments for scale) in its hazardous substances regime compared to benchmarked countries. While Budget 2023 provided an additional $1.1m in new funding for 2023/24,[4] this remains well short of what is needed for an effective assessment regime.

Current levels of funding are constraining the volumes of applications the EPA can progress each year. Over time this constraint could affect the adoption of new chemicals – limiting commercial innovation, inhibiting primary sector productivity, and restricting the country's ability to transition to 'greener' chemicals that have improved environmental outcomes.

An increase in funding for the EPA's hazardous substances activities will support the EPA to materially reduce the volume of applications that are waiting to be processed, increase its reassessment activity

[3] Fishbone template sourced from TemplateLab.com
[4] Not all this additional funding is allocated solely for assessing hazardous substances.

of already-approved chemicals, and to make much-needed investment to modernise its ecotoxicity models. The consequences of an underfunded EPA in this area could be serious, with the potential for risks to health, environmental and economic outcomes.

# 1. Context

Sapere was asked by the EPA to describe its role under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) relating to hazardous substances applications and to benchmark its performance in relation to its assessment functions against comparable overseas regulators.

This report provides an overview of the EPA's responsibilities, processes for assessing hazardous substances, a comparison of the EPA to other regulators charged with the management of hazardous substances, and a summary of the context and issues the EPA faces in delivering on its functions, powers, and duties.

This report is structured as follows:

- Section 2 provides a summary of the EPA's legislative responsibilities under the HSNO Act and sets out how the EPA undertakes its functions.
- Section 3 examines the resourcing of the EPA's hazardous substances functions and makes comparisons with overseas regulators (including on assessments and reassessments).
- Section 4 sets out how long it is taking the EPA to make assessment decisions and compares the EPA's performance with overseas regulators.
- Section 5 summarises some of the steps the EPA has taken to modernise its processes and highlights the need for urgent investment in new ecotoxicology (ecotox) models.
- Section 6 benchmarks the EPA's fees and cost-recovery against overseas regulators

The conclusions drawn from this benchmarking exercise are based on publicly available information and should be treated with some caution. It is beyond the scope of this report to document the differences between each country's statutory and regulatory framework for hazardous substances. While the funding and resources applied in each country may show each country's relative commitment to assessing hazardous substances, it may also reflect that some countries have more permissive/restrictive regimes – which necessitate less/more involvement by the regulator.

# 2. The EPA's role under the HSNO Act

The EPA has many touchpoints across society, the economy and the environment. The HSNO Act is one of the key pieces of legislation for the EPA and defines a considerable range of responsibilities and powers.

## 2.1 The EPA's hazardous substances responsibilities

The purpose of the HSNO Act is to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. Its principles concerns safeguarding the life-supporting capacity of air, water, soil, and ecosystems, and being able to maintain and enhance the way in which people and communities live and provide for their cultural, economic, and social wellbeing now, as well as in the future.

The EPA has a range of hazardous substances powers, functions, and duties under section 11 of the HSNO Act, which broadly include:

- Assessments and reassessments – the EPA is responsible for deciding whether certain hazardous substances should be permitted to be imported or manufactured in New Zealand and, if so, under what conditions. This includes developing, maintaining, and updating 'group standards', which are approvals for a group of hazardous substances of a similar nature, type, or use.[5]
- Notices and rules – the EPA issues notices that define the rules people must follow when dealing with certain hazardous substances.
- Advisory – the EPA provides information to the Minister on any matters relating to the HSNO Act.
- Monitoring and reviewing – the EPA routinely assesses regulated parties' compliance with the HSNO Act, incidents or emergencies relating to hazardous substances, and the impacts the EPA's decisions under the HSNO Act have on the environment and people. Where necessary, the EPA uses the enforcement powers given to it under the HSNO Act.
- Educating – the EPA uses its platform to educate regulated parties and the public more broadly about the adverse effects of hazardous substances and how they can be prevented, managed, or mitigated.
- Collaborating – the EPA contributes to a multitude of international conventions, agreements, and groups and help give effect to New Zealand's international obligations.

[5] The EPA-set group standards allow for new hazardous substances, which fit the scope of the standard, to be deemed approved and are allowed to be imported or manufactured in New Zealand. Group standards cover a large majority of hazardous substances in New Zealand, including most domestic and workplace chemicals.

## 2.2 What are hazardous substances?

A substance is generally considered hazardous if it exhibits one or more of the following properties:[6]

- explosiveness
- flammability
- a capacity to oxidise
- corrosiveness
- toxicity to humans (including the ability to cause cancer)
- toxicity to the environment
- ability to generate a different hazardous substance on contact with air or water.

Hazardous substances by nature can have some form of negative impact on the environment, human health, or both. But hazardous substances can also create considerable benefits and enhance the environment, public health, the economy, people and communities, and Māori culture. The EPA therefore must consider the benefits of approving a hazardous substance and whether they outweigh the accompanying risks and costs.

The EPA's understanding of hazardous substances evolves over time as knowledge, science and technology become more advanced. Introducing new substances is important to support commercial innovation and to also support improved environmental outcomes by helping to phase-out of the use of older, more hazardous products. It is just as important for the EPA to be able to assess new hazardous substances for introduction as it is to reconsider the risks posed by hazardous substances that have previously been approved.

Global trends are changing and our trading partners (plus their initiatives, such as the European Green Deal[7]) will inevitably be examining New Zealand's supply chain and the use of products/chemicals that are not permitted overseas.

### 2.2.1 The EPA's remit for hazardous substances

The EPA in New Zealand deals with both agrichemicals and other hazardous substances (such as industrial and domestic chemicals) under the HSNO Act. In other jurisdictions there is often a functional split separating agrichemicals and other hazardous substances.

The EPA operates a group standard approval framework, which covers the majority of chemicals and hazardous substances in New Zealand. Group standards specify the conditions for safe management of like groups of hazardous substances, and people wanting to import, manufacture, and use these chemicals can assign a substance to these approvals if they meet the scope and requirements of the standards. Individual assessments, which we talk about throughout this paper in more detail, are for

[6] Hazardous substances are defined in section 2 of the Act and further categorised and distinguished in the Hazardous Substances (Hazard Classification) Notice 2020.

[7] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

classes of substances where there is likely to be higher risks to either people or the environment and require bespoke controls to manage these risks.

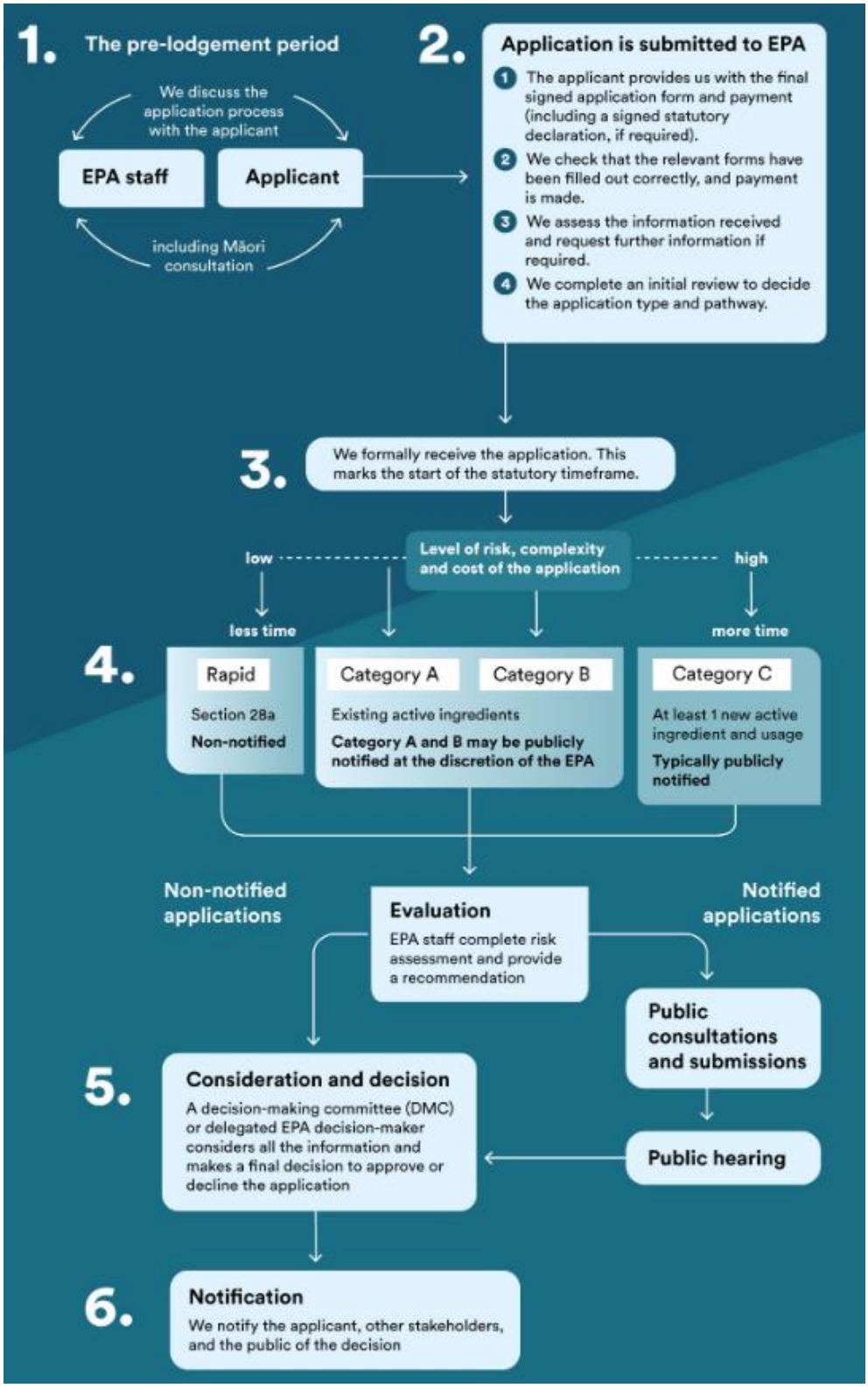
The EPA typically conducts an individual assessment of agrichemicals, vertebrate toxic agents (VTAs), some veterinary medicines, fumigants and timber treatment chemicals, and anti-fouling substances. Some hazardous substances also require separate approval by the Ministry for Primary Industries (MPI) under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act). Most food and medicines are outside the scope of the EPA's hazardous substances remit and are dealt with by MPI and Medsafe respectively.[8]

## 2.3 How hazardous substances assessments work

The application process for an individual assessment broadly has six steps, as shown in Figure 2 below. Further detail on each step is outlined in Appendix B. These assessments under the HSNO Act are to import or manufacture a substance for release, commonly known as 'release' applications or 'full approvals'. As above, for agrichemicals, applicants are also required to seek approval from the MPI under the ACVM Act 1997.

[8] However, medicines under the Medicines Act 1981 also intended for veterinary use are to be considered by the EPA.

Figure 2: The standard process for a new hazardous substance application




Once a release application has been formally received (step 3) it has been assigned to the pathway that reflects the potential risk associated with the substance and the degree of resourcing likely to be required to assess the application:

| Category of application | Typical description of pathway |
|---|---|
| Rapid assessment (import/manufacture) | The hazardous substance has an existing active ingredient(s), comparable substances are already being used in a similar way, with similar known risks to the environment or human health |
| Category A (import/manufacture) | Contains an active ingredient(s) already approved in another substance with a similar use pattern. The EPA carries out a qualitative human health and ecotoxicology risk assessment. |
| Category B (import/manufacture) | Contains an existing active ingredient(s) but requires a greater level of risk assessment due to different use patterns, or new combinations of active ingredients that haven't been assessed in combination. A mixture of qualitative and quantitative risks assessment. |
| Category C (import/manufacture) | Requires an extensive information package and full quantitative risk assessment. Usually reserved for active ingredients that are new to New Zealand. Are typically notified and undergo public consultation. |

Category A, B, and C applications are not official pathways under the HSNO Act – they represent a tiered approach to risk devised by the EPA for assessment and processing purposes. Rapid assessments have criteria defined in section 28A of the Act. There are also containment approvals, which are granted for the import or manufacture of hazardous substances primarily for research and development purposes. Containment applications have their own defined and identifiable application process.

### 2.3.1 The EPA's statutory timeframes

The EPA's statutory timeframes, established in section 59 of the HSNO Act, set the functional length of time for the EPA to conduct different stages of the application. Table 1 below shows the statutory timeframes the EPA works to. Operationally, these timeframes only begin when the EPA has formally received an application, meaning the application forms are complete and signed, the application fee has been received, and the pathway assessment has been conducted (step three in Figure 2).

For publicly notified applications, the overall statutory timeframe comprises four timeframes corresponding to different stages of the assessment.

Table 1: Statutory timeframes for hazardous substances assessments

| Application type | Timeframe (working days) |
|---|---|
| Import or manufacture of a new hazardous substance in a contained location (section 31) | 30 |
| Rapid assessment applications under section 28A | 10 |
| Non-notified assessment (i.e. no public consultation) (section 29) | 30-60 |
| Publicly notified (i.e. public consultation) (section 29) | 70-100 |

Time waivers and extensions may be granted in cases where the EPA requires more information, wants to increase the length of submission period, or wants to postpone commencement of a hearing. Time extensions are also used to allow the EPA to complete a thorough risk assessment of the large amount of information provided by applicants, commonly for Category B and Category C applications. Applicants can also request time waivers. When these waivers are granted, the statutory timeframe for that stage of the assessment stops, and only restarts when the EPA has the additional information requested, the additional time for submissions ends, the delayed hearing is completed, or the application progresses to the next stage.

### 2.3.2 How the EPA evaluates an application

The EPA assesses the hazards, risks, costs and benefits of using a hazardous substance in a New Zealand context (including its environment and people). To be able to be approved, a hazardous substance's benefits must outweigh its costs (and the risks it posed to the environment and people). The EPA's assessment of risks, costs, and benefits is informed by the extent of possible effects and the likelihood of their occurrence.

The applications received include an indicative classification of the level of the substance's hazard and a demonstrated understanding of the substance's life cycle, which includes information about:

- where the hazardous substance would be used and how much would be used
- where it would end up based on its use pattern (environmental fate)
- how the hazardous substance would be disposed of.

The EPA's evaluation of evidence is largely dependent on data and modelling, which includes science-based evidence as well as other evidence like mātauranga Māori (Māori knowledge, experience, values and philosophy)[9]. A number of ecotoxicological models in particular are used to help predict the environmental concentrations that chemicals might have (discussed in more detail below in section 2). The EPA's decisions must consider Te Tiriti o Waitangi, and for example, must weigh up how a hazardous substance may impact Māori culture and traditions.

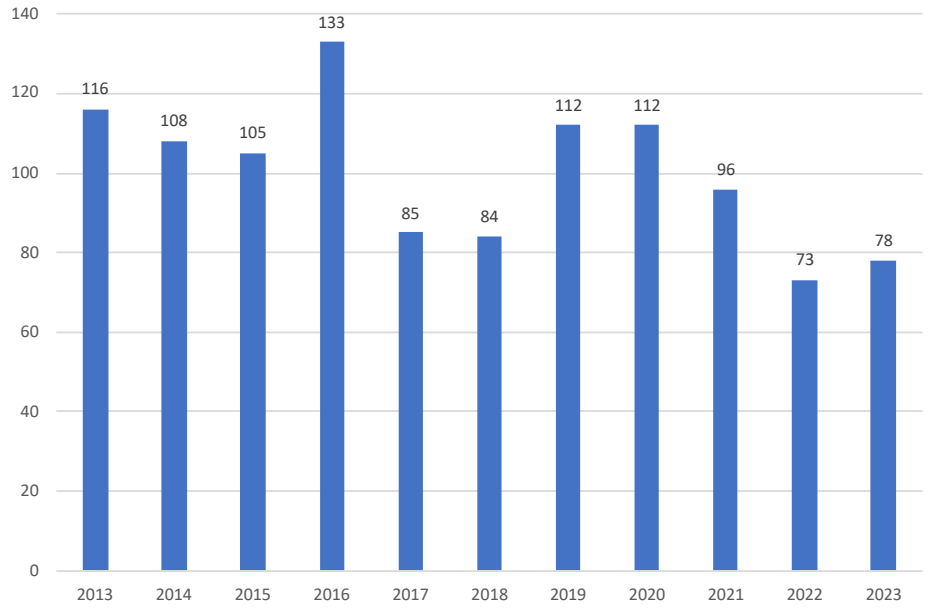
The recommendations formed during an evaluation are also influenced by the EPA's ability to assign suitable controls to the use of the hazard substance, such as maximum application rates and frequencies, where and how the substance can be used and stored and who can access it. These controls are an important factor in how risk can be mitigated or minimised.

### 2.3.3 The EPA's assessment activity has trended downward over time

The number of assessment decisions made by the EPA each year has been trending downwards over the past decade, as shown in Figure 3 below.

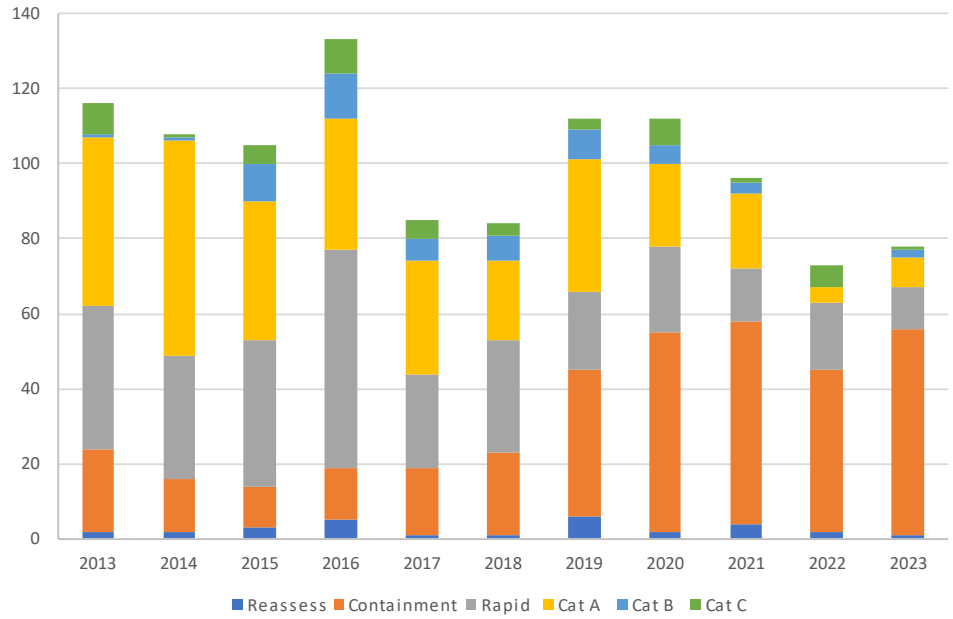
[9] https://www.epa.govt.nz/te-hautu/matauranga/

Figure 3: Volume of hazardous substances decisions to September 2023 (containment, rapid, Categories A-C, and reassessments)




The make-up of those decisions has also evolved, as shown below in Figure 4. The higher-profile and more complex decisions (Categories A, B and C) now make up a much smaller component of decisions – falling from 47 per cent of all decisions in 2013 to only 14 per cent of decisions made so far in 2023. By contrast, the less complex decisions to permit the introduction of hazardous substances into containment areas (which are also generally the fastest decisions to make) now makes up 71 per cent of the EPA's decisions – up from 19 per cent in 2013.

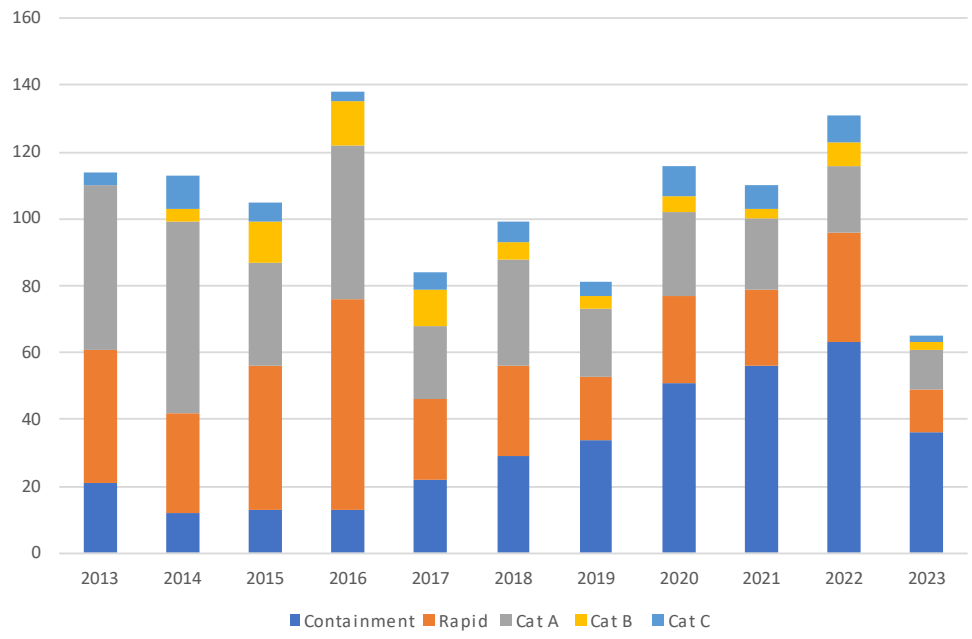
Figure 4: Type of hazardous substances decisions to September 2023 (containment, rapid, Categories A-C, and reassessments)



As we outline in the following chapters – the reduced volume of Category A, B and C decisions is not a product of reduced demand from industry. Application numbers remain relatively constant for most application types, as seen below in Figure 5.

There has been some degree of focus by the EPA on prioritising containment applications in recent years as these applications are typically the least complex, do not require toxicological or ecotoxicological modelling, and allow applicants to continue with research and development activity. While these containment applications might make up 71 per cent of the number of decisions made, they do not occupy 71 per cent of available resources. Consequently, those which are not prioritised sit in the queue awaiting appropriate resource to have capacity to assess.[10]

Figure 5: Estimate of applications lodged to September 2023 (containment, rapid, Categories A-C)




There are other reasons for the decline over time in the number of hazardous substances decisions made by the EPA:

**The establishment of the reassessments teams shifted resources**

The EPA's hazardous substances funding and resourcing covers assessments and reassessments (which are typically initiated by the EPA). Historically the same staff were responsible for both functions, with decisions to initiate reassessments often being impacted by resourcing pressure from demand-driven applications.

In 2020 the EPA established two new teams dedicated to reassessing already approved substances. This team currently receives 39 per cent of the funding allocated to the EPA's hazardous substances

[10] This is complicated slightly in that some assessments span multiple years and therefore the year in which the decision is notified may not always be the same year where the bulk of the assessment workload falls.

work, which has had the flow on effect of reducing the number of new substance applications the EPA can process.[11]

As we explore below in the following chapter, undertaking reassessments is – and should be – a strategic priority for the EPA and is an important means of ensuring the health of New Zealanders and the environment are not being compromised by substances currently being used.

**A general uplift in the standards and level of analytical rigour expected**

The hazardous substances themselves are not becoming more complex to assess over time. But there has been a general increase in the minimum standard expected of scientific evaluation and the rigour of analysis required as science and technology has advanced. Arguably it is the expectation of the public (i.e. in the EPA's social contract to operate) that the EPA conducts itself to the highest practical level of analytical rigour allowed by its resources. Globally there has been a marked increase in the amount of evidence and data available to regulators to inform their assessments and therefore it takes a lot longer to consider all the evidence available and to form robust conclusions.

Anecdotally we have heard that ten years ago for a Category C application there may have been a handful of studies to consider, whereas now, there can be upwards of 1,500 pages of evidence and 200 separate reports to evaluate and consider.

**Assessment of hazardous substances must be holistic which increases the quantity and complexity of evidence to consider**

The EPA's assessment of a hazardous substance is not only focused on the substance itself. Section 5(b) of the HSNO Act states the EPA, in exercising its relevant powers, functions, and duties, should recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations. The EPA's decisions must also consider Te Tiriti o Waitangi.

Therefore, the EPA's assessments of hazardous substances needs to also include cultural and economic benefits and risks (much wider than just the benefits and risks of the hazardous substance alone), and those which are context-specific to New Zealand. This has implications for the volume of evidence to consider as well as the time taken for assessment.

**Challenges attracting skilled scientists and the right expertise for the job**

The market for the expertise the EPA requires for hazardous substances assessments is global, which can make it extremely difficult for a small regulator like the EPA to attract expertise to New Zealand.

The teams doing assessment work at the EPA are small, which means that any staff departure or illness can quickly lead to significant disruptions. For example, there are only eleven roles at the EPA at present for toxicologists and ecotoxicologists across both the new applications and reassessments teams, of which three roles are currently vacant. These staff are the key staff for assessing Category B and C applications, as well as reassessments, and their skillsets are very scarce and primarily sourced

[11] Reassessments work is low volume but highly complex work. The EPA has made an average of 2.6 reassessment decisions per year over the past decade.

from overseas. Recruitment for overseas candidates in these areas takes at least six months due to the recruitment process, extended notice periods in other countries, and immigration and relocation time. Once new staff have joined the EPA there is still significant training time to learn the processes, systems and models.

The challenges facing the EPA in attracting staff has contributed to the large queue of unprocessed applications and increasing industry dissatisfaction with waiting times.[12] While unconfirmed, in recent years this may have been compounded by the inability to recruit skilled workers internationally due to border restrictions.

[12] See for example Richard Rennie 'EPA drops ball on crop treatment options' *Farmers Weekly* (27 September 2023).

# 3. Resourcing: the EPA's hazardous substances functions are under-resourced

The EPA's total expenditure in the 2022/23 financial year was $38m. It is estimated that $3.9m was directly spent on processing hazardous substances applications and reassessments (excluding overheads and shared costs).[13]

Budget 2023 provided the EPA with an annual uplift in baseline funding of $7.2m for 2022/23, of which $1.1m in new funding was provided to support the EPA to deliver its hazardous substances work (not all this funding is available to assessments/reassessments and includes funding for compliance, monitoring and enforcement, support and advice through the Kaupapa Kura Taiao (KKT) team, and general overheads).

Even with the additional funding, it is apparent the EPA's hazardous substances functions are under-resourced; it will not be able to achieve the necessary volumes of throughput with the existing funding. The 2023/24 funding, of slightly over $5m including likely fees revenue, is low by international comparison and is preventing a timely assessment of hazardous substances.

## 3.1 The EPA has far fewer resources dedicated to assessments than comparable regulators

Other comparable regulators around the world appear to have greater resources which they can dedicate toward hazardous substance assessments.

**The EPA has 27 FTEs that are actively involved in assessing hazardous substances[14]**

The number of employees allocated to work on hazardous substances assessments/reassessments (reflecting the increase in numbers from Budget 2023 (4 FTE) and including current vacancies) is:

- **Assessments**: two teams totalling 19 employees are responsible for processing and managing applications, 14 of whom (including vacancies) actively assess the applications with others supporting them (e.g. managerial[15] and administrative roles).[16]
- **Reassessments**: two teams totalling 17 employees are responsible for processing and managing reassessments, 13 of whom actively do the reassessments.[17]

[13] EPA estimate. This reflects EPA cost codes 102 and 105, which covers hazardous substances assessments and reassessments, as well as other functions (therefore potentially overstating available funding). It does not include shared costs or support functions (e.g. CE, legal, KKT).
[14] The HSNO team receives support from all the other operational and support groupings within the EPA to be able to perform its functions. The FTE numbers expressed in this section do not include this support.
[15] While managerial staff do not actively assess applications, they are responsible for delegated statutory decision making functions, internal and external communication, and operational tasks and are therefore key to the overall application process.
[16] Teams HS2 and HS4
[17] Teams HSR1 and HSR2

The expertise required by staff to undertake assessment and reassessment work is technical and requires unique scientific skillsets. The talent pool for ecotoxicologists and toxicologists is global, which poses recruitment challenges and can lead to additional bottlenecks when staff leave the EPA. The EPA is working to establish networks and paths to recruit such specialists from overseas and has connections with relevant tertiary institutions and CRIs to support the development of New Zealand based expertise, however this is a long-term goal.

## 3.2 The EPA receives less funding and processes far fewer complex applications than comparable regulators

When the EPA receives an application to approve a hazardous substance it has to undertake a similar process to regulators overseas. The 2022 amendments to the HSNO Act allow the EPA to rely more on information from overseas regulators in certain assessments, such as a new rapid pathway, however they cannot adopt the decisions of other regulators. All assessments still need to consider the New Zealand context including the impact on the relationship of Māori to the environment, and the economic costs and benefits of using the substance. This means there are limited opportunities to reduce costs or to do more 'light touch' assessments than what takes place overseas. Consequently, the EPA's 'throughput' of hazardous substances applications is primarily a function of its funding.

Table 2 below shows how the EPA compares with other hazardous substances regulators in terms of funding levels and the volume of work it can undertake (reflecting the split that occurs in some countries between regulatory approval to import/manufacture certain products). While it is challenging to make comparisons across jurisdictions (with the workload and resources dependent on the peculiarities of each country's statutory framework), the EPA spends substantially less than comparable regulators on hazardous substances applications, which is shown by undertaken fewer complex assessments or reassessments than any comparable regulator.

Table 2: Comparison with international regulators (2021/22 unless stated)[18]

| Regulator | Estimated direct expenditure on hazardous substances assessments (NZD) | FTEs working on processing and assessing hazardous substances | Number of applications per year | Number of complex assessments (new active ingredient) |
|---|---|---|---|---|
| EPA (NZ) | $3.0m | 32[19] | 123 | 6[20] |
| Australian Industrial Chemicals Introduction Scheme | $20.3m (includes CME) | - | 107 | 7 |
| Australian Pesticides and Veterinary Medicines Authority | $21.1m | 89 | 309 | 15 |
| Health & Safety Executive: biocide and plant protection (UK) | $37.9m (includes CME) | 320 | 414 (biocides only) | 39 |
| Health & Safety Executive: REACH chemical functions (UK)[21] | $9.3m | 35 | - | 8 |
| Pest Management Regulatory Agency (Canada) | $15.0m | 80 | 94 (active ingredients) | 10 |
| Environment and Climate Change Canada | $6.5m | - | - | 5 |
| Environmental Protection Authority (United States) – Insecticide, Fungicide, Rodenticide Act | $56.1m | 134 | - | 35 |
| Environmental Protection Authority (United States) – Toxic Substances Control Act | $271.3m (includes testing and CME) | 250 | 514 | 197 |
| European Chemicals Agency – Pesticides (EU) | $18.4m | 65 | - | 19 |
| European Chemicals Agency – REACH chemicals functions (EU) | $142.5m | 483 | - | 33 |

Table 3 below shows the total expenditure on hazardous substances applications by country, confirming that New Zealand spends considerably less than other countries.

[18] Detail and sources in Appendix A. Note, to enable comparisons with overseas regulators we have used relevant cost and activity data from the 2021/22 financial year.

[19] Reflecting the 36 FTEs referenced in the preceding section, minus four FTEs added as a result of additional Budget 2023 funding (to reach 2021/22 FTEs).

[20] 2022 calendar year

[21] Covering only the HSE's REACH functions (chemicals), so excluding its assessments of biocides and plant protection, which are assessed by the HSE through a separate regulatory framework. See Appendix A for details.

Importantly, Table 3 shows the EPA is making far fewer 'complex' decisions on whether substances with new active ingredients should be permitted to be imported into, or manufactured in, New Zealand. The EPA's 'complex' assessments of substances with new active ingredients represents 3 per cent of the volume of the United States' complex assessments, 10 per cent of Canada's, 13 per cent of the United Kingdom's, 12 per cent of the European Union's, and 18 per cent of Australia's assessment volumes.[22] Given the relatively low throughput, industry in New Zealand will be waiting considerably longer than their counterparts overseas to access new chemicals that could spur productive and technological breakthroughs.

Table 3 also includes two comparator metrics:

- total hazardous substances expenditure divided by the number of complex assessments undertaken in each country (e.g. products with new active ingredients). This is not the marginal cost of each assessment, but provides a proxy for comparing how much is invested in each country compared to the volume of high-profile and complex applications.
- total hazardous substances expenditure per $1m generated by each country's agricultural, forestry, fisheries and manufacturing sectors. These are the sectors are most impacted by the approval/reassessment of chemicals.

Table 3: Comparison of total hazardous expenditure by country (2021/22, NZD)

| Country | Total expenditure by the regulator on hazardous substances assessments | Number of complex assessments (new active ingredient) | Total expenditure divided by number of complex assessments | Total HS expenditure per $1m of GDP generated by agriculture, forestry, fisheries and manufacturing[23] |
|---|---|---|---|---|
| New Zealand | $3.0m | 6 | $0.5m | $52 |
| European Union | $142.5m | 52 | $3.1m | $61 |
| United States (includes testing and CME) | $327.4m | 232 | $1.4m | $72 |
| Canada | $21.6m | 15 | $1.4m | $74 |
| Australia (includes CME, comms) | $41.5m | 33 | $1.9m | $208 |
| United Kingdom (includes CME, comms) | $47.3m | 47 | $1.0m | $221 |

[22] Figures calculated by adding budgets of multiples regulators within each jurisdiction.

[23] 2022 GDP sectoral data sourced from World Bank, https://data.worldbank.org/indicator/NV.AGR.TOTL.ZS. The fisheries sector was included only because it was reported in an aggregated manner with agriculture and forestry. The relative rankings of these countries is unaffected if expenditure is instead divided by total GDP in each country.

From the data presented in Table 2 and Table 3 we conclude:

- New Zealand is investing considerably less on hazardous substances assessments and reassessments than comparable countries. Our spend on hazardous substances as a proportion of size of the most affected sectors is well below that of our trading partners – we spend only a quarter of what Australia and the United Kingdom do and 70 per cent of what each of Canada and the United States does, who also have the benefit of economies of scale.
- There is no evidence the EPA is inefficient. While some countries may have more permissive/restrictive regimes for lower risk substances, all have a common approach where new active ingredients require prior approval from the regulator – expenditure on these complex applications shows the EPA is providing a relatively low-cost assessment model.

We are satisfied that New Zealand's throughput (or cost per application) is reasonable given current funding levels. However, current funding levels are severely constraining the EPA's ability to process the volume of applications it is receiving.

## 3.3 The EPA has a comparatively limited ability to reassess the safety of in-use chemicals

As scientific knowledge develops it is important that a hazardous substances regulator reassesses whether previously approved chemicals should continue to be permitted under existing controls. Substances that were previously considered safe may now be known to have adverse effects for human health and/or the environment and a responsive regulator needs to have processes in place for re-examining their continued use.

In 2018 the EPA identified 39 chemicals that were prioritised for reassessment and put in place a workplan to re-examine their use. As of October 2023, the number of chemicals on the priority chemical list now stands at 43.[24]

In 2020 the EPA established dedicated chemical reassessment teams within the organisation that would be dedicated to its reassessment work – as outlined above, nearly half of the EPA's staff working on hazardous substances are focused primarily on reassessments. This step recognised the importance of reviewing high-risk chemicals and to make sure reassessments were not competing with other usual business activity.

[24] EPA, Priority Chemicals List, https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/adding-to-the-reassessments-work-plan/ (accessed 30 October 2023).

**The EPA's reassessment volumes materially lags those of comparable regulators**

The EPA completes a median of two reassessments per year,[25] with recent decisions taking a median of 343 days from formal receipt of the application.[26] Table 4 below shows that New Zealand is falling well behind other countries in the volume of reassessment decisions it is making.

We note it is difficult to know the exact scope, complexity, and processes when it comes to reassessments or evaluations of already-approved hazardous substances. It is possible some of these comparator jurisdictions are doing less-intensive and/or administrative reassessments of hazardous substances compared to the New Zealand EPA's targeted reassessments programme that is focusing on high-priority chemicals.[27] In particular, the Australian Industrial Chemicals Introduction Scheme (AICIS) has acknowledged its activity is focused on reassessing chemicals that were previously approved without a risk assessment being undertaken, rather than necessarily chemicals with known new risks (as occurs elsewhere).[28]

Table 4: Comparison reassessment decisions made by hazardous substances regulators

| **Regulator** | | **Number of reassessments completed (2021/22 unless stated)** | |
|---|---|---|---|
| New Zealand - EPA (2022 calendar year) | | 2 | |
| Australia | Australian Industrial Chemicals Introduction Scheme | 36[29] | 39 |
| | Australian Pesticides and Veterinary Medicines Authority | 3 | |
| Canada | Pest Management Regulatory Agency (Canada) | 4[30] | 16 |
| | Environment and Climate Change Canada | 12 | |
| United States | | 16 (pesticides only)[31] | |

[25] Median reassessment decisions 2011-2022.
[26] Median time to make a reassessment decision for decisions made between January 2021 – October 2023, from formal receipt to decision notified.
[27] The same holds for general assessments / processing of applications of new hazardous substances.
[28] See AICIS Annual Report 2022/23, https://www.health.gov.au/sites/default/files/2023-10/department-of-health-and-aged-care-annual-report-2022-23_0.pdf
[29] 2022/23 evaluations. 2021/22 data showed AICIS undertaking 89 evaluations, which appeared to be an outlier. Many of these will be light-touch evaluations as AICIS has a programme of activity to re-evaluate all previously approved chemicals. In 2022/23 it removed approval for two chemicals.
[30] Special Reviews only, which are triggered by new information about specific concerns with a pesticide. The PMRA also undertook 7 're-evaluation' decisions as part of its rolling programme of re-evaluations.
[31] The EPA under the Insecticide, Fungicide, Rodenticide Act only (excluding other chemicals)

Our comparison highlights the EPA is not making sufficient progress in reassessing chemicals that have already been approved for use in New Zealand. This is a direct result of the considerably lower levels of funding available to the EPA compared to its counterparts overseas. We concur with the view of the Parliamentary Commissioner for the Environment, who noted in 2022:[32]

> [Reassessments are] a costly business and the EPA has never had anywhere near the resources to conduct more than a handful of reassessments per year, with only a few hundred ever having been completed.

## 3.4 Consequences of underfunding

The consequences of the EPA's continued underfunding may be significant and may create risks for the environment, human health and productivity.

New Zealand is falling behind trading partners in reassessing already-approved chemicals. The EPA's current priority list (43 chemicals) represents a substantial known pipeline of reassessment activity, given current rates of completing two reassessments per year. However, it is almost certain that this pipeline will continue to grow as new information emerges about existing chemicals. Substances with undesirable risk profiles may therefore continue to remain in use in New Zealand longer than in overseas countries.

The lack of funding also means there is a barrier to industry and households in New Zealand potentially being able to use newer, safer, and more productive chemicals and substances. As we set out in the following chapters, the lack of resourcing for the EPA is constraining its ability to process the volume of hazardous substances applications it receives and is also limiting its ability to upgrade outdated (and conservative) modelling tools.

[32] Parliamentary Commissioner for the Environment 'Knowing what's out there – Regulating the environmental fate of chemicals' (2022), p6. https://pce.parliament.nz/media/g0pk2axl/regulating-the-environmental-fate-of-chemicals.pdf

# 4. Timeliness: applicants are facing significant, and increasing, wait times

The EPA's staff are experts in their fields, and we are not aware of any concerns with the content or quality of the EPA's staff's assessments. Our analysis of overseas regulators shows that the EPA's decision timeframes remain within international norms for making complex hazardous substances decisions – when measured from the start of the internal assessment process to a decision being made.

What is concerning is the increasing length of time it takes for the EPA to begin processing an application (step three in Figure 2 above).[33] The large queue of unprocessed applications means applicants have been waiting considerably longer for decisions over the past 24 months than historically. The additional funding in Budget 2023 was less than what was sought – it will enable the EPA to process more applications, but not at a volume that will reduce the number of queued applications.

## 4.1 The EPA's processing timeframes remain broadly comparable with overseas regulators

Table 5 below sets out the processing times for hazardous substances applications, showing that the EPA's current timeframes remain comparable to other regulators, recognising that the statutory/target timeframe to approve a product with a new active ingredient is considerably lower in New Zealand than for other comparable jurisdictions. The statutory timeframe in New Zealand is set out in the HSNO Act and is clearly too ambitious.

However, these figures only reflect the time to make a decision on an application once that process has commenced – there is no public information on how long it takes each regulator to commence an assessment. As set out above, we note that the steadily increasing number of applications that are sitting in a queue awaiting processing, and the lengthening period they wait there until resourcing permits the assessment to begin.

Table 5: Target and actual processing times

| Regulator | Statutory/target timeframe to approve a product with a new active ingredient | Actual time to approve a product from commencement of assessment (not receipt) (2021/22) |
|---|---|---|
| EPA (NZ) | 100 working days (~5 months) | 30.5 months |
| Australia (APVMA) | 18 to 25 months | 29 months |
| United Kingdom | 36 months | 78% within deadline |

[33] During our search of other regulator's processes and reporting (limited to publicly available information) we were unable to determine whether other regulators operate a similar pre-application process and therefore have a pre-application queue. The answer to this may materially change applicant's perceptions of wait times.

| | | |
|---|---|---|
| Canada | 24 months | 82% within deadline |
| EU | 18 months[34] | - |

## 4.2 The EPA's processing and decision-making timeframes have increased significantly

The time it takes the EPA to make hazardous substances decisions across six key categories is set out below in Table 6.

Table 6: Median number of days to make hazardous substances decisions (2022 decisions, calendar days)

| Type of decision | Time faced by applicants for a decision (end-to-end) | Time to decision notified once EPA initiates assessment process | Number of decisions |
|---|---|---|---|
| **Containment decisions**<br>Approval under s31 to import or manufacture a hazardous substance in a contained location | 150 | 35 | 43 |
| **Rapid assessments**<br>Approval under s28A, including where a substance with a similar composition and properties has been approved | 292 | 14 | 18 |
| **Category A**<br>Has a previously approved active ingredient but requires a human health and ecotoxicology risk assessment | 335 | 43 | 4 |
| **Category B**[35]<br>Has a previously approved active ingredient but requires a greater level of risk assessment. May be publicly notified | 843 | 663 | 2 |
| **Category C**<br>At least one new active ingredient and usage. Typically publicly notified and may have a public hearing | 1,084 | 905 | 6 |
| **Reassessments**<br>A review by the EPA (either on its own initiative or by application) as to whether approvals and controls applied to substances should continue | 558 | 405 | 2 |

The data shows that the time it takes for the EPA to make a decision correlates to the potential risks associated with a hazardous substance. In 2022 low-risk rapid assessments were completed (and notified to the applicant) with a median time of 14 days, while the most complex Category C assessments (introducing a substance with a new active ingredient into New Zealand) took a median time of 905 days to complete.

[34] Based on 10 months for draft opinion to be published, two months for applicant comments, and six months for a published authorisation decision (high risk chemical). See the ECHA process description here.
[35] 2023 data used for Category B decisions, as no Category B decisions were made in 2022.

Of particular relevance to applicants is the length of time applicants are experiencing after they have submitted their application but before the EPA has completed its screening and decided the application to a pathway (known as the 'formal receipt' of the application). So, although a rapid assessment in 2022 may have only taken a median of 14 days to assess and inform the applicant of the outcome, the median time from decision lodged to decision notified was 292 days. It should be noted however, that significant work is done during the pathway assessment to determine which application pathway is appropriate for assessment.

**Applicants are waiting considerably longer than compared to a decade ago**

The EPA's assessment timeframes have increased since 2021. While the EPA's assessment timeframes remain within international norms (once an application is under active consideration), applications are now spending much longer in a queue awaiting pathway allocation. Of the applications decided in 2023 this far, the median time containment and release applications were in the pre-application stage was 62 days and 336 days respectively before capacity allowed the pathway and formal receipt to be completed.[36]

Of the release applications currently in the pre-application queue, the median time since lodgement is now 387 days.

Table 7: Timeframes faced by applicants making a hazardous substances application to the EPA; median timeframes for decisions made in 2013-15 compared to 2021-23

| Type of decision | Time to decision from date of application (end-to-end) | |
|---|---|---|
| | 2013-2015 | 2021-2023 |
| Containment decisions | 60 days | 90 days |
| Rapid assessments | 50 days | 297 days |
| Category A | 98 days | 354 days |
| Category B | 176 days | 656 days |
| Category C | 402 days | 1,048 days |
| Reassessments | 464 days | 520 days |

The volumes and timeframes for EPA decisions are set out in more detail Appendix C.

**The queue of unprocessed applications has grown steadily over the last three years, but efforts in streamlining assessment of containment applications has made a difference**

Since February 2020 the EPA has received an average of ten assessment applications each month,[37] but has averaged only eight assessment decisions each month. Over the same period, the queue of

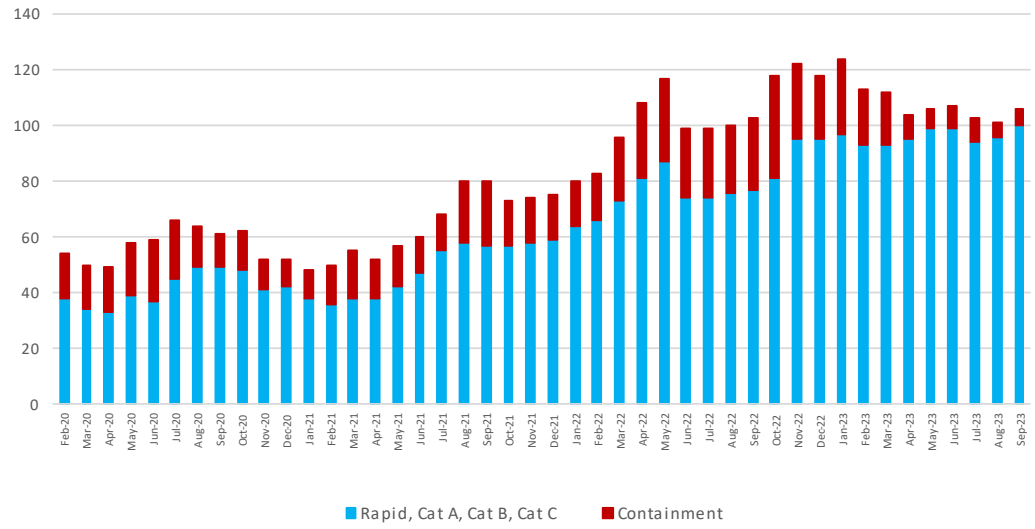
[36] Median time from application being lodged to being formally received by the EPA, for decisions made in 2023

[37] Mean of the monthly volume of applications lodged (for pathways subsequently determined as being for containment assessments, rapid assessments, and categories A, B and C assessments).

applications in pre-application has increased from 54 to 106. The inability to process the incoming volume of applications is leading to a growing queue and thus delays for applicants.

Figure 6 below shows the EPA's queue of unprocessed hazardous substances applications at the EPA.

Figure 6: Unprocessed applications to the EPA for an assessment of a hazardous substance

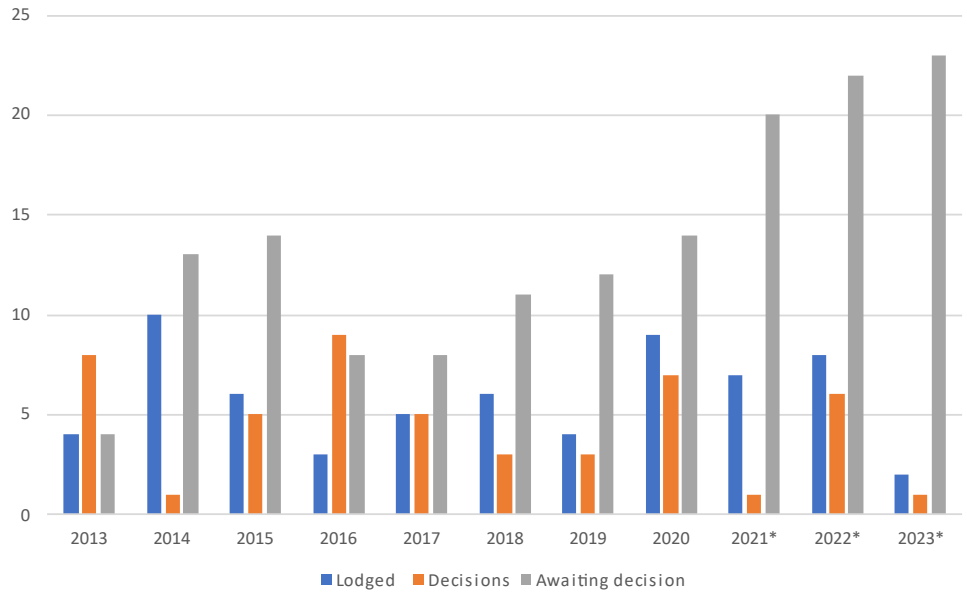



Interestingly, the overall peak in total unprocessed applications was in late 2022 and has started to slowly decline over the course of 2023. It is clear that the EPA has made inroads into clearing the queue of containment applications however the pool of release applications continues to grow.

The following chart demonstrates the increasing queue of Category C applications, which are the most complex assessments for the potential introduction of new active ingredients into New Zealand. When there are more applications lodged than the EPA can process in a year, the queue increases.

While we only looked at data from 2013 -2023 it is notable that none of the Category C applications decided in 2013 were lodged in 2013 – meaning that the queue of Category C applications has likely existed (and has been growing) for more than a decade.

Figure 7: number of applications lodged, decisions and queued applications for Category C (complex) assessments




* Includes likely Category C applications that have been lodged, but which are in the queue and have not yet been formally received

As of October 2023, there are 23 known (or likely) Category C applications where decisions have yet to be made, with seven currently under assessment. For context, the 23 likely Category C applications awaiting a decision equates to the total number of Category C decisions the EPA has made in the past seven years (2017 onwards).

## 4.3 It would take the EPA 2-4 years to clear the queue – if it halted all other assessment activity

It is estimated the queue stood at 106 applications as of September 2023. The make-up of the queue is somewhat unknown because the applications have not gone through a more detailed initial assessment to determine the appropriate application pathway. However, Category C applications are relatively easy to identify because they typically involve substances containing an active ingredient(s) that are brand new to New Zealand. Containment applications are also easily identified because of their unique application pathway.

An attempt has been made to estimate the make-up of the 106 applications in the queue based on the historical proportional split of application types,[38] as well as current EPA estimates of containment and Category C applications in the queue (which are more easily known). This estimate assumes the

[38] This average proportion was calculated based on 2013 – 2021 applications lodged. We excluded 2022 and 2023 since we know there are applications from these years sitting in the queue that may not show up (i.e. 0 Category C applications in both 2022 and 2023) and therefore would bias the average.

queue is entirely made up of applications that have not yet been processed (recognising there are other applications currently being processed, but where decisions have not yet been made).

Table 8 below shows the estimated number of applications in the queue, the three-year average for the numbers of decisions made per year (2020-2022), and the estimated years required to clear the queue for each application type.

Table 8: Estimation of the time taken to clear the pre-application queue

| | Containment | Rapid | Cat A | Cat B | Cat C |
|---|---|---|---|---|---|
| **Estimated number of applications in queue** | 6 | 38 | 39 | 7 | 16 |
| **Average decisions made 2020-2022**[39] | 50 | 18 | 15 | 3 | 4 |
| **Estimated time to clear applications (years)** | **0.12** | **2.1** | **2.6** | **2.3** | **4.0** |

Assuming no new applications are accepted by the EPA and ignoring any applications being processed by the EPA currently, it is estimated it would take the EPA between two to four years simply to clear the existing queue of applications.

Notably, the work done by the EPA to increase efficiency of assessing containment applications over the past year appears to be working, as the number of containment applications awaiting assessment corresponds to only about 6-weeks' of resource.

Conversely, while the EPA typically averages close to four Category C decisions a year, there are an additional seven Category C applications already formally received in various stages of assessment. It is likely that none of these will be decided in 2023, meaning that based on past performance there is an additional 12-18 months of assessment to be conducted on top of the four years' of assessment activity estimated to be in pre-application.

These calculations are likely an underestimate as they assume the current level of resourcing stays constant and again, that the EPA receives no new applications, and excludes the applications currently being processed by the EPA.

## 4.4 There are potential health, environmental and economic gains from increased investment

Current levels of funding are constraining the volumes of applications the EPA can progress each year. Over time this constraint could affect the adoption of new chemicals – limiting commercial innovation, inhibiting primary sector productivity, and restricting the country's ability to transition to 'greener' chemicals that have improved environmental outcomes. An inability to make rapid progress in

[39] 2023 has been excluded for all categories except Category C since it is a partial year.

reassessing priority chemicals could also have significant impacts on the environment and health outcomes.

Applicants may have invested large amounts into research and development of the hazardous substances and time delays (assuming the substance will eventually be approved) will push out their opportunities to recoup those costs. These costs will be passed onto end-users and may, over time, influence market-entry decisions for multinational manufacturers.

Without further action to address the queue of unprocessed applications there will likely be reputational risks for both the EPA, with applicants and industry potentially losing confidence in the effectiveness of the EPA.

# 5. The EPA is relying on outdated ecotox modelling tools

A lack of funding means that that EPA has been unable to invest in upgrading the ecotox models that are used to assess applications. The current models are no longer fit-for-purpose. The EPA (and predecessor organisation the Environmental Risk Management Authority, ERMA) have struggled to deliver a consistent and consolidated approach to environmental fate and ecotoxicological modelling. Rather, the introduction of new models and updates to existing models have occurred on an *ad hoc* basis.

Several models applied by the EPA have been superseded in their original jurisdictions. As best international practice is not being followed and applied, staff have difficulty analysing if human health (e.g., drinking water), environmental, and Māori values are being adequately protected. From an organisational perspective, the EPA's ability to continue to use obsolete models may be compromised at any time due to operating system upgrades and/or changes to system compatibility.

Some of the models used by the EPA are screening tools that offer limited or no ability to move through a tiered approach. This may lead to decision-making that is too conservative and lead to onerous controls and flow-on economic effects (e.g., ineffective crop protection; favourable use of older—more toxic—chemistry which have less onerous controls).

## 5.1 EPA has been modernising its hazardous substances work

The EPA has had a significant programme of work underway to improve the efficiency of its hazardous substances functions. Four key developments include:

- **Moving to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).** In 2021, the EPA transitioned New Zealand's chemical classification system to align with an updated version of the internationally agreed Globally Harmonised System of Classification and Labelling of Chemicals (GHS) as used by all OECD nations.
- **A new database for storing chemical and substance information.** The system/platform underpinning the storage of all hazardous substance information was replaced in 2021 to the International Uniform Chemical Information Database (IUCLID) platform (developed by the European Chemicals Agency). This platform provides for continuous updates to international standards. The hazardous substances databases are the primary repository of information on chemicals that can be used in New Zealand.

- **Greater ability to rely on overseas information.** Recent amendments to the HSNO Act enable the EPA to rely more on data and assessments from recognised overseas regulators while still considering the New Zealand context, for two specific pathways.[40]
- **A programme of prioritised reassessments.** As we explore in the following chapter, the EPA has undertaken a risk analysis of already-approved substances, to identify those that are a priority for being reassessed in light of scientific developments.

The next obvious area of improvement is to address the models it relies on for its assessment of the risks posed by hazardous substances.

## 5.2 The EPA's internal ecotoxicological models urgently need updating

As part of its risk assessments, the EPA quantifies the risks posed by substances by using ecotox models to help predict the environmental concentrations that the chemicals might have. The models need to give accurate information for New Zealand contexts to ensure that appropriate controls and measures can be in place when new chemicals are introduced or reassessed.

Most chemicals that the EPA assesses using ecotoxicological modelling are agrichemicals. Agrichemicals used in agriculture, horticulture, and forestry have a wide range in type, toxicity, and uses in the environment, which means monitoring and managing the environmental effects of agrichemicals is complex and difficult – and that the economic consequences for New Zealand from inadequate risk assessment could be significant.

**Consequences of the EPA relying on outdated ecotox models**

The ecotox models used by the EPA are summarised in Table 9 below. As is evident, four models are now over 20 years old, while others are obsolete and no longer being used by comparable regulators overseas.

Table 9: Summary of key ecotox/e-fate models used by the EPA

| Name of the tool/model | Function | Origin | Age | EPA comments |
|---|---|---|---|---|
| GENEEC2 | Calculates predicted environmental concentration in surface water from pesticide application (spray drift and run off) | USEPA (2001) | > 20 years | Obsolete – USEPA now uses the Pesticide in water calculator (PWC), version 2.001. |
| Sci-Grow (sg23) | Calculates predicted environmental concentration in groundwater from pesticide application | USEPA (1997) | > 20 years | Obsolete – USEPA now uses the Pesticide Root Zone Model (PRZM-GW, version 5) and PWC |

[40] Rapid assessments under section 28A of the HSNO Act and modified reassessments under section 63D of the HSNO Act.

| | | | | |
|---|---|---|---|---|
| AgDISP | Calculates predicted environmental concentration in surface water from aerial pesticide application | USEPA (2002) | >20 years | USEPA using version 8.26 |
| AgDRIFT | Calculates predicted environmental concentration in surface water from ground pesticide application | USEPA/APVMA (2010) | 13 years | Obsolete spray drift curves.<br>APVMA updated the spray drift curves in 2019, we still use old curves. |
| Birds | Assessing both, direct acute and reproductive risk to birds | EFSA Europe (2009) | 14 years | Obsolete – replaced by 2023 version, and a new online tool |
| BeeREX | Assess exposures of bees to pesticides | US EPA (2014) | 8 years | USEPA now lists this as a Tier 1 screening tool.<br>2023 European guidance is expected to be ratified 2024. |
| Non-target plants | Predicts environmental concentration off-field from spray drift curves for threatened and non-threatened species | Europe (2014) and USA (2001) | 10 years | No harmonised approach. |
| Soil organisms Modified FOCUS 2007 equations | Predicts environmental concentration within the top layers of soil | Europe (2007) | 15 years | Not a true model Spreadsheet calculations. |
| Non-target arthropods<br>ESCORT2 guidance equations | Predicts environmental concentration in-field and off-field using spray drift | Europe (2000) | >20 years | EFSA may be reviewing this guidance in the near future. |

Modelling limitations introduce great uncertainty about the potential for chemicals to cause contamination in the environment – meaning the EPA is aware that its models could underestimate chemical contamination. This leads to the EPA having to take a conservative approach in considering potential risks and determining controls for use or declining an approval. Taking a conservative approach potentially prevents the use of new chemicals or innovations that could be beneficial to primary sector productivity and better environmental outcomes.

Some of the severe limitations of the models include:

1. *Out of technical support* - at times there have been technical issues with the models that have led to variable results from different users for the same inputs. A lack of technical resolution has meant the modelling needs to be scrutinised to a higher degree as compared to being able to fully rely on the modelling results.

2. *Limited in ability to include New Zealand specific scenarios* - the models currently do not consider a number of critical elements including surface water drainage impact on fish, aquatic invertebrates, algae, and aquatic plants, impact on native bee and other native

pollinators, and impacts on amphibians, reptiles and fungi. A joint working group of the EPA and the EPA's Māori advisory group, Te Herenga, undertook a Native and Surrogate Species Project in 2019 that identified the latter impact gap as a fundamental concern.

3. *Models are limited in what can be input* - some of the models have a limited set of parameters that can be used, and therefore important data that does not fit within the scope of parameters for the model may not be able to be used in productive ways.

4. *Cannot be accessed by applicants to incorporate their results into applications* - unlike in other jurisdictions, the current models cannot be accessed by applicants to then incorporate results into their applications. This means the EPA is required to modelling and verification work that could otherwise be done in advance by applicants.

5. *Divergence from international norms* - as the EPA is increasingly becoming an outlier with the ecotox models it uses, the less it is able to rely on overseas decisions and information (which it cannot interrogate or verify with its own models).

**Additional funding is required to upgrade ecotox models**

Many of the models used by the EPA are no longer reliable. They are driving additional costs, increase the time it takes to make decisions, and are causing the EPA to take a conservative approach to in assessing risks.

We agree with the position of the Parliamentary Commissioner for the Environment:[41]

> Some of the models used in the EPA's risk assessments are outdated and lack specificity for New Zealand's environmental context …. The EPA should be specifically funded to improve its modelling capabilities in line with international best practice and to incorporate New Zealand specific environmental exposure scenarios.

The EPA would have to compromise its existing activities to fund the upgrades needed to its ecotox models. We have not been able to identify a likely cost estimate for the priority upgrades, but we understand they are likely to be significant (the EPA has unsuccessfully sought funding in the past to scope the level of likely level of investment required).

[41] Parliamentary Commissioner for the Environment 'Knowing what's out there – Regulating the environmental fate of chemicals' (2022), p134. https://pce.parliament.nz/media/g0pk2axl/regulating-the-environmental-fate-of-chemicals.pdf

# 6. Fees: the EPA recovers significantly less of its costs than comparable regulators

The EPA's application fees for hazardous substances assessments are low – both with respect to the absolute fees charged by comparable regulators overseas and as a proportion of costs that are recovered from applicants. As we set out below, there is a case for the EPA to review its fees with a view to setting more cost-reflective rates. This will provide additional resourcing for the EPA, but is unlikely to be sufficient to address the funding shortfall facing the EPA.

## 6.1 The EPA recovers 16 per cent of its assessment costs through fees

The Act empowers the EPA to set charges "so as to recover the actual and reasonable costs incurred in the exercise of that function, power, or duty".[42]

Over the past five financial years the EPA has spent $15.4m on hazardous substances assessments and reassessments and has generated $2.5m in revenue through its fees (16 per cent cost recovery). On an annual basis the cost recovery has been as high as 24 per cent (2020/21) and as low as 8 per cent (2022/23); and if reassessments are excluded (as often the EPA is the applicant) the EPA recovers on average 20 per cent of its cost.[43] The remainder of the EPA's costs are funded through baseline funding, including contributing to the EPA's draw-down on its cash reserves.

The fees set by the EPA vary depending on the nature of the application. Its most common pathways for importing or manufacturing hazardous substances are set out below:[44]

Table 10: EPA fees depending on category of application

| Category of application | Fee |
|---|---|
| Rapid assessment | $4,400 to $5,500 |
| Category A | $5,500 |
| Category B | $11,000 |
| Category C | $27,500 |

[42] HSNO Act 1996, section 21(1)(a). It is permitted to set a scale of charges for a particular function or to set charges based on the time involved in undertaking the work.

[43] The 20 per cent cost recovery is the median revenue received as a share of Part V and Part VI activity over the past five years.

[44] https://www.epa.govt.nz/applications-and-permits/fees-and-charges/

## 6.2 The EPA's fees are substantially lower than most comparable regulators

Table 11 below shows that, of the regulators we analysed, only Environment and Climate Change Canda recovered a lower proportion of its costs from applicants and set a lower application fee. The EPA is therefore generally much more reliant than other regulators on receiving adequate baseline funding from the government to fund its hazardous substances activities.

Table 11: Comparison of cost-recovery by comparable regulators

| **Regulator**[45] | **Fee for complex assessments (new active ingredient) (NZD)** | **Proportion of assessment costs recovered from industry** |
|---|---|---|
| Environment and Climate Change Canada | $4,645 | 6% |
| **EPA (NZ)** | $27,500 | 14% |
| Environmental Protection Authority (United States) – Toxic Substances Control Act | $33,000 | 25% |
| Health & Safety Executive: biocide and plant protection (UK) | $50,000 (average for a single product)<br>$318,000 (average for active substance approval) | 83% |
| Environmental Protection Authority (United States) – Insecticide, Fungicide, Rodenticide Act | Up to $1.4m<br>(for a new active ingredient that proposes a food use) | 85% |
| Australian Pesticides and Veterinary Medicines Authority | $123,000<br>plus an annual levy of 0.25% of revenue (on sales exceeding $5m) | 89% |
| Health & Safety Executive: REACH chemical functions (UK)[46] | $94,000 | 100% |
| Pest Management Regulatory Agency (Canada) | $299,000<br>(max for a pesticide) | 100%<br>(21% of total agency costs) |
| Australian Industrial Chemicals Introduction Scheme | $37,000<br>plus an annual levy of $32,380 (if value exceeds $5m) | 127% |

[45] Regulators in bold are those most comparable to EPA in assessing a new agrichemical or VTA

[46] Covering only the HSE's REACH functions (chemicals), so excluding its assessments of biocides and plant protection, which are assessed by the HSE through a separate regulatory framework. See Appendix A for details.

## 6.3 The EPA currently sets below-cost fees in recognition that the public benefit from assessments

The EPA's Board has the power to set its fees to recover the actual and reasonable costs incurred in the exercise of its functions, powers, or duties under section 21 of the Act. The EPA's fees (and those of its predecessor, the Environmental Risk Management Authority) have broadly been in line with a 2003 Cabinet decision that set fees at a 17 per cent average cost recovery rate (although the Cabinet decision did not mandate a cost recovery target).[47]

**2017 EPA review of third-party funding and cost recovery levels**

In 2016/17 the EPA undertook a review of its third-party funding, recognising its funding levels at the time were unsustainable and some of its Crown funding was at risk (i.e. fixed term). The EPA conducted activity-based costing of its services to be able to understand whether its fees and the level of costs recovered for HSNO activities remained appropriate. A subsequent Cost Recovery Impact Statement (CRIS) was developed by the EPA.[48]

The CRIS showed the preferred options to increase fees by between 33 and 700 per cent for different activities under the Act, with the highest fee increase being $10,000 for complex (Cat C) assessments (this would leave applicants paying for 23 per cent of the total cost of doing a Cat C assessment). The CRIS noted that higher fees would increase costs for users and thereby reduce demand for new assessments, but would allow for investment in systems and capability, plus faster progress on chemical reassessments.

In 2018 the EPA consulted on the proposed fee increases and subsequently imposed fees broadly in line with what was proposed in the CRIS. In 2023, fees were further increased, although by much smaller increments and not universally.[49]

**The case for below-cost fees**

The EPA has not sought full cost recovery from applicants "to recognise the benefits to the economy and the environment from encouraging new and innovative chemistry that will have fewer impacts on both people and the environment."[50]

As part of the CRIS in 2017 the EPA estimated the benefits that would accrue to the applicant for each of the hazardous substances services. The EPA recognised that for most of its services the proportion

[47] Ministry for the Environment 'Environmental Protection Authority Cost Recovery Practices: a component of the review of the effectiveness of the Environmental Protection Authority" (2015) https://environment.govt.nz/assets/Publications/Files/epa-cost-recovery-practices.pdf

[48] https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Fees-consultation-2018/fec4bf9bec/HSNO-Fees-Cost-Recovery-Impact-Statement.pdf

[49] https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Fees-consultation-Feb-2023/New-HSNO-fee-schedule-2023.pdf

[50] EPA 'Hazardous Substances and New Organisms fee proposal' May 2023 (https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Fees-consultation-Feb-2023/HSNO-fees-Submissions-analysis-and-recommendations-report.pdf). By contrast the EPA has historically targeted full cost recovery in the fees it charges for nationally significant consenting proposals and marine consenting.

of the total processing costs borne by applicants (i.e. the fee charged) was lower than the estimated private benefit that would accrue to the applicant.

There are undoubtedly public benefits from the EPA's assessment work. For example, approving a new pesticide could have significant benefits to the primary sector, while approving a new substance that results in lower toxicity from run-off will benefit the environment and nearby communities. Removing a possible financial impediment to the use of such substances could result in substantial public benefits and could incentivise global manufacturers to bring their products to market in New Zealand.

We understand that one reason to not seek full cost recovery is that the private benefits of an approval will not necessarily accrue solely to the applicant. The EPA's approvals are specific to a substance with a particular active ingredient(s) and hazard classifications – they are not specific or restricted to the applicant.[51] As such, while the applicant will bear costs from going through an EPA assessment process, the subsequent approval may benefit businesses who are subsequently able to import or manufacture a "matching" or "equivalent" substance (if there are not proprietary rights involved).

**Our position: there is likely to be a case to set fees that better reflect costs**

The EPA should review its fee structure for hazardous substances assessments, with a view to increasing its fees to better cover the costs it incurs.

Charging fees that are more reflective of costs recognises that assessing applications to import or manufacture new substances will often provide private benefits to the applicant. For example, a global manufacturer seeking approval to import their products will potentially derive substantial commercial value in having access to the New Zealand market that will dwarf any fee set by the EPA.

We are not aware of any evidence that demand for hazardous substances assessments is highly elastic – that is, we have seen no evidence that applicants are highly sensitive to price and will be deterred from introducing new products to New Zealand if their applications do not continue to be subsidised.

The fact that the EPA's cost-recovery is low by international standards indicates that, certainly for larger more complex applications, relatively higher application fees are unlikely to put off an applicant from looking to introduce a new substance to a market. Obviously New Zealand's smaller market size (and smaller commercial opportunities) will mean there is a limit to which the application fee can be increased. However, a 16 per cent recovery rate appears extremely low.

Finally, we note that there does not appear to be particularly strong demand from applicants for fees to remain as low as they are. During the EPA's 2023 consultation on increasing its fees by 10 per cent (still considerably below-cost) it only received four submissions.[52]

[51] If a new substance does not fit within the scope of an existing approval or group standard an application for approval or import or manufacture the substance must be made. The application can be for individual approval of the substance, a new group standard, or an amendment to an existing group standard.

[52] EPA 'Hazardous Substances and New Organisms fee proposal: Submissions analysis and recommendations' (2023) https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Fees-consultation-Feb-2023/HSNO-fees-Submissions-analysis-and-recommendations-report.pdf

**Fee increases are not the panacea but could help ease some pressure in the longer-term**

As described throughout the paper and illustrated in Figure 1, there are many factors impacting the EPA's hazardous substances processing timeframes. Increasing fees will not necessarily lead to the EPA being able to process more applications in the short-term because other issues remain around staffing and resourcing, models and tools, and the application pipeline, which are to an extent independent.

However, in the longer-term increasing fees to be more reflective of the costs of service and more aligned with the level of private benefits that are estimated to accrue to applicants might help to ease some of the pressure on the EPA's HSNO system, particularly where additional revenue from fees can be invested in the system itself (and all its components).

# Appendix A - How we compare internationally

This appendix aims to provide a brief summary of international regulators who have similar responsibilities to the EPA in terms of hazardous substances.

The conclusions drawn from this benchmarking exercise should be treated with some caution. It is beyond the scope of this report to document the differences between each country's statutory and regulatory framework for hazardous substances. While the funding and resources applied in each country may show each country's relative commitment to assessing hazardous substances, it may also reflect that some countries have more permissive/restrictive regimes – which necessitate less/more involvement by the regulator.

## New Zealand - Medsafe

Medsafe operate a similar approval function under the *Medicines Act 1981* but for medicines for human use. Applications must be made to Medsafe and the specified indication or use of the medicine must be approved by Medsafe before a medicine can be used in New Zealand.

Medsafe charge fees relating to the applications, and the fees vary dependent on the nature of the medicine and whether it contains new active substances, its general risk level, and things to do with its commercial marketing characteristics and formulation and strength. Table 12 shows the fees since 2022 for new medicines. An NCE application (i.e. the first row of the table) may be most similar to an EPA Category C application, where there is an active ingredient involved that has not otherwise been introduced to New Zealand before.

Table 12: New Medicines Application (NMA) fees, since 2022

| Type of application | Fee (GST inclusive) $NZD |
|---|---|
| Higher-risk medicine containing one or more new active substances (NCE) | 106,503 |
| Any other new higher-risk medicine, including biosimilars | 79,877 |
| New intermediate-risk medicine – prescription medicine | 53,251 |
| New intermediate-risk medicine – non-prescription medicine | 26,626 |
| New lower-risk medicine | 10,649 |
| Additional dose form – higher-risk medicine – Grade 1 or 2 | 53,252 |
| Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2 | 53,252 |
| Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2 | 26,626 |
| Additional dose form – lower-risk medicine – Grade 1 or 2 | 10,649 |
| New combination product – novel combination of approved active ingredients | 70,292 |
| New combination pack containing two or more currently approved products | 3,835 |

Source: https://www.medsafe.govt.nz/regulatory/fees.asp, accessed 10 October 2023

Note: There are also abbreviated evaluation periods, which have lower fees attached, for use when the medicine is likely to have significant clinical advantage or significant potential cost savings for the New Zealand taxpayer.

## Australia

There are two main regulators of hazardous substances in Australia of relevance for comparison:[53]

- Within the Australian Government Department of Health and Aged Care, **Australian Industrial Chemicals Introduction Scheme (AICIS)** regulates industrial chemicals, including paints, adhesives, inks, plastics, glues, solvents, soaps, and cosmetics.
- **Australian Pesticides and Veterinary Medicines Authority (APVMA)** regulates agricultural and veterinary chemicals, such as pesticides, animal medicines, insect repellents, garden sprays, and some pool chemicals.

### Australian Industrial Chemicals Introduction Scheme (AICIS)

AICIS replaced what was formerly known as the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989*. It sits within the Australian Government Department of Health and Aged Care. The purpose of AICIS is to regulate the use of industrial chemicals.

AICIS uses a cost-recovery model to pay for its regulation activities in two parts: fees for services and a levy. Those wanting to produce or import industrial chemicals into Australia must register with AICIS and pay an annual registration cost (levy) based on the value of the chemicals imported or manufactured in the previous financial year.[54] Effectively, the registration charges scale with the value of the chemicals introduced in the last financial year. Table 13 shows the registration charges (in $AUD) for 2023/24. Each of the registration categories is subject to a $75 fee (included in the charges figure).

Table 13: AICIS registration fees and charges for 2023/24

| Registration category | Value of industrial chemicals introduced in last FY | Charges in $AUD (excl. GST) |
|---|---|---|
| Level 1 | < $50,000 | 75 |
| Level 2 | $50,000 - $74,999 | 140 |
| Level 3 | $75,000 - $99,999 | 155 |
| Level 4 | $100,000 - $249,999 | 280 |

[53] The Therapeutic Goods Administration and Food Standards Australia New Zealand are responsible for the approval of medicines and food-related substances in Australia. In New Zealand, Medsafe and Food Standards Australia New Zealand are responsible for the approval of medicines and food-related substances. Both categories are therefore outside the scope of comparison for the New Zealand EPA.

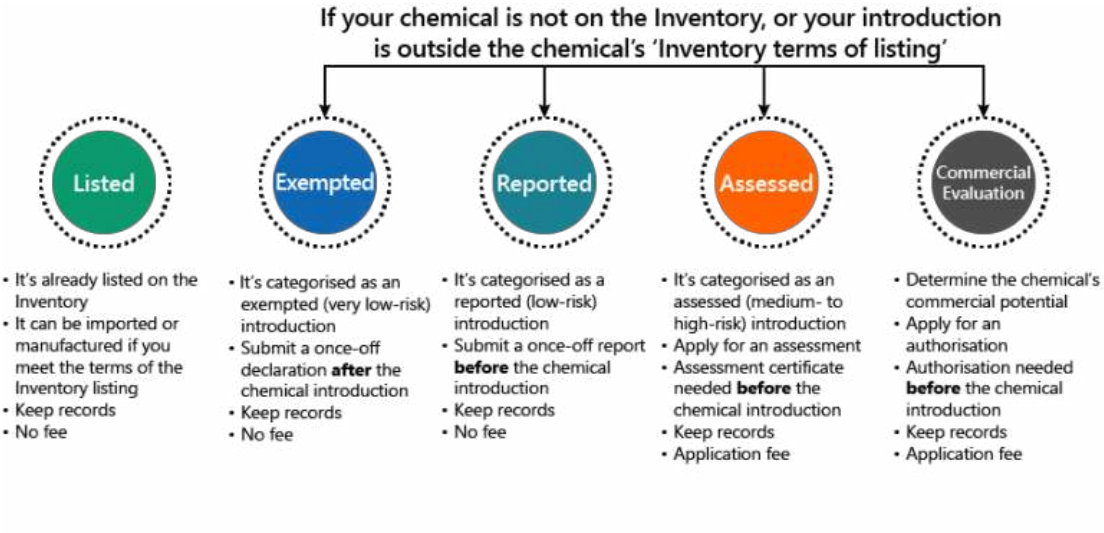
[54] Excludes those importing or manufacturing for personal or hobby use.

| | | |
|---|---|---|
| Level 5 | $250,000 - $499,999 | 475 |
| Level 6 | $500,000 - $2,999,999 | 2,505 |
| Level 7 | $3,000,000 - $4,999,999 | 4,140 |
| Level 8 | $5,000,000 or more | 32,480 |

Source: https://www.industrialchemicals.gov.au/fees, accessed 10 October 2023

The fees for services include the work that goes in to assessing applications for chemicals to be introduced in Australia. Figure 8 below shows the different types of introduction pathways.

Figure 8: AICIS introduction pathways for chemical importation and manufacture




Source: AICIS chemical introduction categories, 2023

Chemicals already listed on the Inventory, AICIS's list of approved uses of chemicals, as well as those that are considered exempted or reported, do not attract fees.[55] Chemicals that are categorised as medium-to-high-risk to the environment or human health or both are called 'Assessed' and attract an application fee. There are strict criteria, but some chemicals may qualify for commercial evaluation and will not be listed on the Inventory.[56] Table 14 shows the major fees for application types. A chemical introduction requiring a 'Health and environment focus' assessment attracts the largest fees because it is likely to have the greatest indicative risk to the environment and human health, and therefore will require more work and analysis to determine an outcome.[57]

[55] Amongst other fee-attracting activities, changes to information or uses of chemicals on the inventory may attract fees, however.

[56] https://www.industrialchemicals.gov.au/guide-categorising-your-chemical-importation-and-manufacture/you-start-categorising-your-introduction

[57] A risk matrix for determining introduction categories can be found here.

Table 14: AICIS fees for introducing chemicals into Australia for 2023/24

| Application / test type | Fee type | Fee in $AUD |
|---|---|---|
| 'Assessed' category | Health and environment focus | 34,965 |
| | Health focus | 23,375 |
| | Environment focus | 23,375 |
| | Very low to low risk | 7,435 |
| | Comparable hazard assessment | 17,515 |
| | Additional chemical that has the same end use as the first chemical and meets similarity criteria | 7,015 |
| | Multicomponent introduction | 2,650 |
| 'Commercial Evaluation' category | Commercial evaluation authorisation | 6,940 |

### Financials of AICIS

Table 15 shows the income statement for AICIS since 2018/19. The industry cost recovered revenue line item represents the levy and fees for services.

Table 15: Income statement for AICIS since 2018/19 ($000)

| Line item | 2018/19 | 2019/20 | 2020/21 | 2021/22 |
|---|---|---|---|---|
| Industry cost recovered revenue | 17,245 | 18,288 | 23,233 | 24,394 |
| Other revenue | 331 | 460 | 965 | 58 |
| Total revenue | 17,576 | 18,748 | 24,198 | 24,452 |
| Total expenses | 15,488 | 16,954 | 19,370 | 19,197 |
| Operating surplus | 2,088 | 1,794 | 4,828 | 5,255 |

Source: Australian Government Department of Health annual reports

**Volumes**

In 2021/22, AICIS issued or varied 18 assessment certificates or authorisations, including 7 new certificates for chemicals that would otherwise would not be permitted in Australia (likely to be akin to the EPA's Category C applications).[58]

AICIS also has a rolling assessment programme as part of its Evaluation Roadmap, focusing on permitted chemicals for which there is not current risk assessment. In the year to 30 June 2022, it undertook 81 chemical evaluations, bringing to a total of 3,761 chemicals that it has reassessed.

**Time frames**

AICIS has a statutory timeframe of 70 working days to process an application / introduction. The timeframe can be adjusted by mutual agreement, and much like in New Zealand, the clock can be paused then resumed (like using a time waiver).[59] Table 16 shows the performance against the statutory timeframes. As discussed throughout the document, performance against statutory timeframes is not necessarily a true indicator of the actual timeframe for an application to be processed, since there can be a lot of time and energy spent pre-application to get the application in a state that can then be assessed within the appropriate processes.

Table 16: Industrial chemical risk assessments and evaluations performance against timeframes

| Target | 2018/19 | 2019/20 | 2020/21 | 2021/22 |
|---|---|---|---|---|
| % within statutory timeframe | 98.7% | 99.5% | 98.2% | 96.8% |

Source: Australian Government Department of Health annual report 2021/22

We were unable to find staffing numbers for AICIS.

## Australian Pesticides and Veterinary Medicines Authority (APVMA)

APVMA is a cost-recovered agency, where registrants pay application fees to register new products and active constituents, amend a current registration or apply for a permit. An annual fee is payable to renew the registration of a product. Product owners also pay an annual levy based on the sales of their registered products.[60]

Levies are imposed under:

- Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994
- the Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994

[58] Department of Health, Annual Report 2021-22, https://www.health.gov.au/sites/default/files/documents/2022/10/department-of-health-annual-report-2021-22.pdf

[59] https://www.industrialchemicals.gov.au/sites/default/files/2020-09/Slides%20Assessed%20Chemical%20Introductions%20%5BPDF%20465%20KB%5D.pdf , https://www.legislation.gov.au/Details/C2019A00012

[60] APVMA Annual Report 2019/20, page 11

- Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994.

Levies are collected under the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994, and the levy rates are prescribed in the Regulations to the Act.

**Timeframes and fees**

The APVMA has a target assessment period of 18 months for approval of an active constituent contained in a chemical product, which starts once an application has passed its preliminary assessment.[61] The legislation describes the assessment period for most application types, but the type of application may mean the period can be extended, in certain circumstances.

There are 27 different application types for approvals and registrations with the APVMA. Across all of them, the maximum assessment period is specified at 18 months. In terms of fees, the maximum is $116,501 for the most comprehensive application type, where an active constituent (part of a chemical product) requires approval and full assessment, and the chemical product related to it requires registration plus its label needs to be approved.[62] Some application types have modular assessment period and fee structures, meaning they are a composite of different activities (where the total is somewhere under the maximum).

The APVMA also collects levies from those manufacturing, importing, and selling pesticides and veterinary chemicals, tiered based on the sales amounts of agricultural and veterinary chemical products in the last financial year:

- 0.63% rate for up to $1 million in product sales
- 0.35% rate for over $1 million and up to $5 million
- 0.25% for over $5 million.[63]

For example, someone selling $6 million worth of pesticides and veterinary chemicals in a financial year would pay $22,800, made up of $6,300 on the first $1 million of sales, $14,000 on the next $4 million of sales, and $2,500 on the last $1 million of sales.

**Delivery against timeframes for the pesticides and veterinary chemicals**

The APVMA discloses how long it takes to make decisions for the most recent year (ending March 2023).[64] During this year it made 15 decisions on pesticide/veterinary products, which could be classified as highly complex (statutory timeframes of 18 months). It took on average 29 months to make decisions on these cases – this only captures time once assessment commences (so is not a true reflection of any backlog or queue in applications that might exist). This is comparable to the 30 month period that it takes for the EPA to formally consider a Category C application.

During the same period the APVMA made 1,445 non-technical assessments, which are analogous to the EPA's rapid assessment category. The APVA took an average of 2.2 months per assessment. This is

[61] https://apvma.gov.au/node/1088
[62] Ibid, accessed 10 October 2023
[63] https://apvma.gov.au/node/4191, accessed 10 October 2023
[64] https://apvma.gov.au/node/26876, accessed 17 October 2023

materially longer than the EPA's median rapid assessment time (from formal receipt) of 14 days (2022).

The following table shows annual performance against statutory timeframes.

Table 17: AMPVA performance against statutory timeframes

| | 2019/20 | 2020/21 | 2021/22 |
|---|---|---|---|
| Pesticide product | 93% | 99% | 98.9% |
| Veterinary medicine products | 89% | 99% | 99.5% |
| Permit approvals | - | 81% | 88.7% |
| Active constituent approvals | - | 96% | 98.3% |

Source: Annual reports from APVMA for the relevant years.

Note: information unavailable on the APVMA website prior to 2019/20.

### Revenue from activities

The table below shows the APVMA revenue from activities for 2019/20 to 2021/22.

Table 18: APMVA revenue from activities, 2019/20 – 2021/22, $000s

| Item | 2019/20 | 2020/21 | 2021/22 |
|---|---|---|---|
| Levies | 18,553 | 20,089 | 22,445 |
| Application fees | 6,489 | 8,449 | 8,276 |
| Annual fees (renewal fees) | 6,009 | 7,311 | 7,985 |
| Other receipts from industry | 2,758 | 2,980 | 2,864 |
| Parliamentary appropriation | 23,430 | 4,400 | 1,923 |
| Other revenue | 226 | 194 | 194 |
| **Total income** | **57,465** | **43,423** | **43,687** |

Source: APVMA annual reports

The APVMA has a broad range of functions (including compliance activities) that are captured in the revenue figures above. It spent $19.944 million (AUD) on Agvet chemical and product assessments in 2021/22 (comprising 45.7% of its total costs).[65]

**Staffing levels at APVMA**

The table below shows the total staffing levels at APVMA over the past three years. These figures include all staff. It is therefore important to consider these figures will not represent the total resource APVMA can or does apply to application processes. But it does give a sense of the scale of the operation.

Table 19: Staff numbers at APVMA, 2020 – 2022

| As at 30 June | 2020 | 2021 | 2022 |
|---|---|---|---|
| Full-time (ongoing) | 138 | 148 | 155 |
| Part-time (ongoing) | 15 | 13 | 17 |
| Non-ongoing and casual | 21 | 19 | 22 |
| **Total** | **174** | **180** | **194** |

Source: APVMA annual reports

**Key finding from the review(s) of APVMA[66,67]**

The APMVA has recently been the subject of a strategic review, as well as a broader system review of how agrichemicals are regulated in Australia. The review noted that over 2019 – 2022, the APVMA's focus was on achieving timeframes for registrations, assessments, and industry stakeholder engagement. The reviewers concluded that APVMA's self-set target for timeframe compliance of 100% is unrealistic, does not reflect best regulator practice, and could contribute to a reduction in regulatory performance.

This finding highlights the importance of balancing the desire to deliver timely decisions for stakeholders with applying the appropriate analytical rigour and checks and processes to ensure decisions are robust and outcomes are appropriate.

## United Kingdom – the Health and Safety Executive

The Health and Safety Executive (HSE) in the UK has an agreement with the Department for Food and Rural Affairs (Defra) in relation to the funding and delivery of functions undertaken by HSE for

[65] Australian Pesticides and Veterinary Medicines Authority 'Cost Recovery Implementation Statement performance report: 2021-22 financial year' https://apvma.gov.au/sites/default/files/publication/108401-cris_performance_report_2021-22_financial_year.pdf

[66] https://www.agriculture.gov.au/sites/default/files/documents/agvet-chemicals-review-final-report.pdf

[67] https://www.agriculture.gov.au/sites/default/files/documents/APVMA%20-%20Strategic%20Review%20Report.PDF

pesticides/PPPs (plant protection products) and detergents; and the functions and enforcing authority for UK REACH (registration, evaluation, authorisation and restriction of chemicals) – regulation that applies to the majority of chemical substances that are manufactured or imported into Great Britain.

Data for the HSE is reported in an aggregate manner by Defra and encompasses a wide range of health and safety activities, making it difficult to examine in detail its hazardous substances work.

**Budget and fees**

The HSE operates on a full cost-recovery basis, which in practice means it charges applicants bespoke fees depending on the nature of the application and the work involved:

- For its assessment of biocides, HSE charges on average, £25,000 for the authorisation of a single product and £160,000 for an application for approval of an active substance.[68]
- HSE's standard REACH fee is £47,229 for an authorisation under Article 62 of UK REACH (analogous to the EPA's Category C application).[69]

In 2022/23 HSE spent £19.1 million on biocides and plant protection assessments, of which it recouped £15.8 million from industry; and spent £4.7 million on REACH assessment (which it fully recovered).[70] The HSE's position on cost-recovery is that:

> "The financial objective of each regime is to fully recover our costs and not make significant surplus or deficit. In both 2022-23 and 2021-22, we made a significant deficit on biocides and plant protection fees. To address, we are currently reviewing fees regulations in this area to ensure we return to full cost recovery by 2024-25."

**Staffing and volumes**

We have been unable to find any publicly available information on the number of applications or assessments undertaken by HSE each year.

A recent audit of HSE states that its Chemicals Regulation Division employed 355 FTEs,[71] 35 of whom include technical staff responsible for REACH authorisations.[72]

In terms of volume of work:

- A 2022 evaluation notes that in the preceding year the HSE had made decisions on 8 applications for REACH authorisations (presumably in the preceding year) and had received five new applications. It anticipated REACH demand increasing to around 60 applications in 2022/23.

[68] HSE Biocides fees, https://www.hse.gov.uk/biocides/fees.htm
[69] HSE Fees and charges, https://www.hse.gov.uk/reach/fees-and-charges-table.htm
[70] HSE 'Annual Report and Accounts 2022/23' https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1171135/hse-annual-report-and-accounts-2022-2023.pdf
[71] National Audit Office 'Regulating after EU Exit' (18 May 2022) https://www.nao.org.uk/wp-content/uploads/2022/05/Regulating-after-EU-Exit.pdf
[72] Department for Environment Food & Rural Affairs 'Evaluation of the Early Transition from EU REACH to UK REACH' (2022) https://sciencesearch.defra.gov.uk/ProjectDetails?ProjectId=21249

- In 2021/22 HSE received 414 biocidal product approval applications and it completed 39 evaluations.[73]

**Timeframes**

There is no publicly available information on the actual time it takes the HSE to make decisions.

The HSE states that it made 78% of its evaluations and authorisations within the required timeframes for biocide products and plant protection products.[74]

The HSE has encountered significant difficulties as its functions expanded post-Brexit and the government recently extended approvals for biocidal active substances due to expire to 2027, while the HSE develops its work programme.

## European Union

The European Chemicals Agency (ECHA) is an agency of the EU and oversees its chemicals legislation. It appears there are two main functional areas for our consideration under the ECHA, one being the EU REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) legislation, and the other being the management of agrichemicals under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) (referred to as BPR).

### EU REACH

The EU REACH legislation generally applies to all chemical substances (research purposes can be exempted). It requires importers, manufacturers, and users to register chemicals and their uses when volumes are over one tonne a year. Registration is not required for some substances that are low risk, naturally occurring, already registered, or covered under other legislation (e.g. radioactive substances).

*Registration*

If registration is required, then it must be done for each substance and use of that substance, and the submission for registration must be made jointly between parties if more than one party is wanting to import or manufacture the substance for that particular use. Registration of a substance incurs a fee, and these fees are determined based on the size of the company applying, reason for submission, submission type, and the volume (tonnes) of the substance likely to be imported or manufactured.

For example, one regulatory consulting firm estimate the cost for registration for a new registration, submitted individually by a large company, for over 1,000 tonnes, at 33,699 EUR.[75]

We have not found any information on the target timeframe for processing registrations once submitted, nor the actual time it takes ECHA to process registrations under REACH.

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[73] National Audit Office 'Regulating after EU Exit' (18 May 2022) https://www.nao.org.uk/wp-content/uploads/2022/05/Regulating-after-EU-Exit.pdf

[74] HSE 'Annual Report and Accounts 2022/23' https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1171135/hse-annual-report-and-accounts-2022-2023.pdf

[75] https://reachcompliance.io/tools/what-are-echas-reach-fees/, accessed 27 October 2023.

*Authorisation*

There is a list of high-risk substances (the Authorisation List) which require authorisation to be able to use.[76] The ECHA assesses the applications for authorisation.

Fees for authorisation also depend on size of company applying, number of substances, and uses. For example, using the ECHA authorisation application fee tool, for a large company applying for one use and one substance, it is estimated at 54,100 EUR. Additional fees would be incurred for applicants based on the estimated tonnage and if there are any additional uses and products for authorisation.

We have not found any information on the actual time it takes ECHA and/or member states to process authorisation applications for under REACH.

In terms of FTEs, the ECHA 2022 annual report suggests there were 88 contract agents and 385 temporary agents (483 total) working under the REACH/CLP legislation. The executed payment amount (which is assumed to be consistent with the expense of the function) for 2022 was 83,469,212 EUR, while the revenue received for the REACH/CLP functions was 33,397,513 EUR.[77]

## Agrichemicals / Biocides

All biocidal products must get authorised before they can be marketed within the EU. There are several ways a product can be authorised:

- National authorisation in an EU country, and mutual recognition, if the product is to be sold only in one country or if other countries in the EU accept mutual recognition of authorisation as well.
- Union authorisation, for all EU countries at once.
- Simplified authorisation, for those products which meet certain requirements in the regulation (e.g. no substances of concern in the product).
- Same biocidal product authorisation, where an identical product is already authorised or ongoing.[78]

In the case of a new active substance (assumed to be the most complex application type, and therefore the ones to attract the highest fees, analytical rigour, and time taken to reach a decision), companies must apply for approval to the ECHA and supply a dossier of evidence, which is then checked by ECHA and evaluated by an authority of one of the members of the EU. This evaluation can take up to one year.[79]

There are fees for registration which are paid annually (to keep the registration active). It appears there are different fees dependent on the member state of the EU in which the registration is made (if

[76] https://echa.europa.eu/authorisation-list
[77] https://echa.europa.eu/documents/10162/51532296/mb_03_2023_annual_report_2022_en.pdf/d6a5b3dd-e4cc-7c99-2962-75a168b8de4b
[78] https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products
[79] https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/new-active-substances

it is a single country authorisation). It is unclear how the fee differs when a union authorisation is sought.

In terms of FTEs, the ECHA 2022 annual report suggests there were 13 contract agents and 52 temporary agents (65 total) working under the BPR. The executed payment amount (which is assumed to be consistent with the expense of the function) for 2022 was 10,782,238 EUR, while the revenue received for the BPR function was 6,756,620 EUR.[80]

We have not found any information on the actual time it takes ECHA and/or member states to process authorisation applications for biocidal products.

## United States

The US Environmental Protection Agency (US EPA) has authority on hazardous substances under two main bits of legislation:

- Toxic Substances Control Act (TSCA), focusing on production, importation, use, and disposal of specific chemicals. It excludes things like pesticides, cosmetics, and food and drugs.
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Pesticide Registration Improvement Acts (PRIA), which manages the registration, distribution, and sale and use of pesticides in the US.[81]

### Toxic Substances Control Act (TSCA)

Parties wanting to import, manufacture, distribute, or use new chemical substances that have not before been approved by the US EPA must first apply to the US EPA (under Section 5). If the chemical is approved it is added to the TSCA Inventory (list of approved chemicals) and can be used, subject to conditions of use that are specified.

The US EPA can issue Significant New Use Rules (SNURs) under Section 5 of TSCA when it identifies a significant new use of a substance or product that could result in exposure to, or release of, a substance of concern. SNURs specify the ways which these can be used and the requirements for parties, including the requirement to notify the US EPA of intention to use.

The US EPA also has the power under Section 4 of TSCA to force manufacturers, importers, and processors to test their chemicals where risks or exposures of concern are found. There are also other reporting, record-keeping, and information sharing requirements for parties under different sections of TSCA.

**Budget and fees under the TSCA**

For TSCA-related work, the US EPA operates on a partially cost-recovered basis. Amendments to the TSCA in 2016 provided the US EPA with expanded authority to collect fees from chemical

[80] https://echa.europa.eu/documents/10162/51532296/mb_03_2023_annual_report_2022_en.pdf/d6a5b3dd-e4cc-7c99-2962-75a168b8de4b

[81] The term 'pesticide' here includes insecticides, herbicides, fungicides, rodenticides, and so forth.

manufacturers and importers to help cover up to 25 per cent of the costs associated with the US EPA's implementation of activities under the TSCA. [82]

The fee amount for each of the application categories was developed by estimating the total annual costs of administering TSCA sections 4, 5, and 6 (excluding the costs of manufacturer-requested risk evaluations) and of collecting, processing, reviewing, providing access to and protecting from disclosure as appropriate confidential business information. The Agency then allocated 25 per cent of those costs (the full amount recoverable under TSCA section 26) across six fee triggering events in sections 4, 5, and 6. Fees for manufacturer-requested risk evaluations are not subject to the 25 per cent limitation in TSCA – the final fee amount is a percentage of the actual cost of conducting the evaluation. Table 20 shows the fees for different categories.

Table 20: US EPA TSCA fee categories

| Fee Category | Total Fee | Maximum Fee for Small Business |
|---|---|---|
| **TSCA Section 4** | | |
| Test order | $11,650 | $2,320 |
| Test rule | $35,080 | $7,020 |
| Enforceable Consent Agreement (ECA) | $27,110 | $5,470 |
| **TSCA Section 5** | | |
| Premanufacture Notice (PMN) and consolidated PMN | $19,020 | $3,330 |
| Significant New Use Notice (SNUN) | $19,020 | $3,330 |
| Microbial Commercial Activity Notice (MCAN) and consolidated MCAN | $19,020 | $3,330 |
| Low Releases and Low Exposures (LoREX) exemption | $5,590 | $1,120 |
| Low Volume Exemption (LVE) | $5,590 | $1,120 |
| Test Marketing Exemption (TME) | $5,590 | $1,120 |
| Tier II exemption | $5,590 | $1,120 |
| TSCA Environmental Release Application (TERA) | $5,590 | $1,120 |
| Film Articles | $5,590 | $1,120 |
| **TSCA Section 6** | | |
| EPA-initiated risk evaluation | $1,605,000 | $320,000 |
| Manufacturer-requested risk evaluation on a chemical included in the Work Plan | 50% of total actual costs with a $1,490,000 initial payment | 50% of total actual costs with a $1,490,000 initial payment |
| Manufacturer-requested risk evaluation on a chemical **not** included in the Work Plan | 100% of total actual costs with a $2,970,000 initial payment | 100% of total actual costs with a $2,970,000 initial payment |

[82] https://www.epa.gov/tsca-fees/fees-administration-toxic-substances-control-act

Source: https://www.epa.gov/tsca-fees/tsca-fees-table

EPA-initiated risk evaluations are for existing / approved chemicals under the TSCA and are done to determine whether a chemical substance presents an unreasonable risk to human health or the environment (like the New Zealand EPA's reassessments). The fees for these evaluations are charged to the manufacturers / importers.[83] There is a Work Plan which identifies the highest priority evaluations and effectively signals the order the EPA will be doing in.

In 2022 it was estimated that the expenditure on TSCA activities by the US EPA was $181.9 million USD.[84]

**Staffing and volumes**

In 2021 there were approximately 250 FTEs within the US EPA working on TSCA related activities.[85]

In terms of volumes, there were:

- 514 Section 5 submissions in FY2022
- 480 risk assessments completed, including notices and applications for exemptions from full pre-manufacturing review processes, of which;
- 197 were assessments for premanufacture (PMNs), significant new uses (SNUNs), and microbial activity notices (MCANs).[86]

There are expected to be no EPA evaluations done on designated High Priority Substances (HPSs) until FY2027, as specified in the US EPA's 2022 annual report.[87]

**Timeframes**

The performance metrics chosen by the US EPA regarding TSCA to be listed in its annual report do not include timeframes for the processing of applications.

## Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA) and Pesticide Registration Improvement Acts (PRIA)

Pesticides must be registered with the US EPA before they can be used. The US EPA consider the ingredients of the pesticide, particular site or crop will be used on, amount, frequency, and timing of use, and storage and disposal practices.

**Budget and fees**

[83] https://www.epa.gov/tsca-fees/tsca-fees-epa-initiated-risk-evaluations#whopays
[84] https://www.federalregister.gov/documents/2022/11/16/2022-24137/fees-for-the-administration-of-the-toxic-substances-control-act-tsca
[85] https://www.epa.gov/sites/default/files/2021-05/documents/fy-2022-congressional-justification-all-tabs.pdf, page xiv
[86] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review, accessed 2022 figures through the Internet Archive (Wayback Machine)
[87] https://www.epa.gov/system/files/documents/2023-04/fy24-cj-15-program-performance.pdf

There is a fee for registration, which varies dependent on the substance's active ingredients, proposed uses (particularly if directly with food), and inherent risk. As a more complex and higher risk substance example, a conventional pesticide with a new, unregistered active ingredient, that will have a food use, the registration fee is $830,274 USD (assuming no waivers are granted).[88] For this type of application the specified decision time is 24 months. Additional fees are charged annually under PRIA for parties to maintain their registration of a pesticide. The fees scale with the number of registrations, starting at $4,875 USD.[89]

The US EPA's FIFRA activities are not fully cost recovered. The US EPA's expenditure for FIFRA in 2022 was $37.6 million USD (direct personnel costs), while its revenue from industry (fees etc.) was $31.8 million USD.[90]

**Staffing and volumes**

Based on the US EPA's 2022 appropriations, it appears at least 135.3 FTEs were allocated for its pesticides licensing programme(s).[91] It is unclear from the US EPA's annual reports what volumes of FIFRA applications and registrations were dealt with in FY2022. However, we do know that the US EPA completed 16 registration review cases – the equivalent of reassessing the controls applied to pesticides.[92]

**Timeframes**

The performance metrics chosen by the US EPA regarding FIFRA to be listed in its annual report do not include timeframes for the processing of applications.

# Canada

## Environment and Climate Change Canada

Canada's New Substances programme consists of officials from Environment and Climate Change Canada (ECCC) and Health Canada. It is responsible for administering the *New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)* made under the *Canadian Environmental Protection Act, 1999* (CEPA). These regulations ensure that no new substances (chemicals, polymers or living organisms) are introduced into the Canadian marketplace before undergoing ecological and human health assessments, and that appropriate control measures have been taken, when required.

[88] https://www.epa.gov/pria-fees/r010-pria-fee-category - the US EPA has a fee determination decision tree that can be used to see what likely fees are due.
[89] See https://www.epa.gov/system/files/documents/2023-01/Updated-2023-Pesticide-Maintenance-Fee-Tables.pdf for more information.
[90] This is an annual fee collection target set by Congress. See https://www.epaoig.gov/sites/default/files/reports/2023-10/_epaoig_20231017-24-f-0003_cert.pdf
[91] https://www.epa.gov/sites/default/files/2021-05/documents/fy-2022-congressional-justification-all-tabs.pdf, pages 64-68
[92] https://www.epa.gov/system/files/documents/2023-04/fy24-cj-15-program-performance.pdf

In 2021/22 the ECCC:[93]

- Assessed 328 new substances notifications. Note, 57 of these were for new substances regulated under the Food and Drugs Act.
- Completed 49 risk assessment summaries, where controls were applied to new substances
- Published 5 Notices of Ministerial Conditions, through which ECCC either prohibited the manufacture/import of new substances or permitted it subject to specified conditions (likely akin to Category C assessments).
- Reassessed 12 already-approved substances.

The ECCC does not charge cost-reflective fees. The fees it charges are nominal and are adjusted depending on the applicant's revenue. The maximum fees payable for a new substance assessment by an applicant who earned less than $13 million in the preceding year is $1,005, increasing to a maximum fee of $4,021.[94] In 2021/2 ECCC spent $5.7 million on assessing new substances and recouped $0.35 million through fees (6 per cent cost recovery).[95]

## The Pest Management Regulatory Agency

Health Canada's Pest Management Regulatory Agency is responsible for pesticide regulation in Canada. In 2021/22 it:[96]

- received 94 Category A applications (active ingredients)
- made 10 Category A decisions
- made 82% of decisions within its service standard of 665 days processing time
- made 4 'special review' decisions on already approved chemicals once new information came to light. It also re-evaluated 7 already-approved chemicals as part of its rolling programme of re-evaluations.

The Pest Management Regulatory Agency sets its fees to reflect current costs. It generated $13m in industry revenue from its fees and levy on registrants, equating to 21 per cent of its total budget (it undertakes much broader pest management activity). The fees that it charges applicants depends on the type of application and the analysis required. In 2023 the maximum fee it could charge was $258,867.[97]

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[93] Environment and Climate Change Canada 'Canadian Environmental Protection Act 1999: Annual Report to Parliament for April 2021 to March 2022' https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/annual-report-2021-2022.html

[94] https://www.canada.ca/content/dam/eccc/documents/pdf/pded/new-substances-notification-form/Fee-table.pdf

[95] Environment and Climate Change Canada 'Fees Report: Fiscal year 2021-2022' https://www.canada.ca/en/environment-climate-change/corporate/transparency/priorities-management/reports-parliament/fees-2021-2022.html

[96] Pest Management Regulatory Agency Annual Report 2021-22, https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2021-2022.html

[97] https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/product-application/cost-recovery.html (accessed 17 October 2023).

The most recent publicly available data is that the Pest Management Regulatory Agency had 385 employees in 2020.[98] By extrapolating its cost-recovery (21 per cent) we can estimate it has approximately 80 employees working on assessing applications.

[98] Pest Management Regulatory Agency Annual Report 2019–2020

# Appendix B - Hazardous substances assessment process

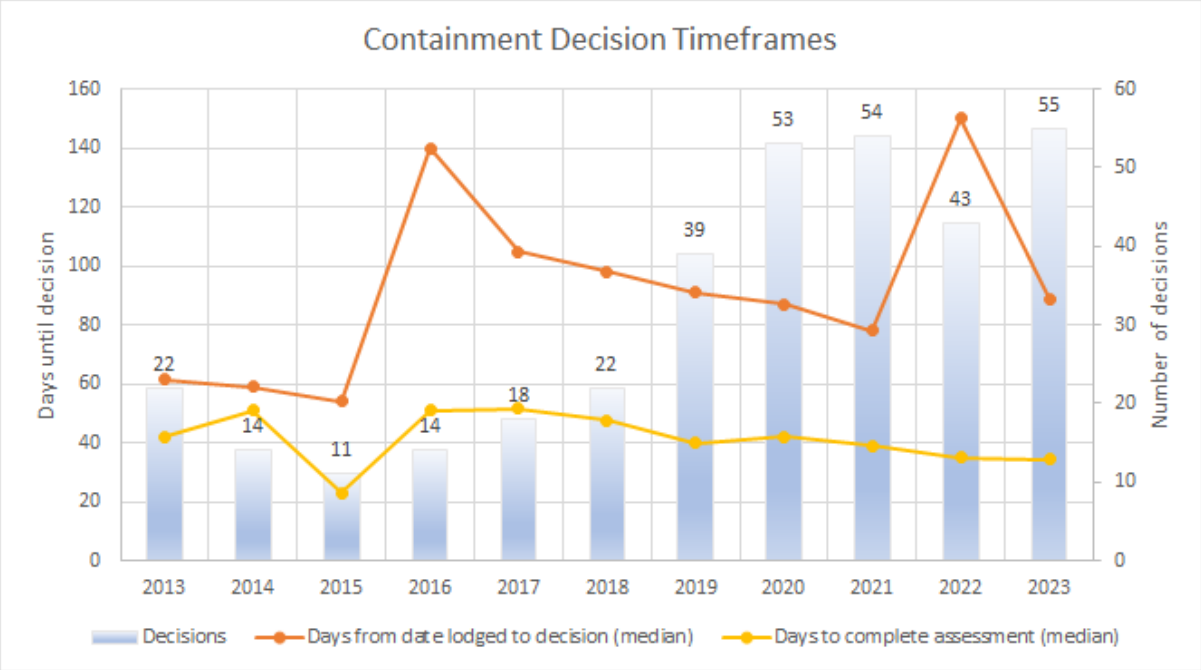
Table 21: Application process for hazardous substances

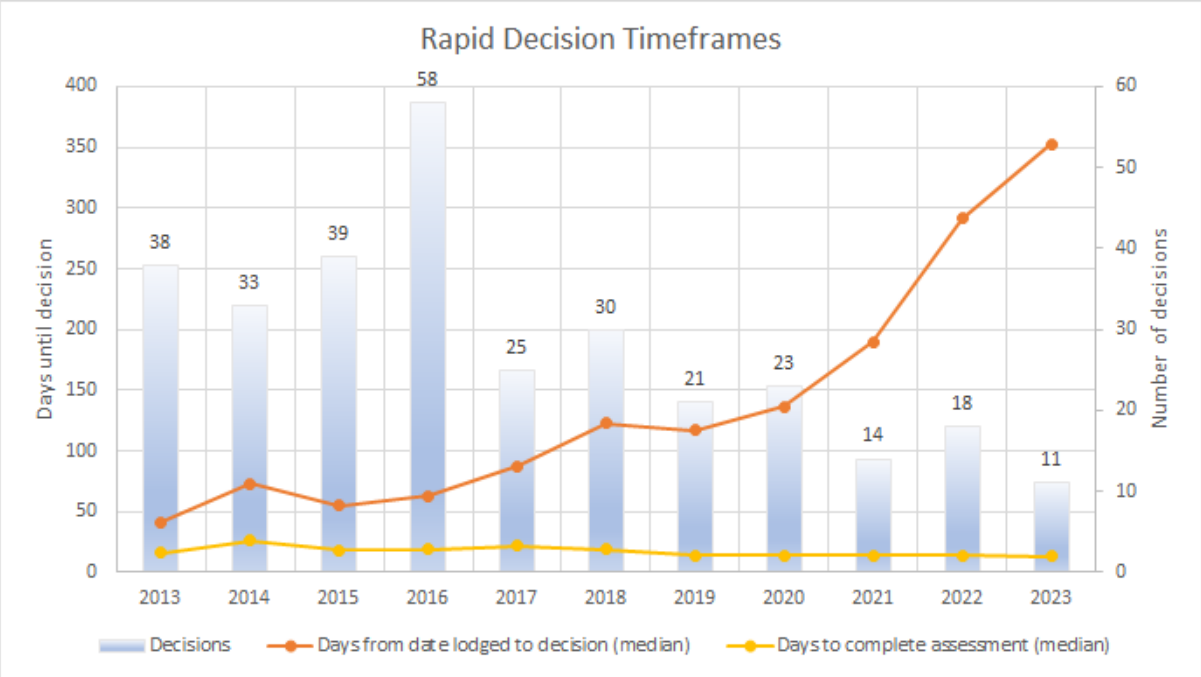
| Step | Description |
|---|---|
| Pre-lodgement | This is where the EPA discusses the application process and information requirements with the applicant. The EPA may suggest consultation with Māori prior to submitting a hazardous substance application. |
| Submission of an application to the EPA | The EPA receives an application from the applicant (in addition to payment of a lodgement fee and a signed statutory declaration if required). It conducts checks to ensure the applicant has provided the right information and may ask for more if needed. At this point it makes an initial judgement of the application to determine the application pathway. The application includes an assessment by the applicant of the hazards, risks, costs, and benefits of using the substance in the New Zealand context. |
| Formal receipt of the application | The EPA formally receives the application once it has all the appropriate information and payment and has completed an initial assessment to determine the pathway. It is at this point that the statutory time frame begins, which is dependent on the pathway of the application. |
| Evaluation of the application | This depends on the pathway, which is determined by the level of risk and complexity associated with the application. The pathways in order of least to most complexity (and therefore time under assessment) are Rapid (under section 28A), Category A, Category B, and Category C.<br><br>Rapid assessments are non-notified (i.e. do not require public consultation and the hearing of submissions), whereas Category A and Category B may be publicly notified if the EPA chooses to do so. Category C are typically publicly notified because of the higher levels of risk and complexity. The EPA conducts detailed risk assessments of the application, including consideration of how the substance might impact the environment, human health, Māori interest and culture, the economy, and our international obligations. |
| Consideration and decision | Decision-making committees (DMCs) or delegated EPA decision-makers consider and make a final decision based on all the information before them, to either approve or decline the application. The decision-maker(s) may find they require more information to make a decision. Applications that are publicly notified include public consultations and submissions, and usually a public hearing. |
| Notification | Once a decision has been made, the EPA notifies the applicant, other stakeholders, and the public of the decision outcome. |

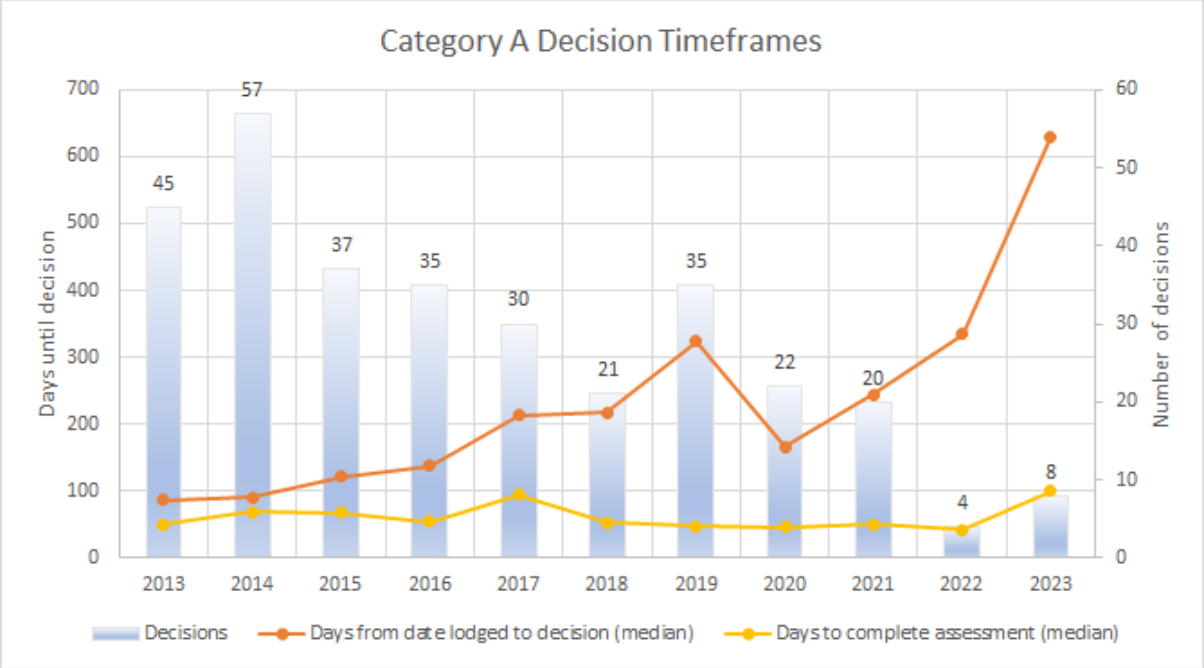
Source: https://www.epa.govt.nz/industry-areas/hazardous-substances/making-an-application/what-is-the-process/processing-new-hazardous-substance-applications/

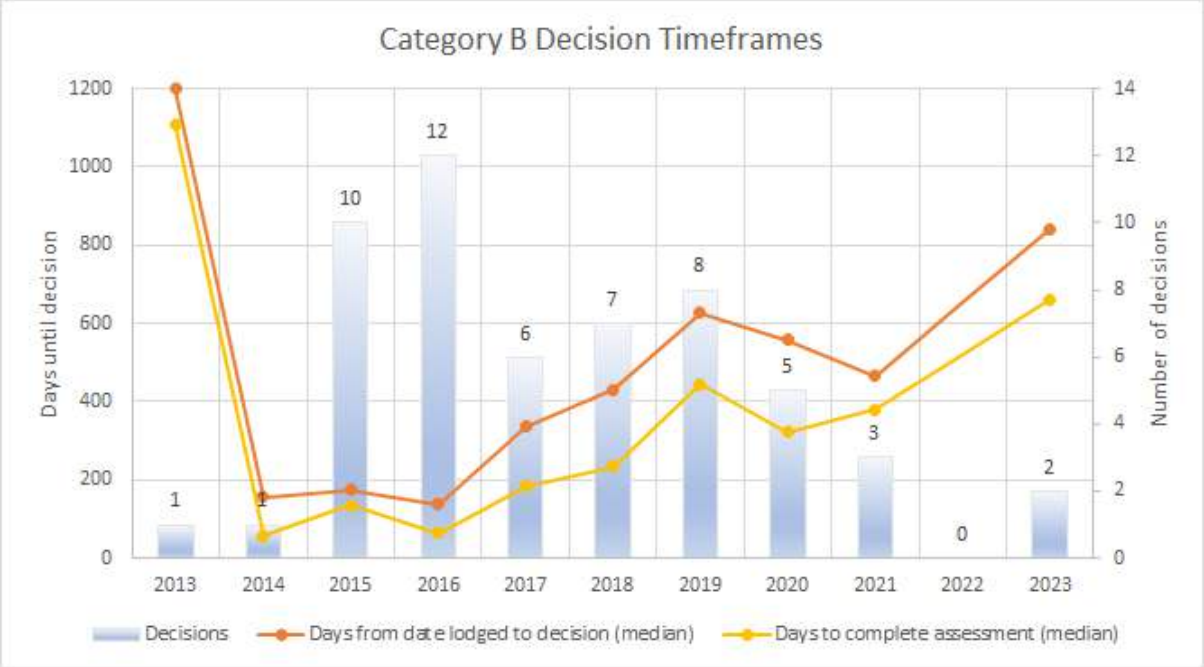
# Appendix C - Assessment volumes and timeframes

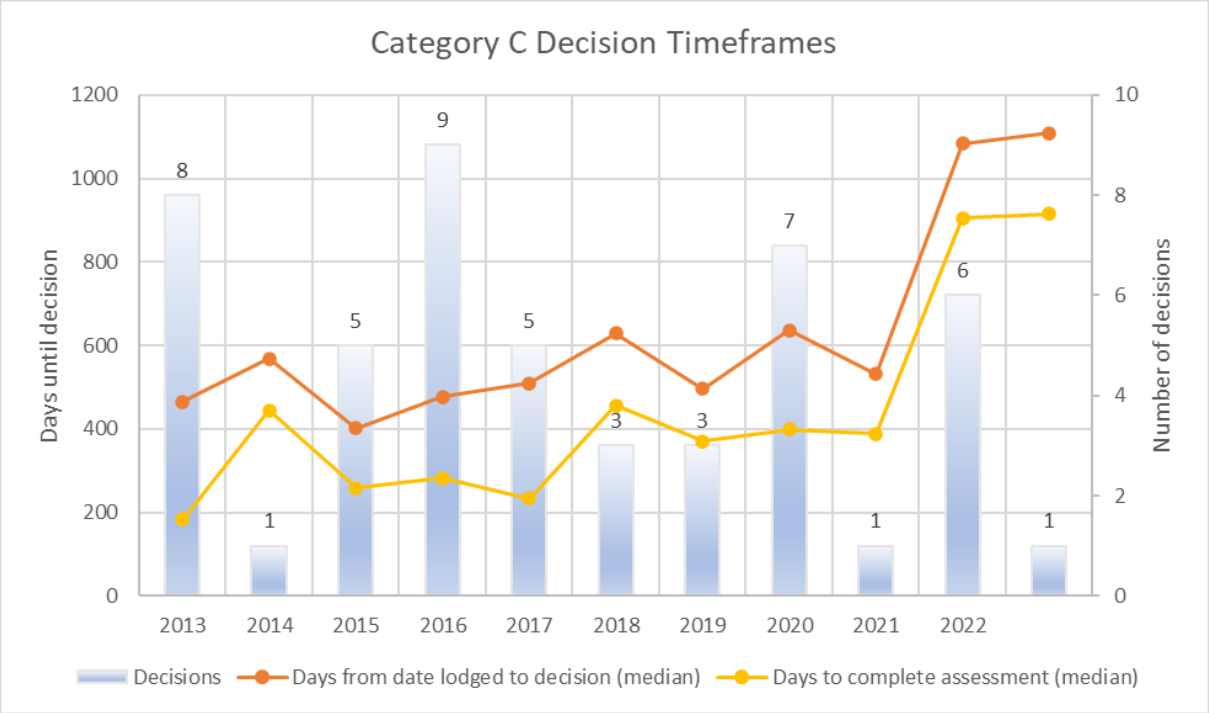
The following six charts show the trends in volumes and time to make decisions for the six categories since 2013.

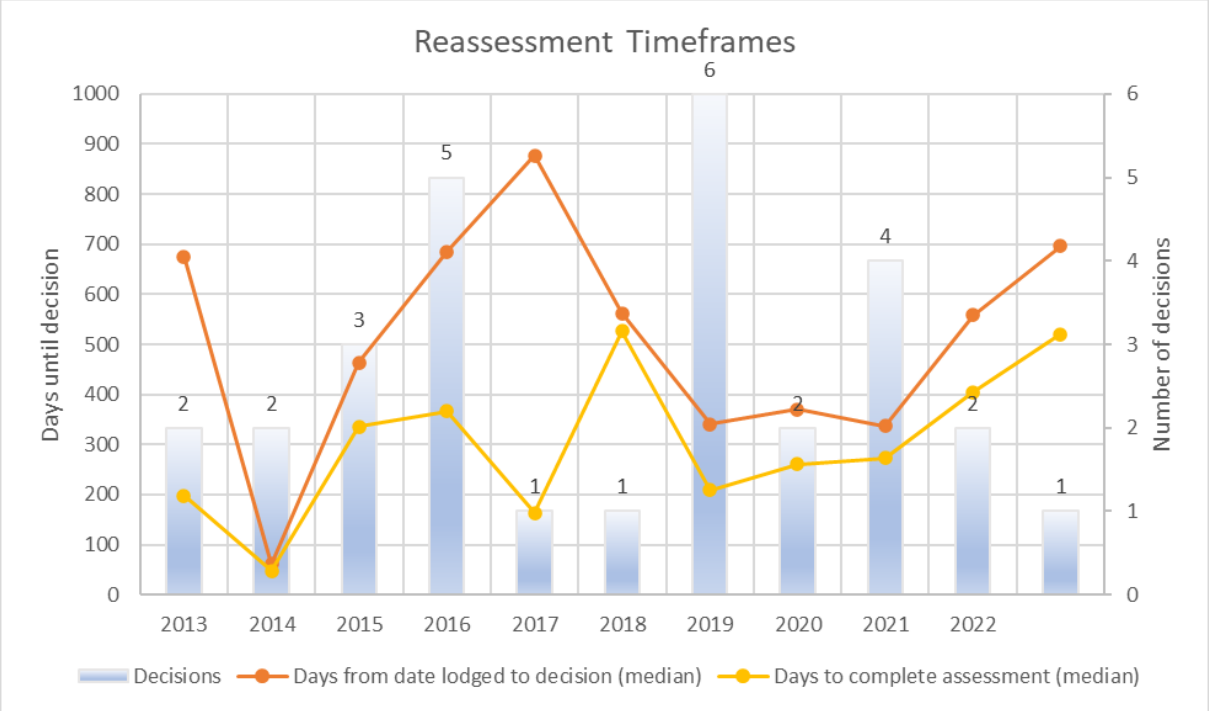



Category A Decision Timeframes
Days until decision
Number of decisions
700
600
500
400
300
200
100
0
60
50
40
30
20
10
0
45
57
37
35
30
21
35
22
20
4
8
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
Decisions
Days from date lodged to decision (median)
Days to complete assessment (median)


Category B Decision Timeframes
Days until decision
Number of decisions
1200
1000
800
600
400
200
0
14
12
10
8
6
4
2
0
1
1
10
12
6
7
8
5
3
0
2
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
Decisions
Days from date lodged to decision (median)
Days to complete assessment (median)


Category C Decision Timeframes
Days until decision
Number of decisions
1200
1000
800
600
400
200
0
10
8
6
4
2
0
8
1
5
9
5
3
3
7
1
6
1
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
Decisions
Days from date lodged to decision (median)
Days to complete assessment (median)


Reassessment Timeframes
Days until decision
Number of decisions
1000
900
800
700
600
500
400
300
200
100
0
6
5
4
3
2
1
0
2
2
3
5
1
1
6
2
4
2
1
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
Decisions
Days from date lodged to decision (median)
Days to complete assessment (median)

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