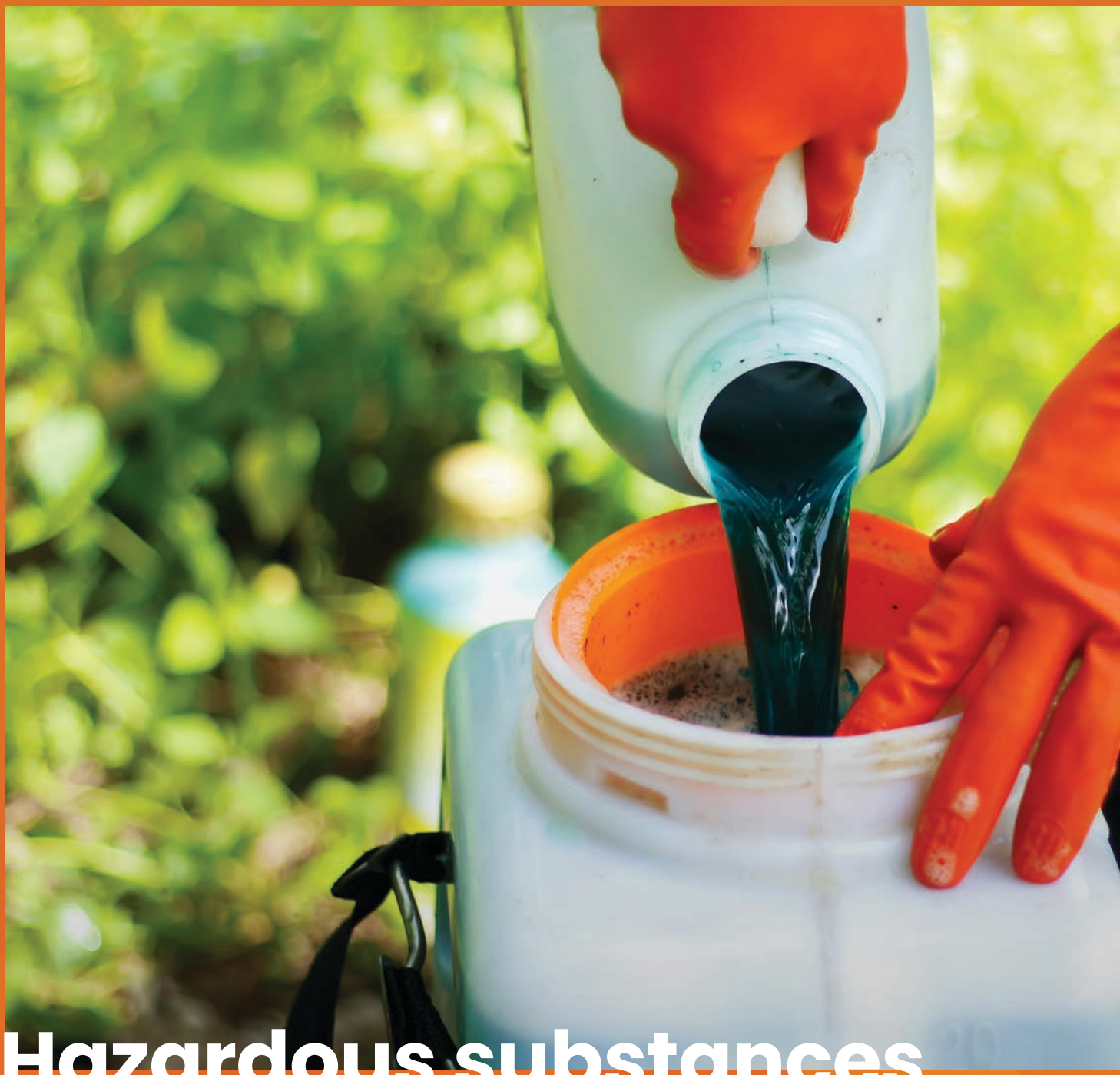

Hazardous substances assessments: Improving decision-making

A discussion document on proposed improvements to assessments and reassessments of hazardous substances

Ministry for the Environment
Manatū Mō Te Taiao

New Zealand Government

This document may be cited as: Ministry for the Environment. 2019. *Hazardous substances assessments: Improving decision-making – A discussion document on proposed improvements to assessments and reassessments of hazardous substances*. Wellington: Ministry for the Environment.

Published in August 2019 by the
Ministry for the Environment
Manatū Mō Te Taiao
PO Box 10362, Wellington 6143, New Zealand

ISBN: 788-1-98-857930-6
Publication number: ME 1426

This document is available on the Ministry for the Environment website: www.mfe.govt.nz.

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Message from the Minister

New Zealand is a small market for chemicals. Some better alternatives to existing chemicals are not approved for use in New Zealand by producers or users because of the process cost. This can result in poorer environmental outcomes.

This document proposes improvements to New Zealand's chemical management system so as to better protect people and the environment.

Our proposal is to adopt a 'trusted regulator' approach. This would enable better use of overseas information when assessing new hazardous substances, and reassessing existing substances that have already been approved for use in New Zealand.

We also consider other improvements to the reassessment process.

The ultimate goal of this project is to incentivise the introduction of beneficial and 'greener' chemicals, and the appropriate management of chemicals in New Zealand.

We seek the views of the agricultural community, the chemical industry, and the public to help us form the direction of these proposals.

We welcome your input.

Hon David Parker
Minister for the Environment

Executive summary

Chemicals are used in many places, from homes to workplaces, on fields, in factories, and even on our bodies. Given the potential risks to people and the environment from exposure to chemicals, the Government is responsible for managing their importation, manufacture, distribution and use.

Current issues with approvals for new substances and reassessments

The Environmental Protection Authority (EPA) approves new chemicals and sets controls over them, and also reassesses chemicals to ensure the existing controls are fit for purpose. Currently, these processes tend to be slow and resource-intensive. If approvals are delayed, beneficial chemicals, including safer alternatives to existing ones or chemicals for urgent use, take longer to get to market. Delayed reassessments can have safety and environmental implications when chemicals, whose controls are not fit for purpose, continue to be used.

Currently, the delays are most notable for reassessments. Like many other OECD countries, New Zealand has a low rate of reassessment. The process is slow, resource-intensive and does not encourage innovation in the industry. Since 2001, the EPA has only been able to complete 51 reassessments, and it has recently identified that a further 39 chemicals are in urgent need of review. With a large number of chemicals in daily use, more responsive reassessment would better address the potential risks to people and the environment.

Lack of incentives

A lengthy and complicated application process can delay the introduction of beneficial chemicals, causing frustration to applicants and discouraging innovation. Chemical approvals in New Zealand are mostly given in perpetuity, with no formal review period. The OECD has acknowledged this enables continued use of existing chemicals, rather than developing or importing safer or more effective alternatives. Consequently, there is little incentive for anyone other than the EPA to apply for a reassessment and incur the costs of the review. Reassessment decisions are difficult to make when there are no safer alternatives to existing chemicals.

Using international data

Increasingly, regulators are seeking to use international data and assessments from other regulators. Better use of consistent data and information creates efficiencies and builds a global approach to regulation. As New Zealand has a low profile in the chemical manufacturing industry, it makes sense not to reinvent the wheel when assessing the risk of harm from a chemical. If the United States, the European Union, Australia, Canada or another ‘trusted regulator’ have already put resources into assessing a chemical, should the New Zealand EPA not just adopt this? The issue is that despite the desire for a global approach there are, as yet, no jurisdictions that automatically apply the decisions of another regulator.

Another issue is: Which agency to trust? In New Zealand the EPA is the independent regulator responsible for both chemical risk assessment and decisions. By comparison, in Europe for example, the European Food Safety Authority prepares the risk assessment, and member countries make their own decisions based on that assessment. Would the trusted regulator be the independent risk assessor or the member country’s ‘political’ decision-maker?

Currently, the EPA can take international information into account in its assessments. However, the processes are not streamlined. There could be an opportunity to use the information more effectively to make quality decisions.

Purpose of this consultation

This discussion document proposes options to make assessments and reassessments of chemicals more efficient. The aim is to:

- make better use of international information
- make appropriate decisions to protect people and the environment, and derive benefits from chemicals
- manage existing substances with the most appropriate controls
- review the most harmful substances as efficiently as possible
- incentivise the substitution of high-risk substances for safer alternatives.

Options for improvements

This discussion document sets out the following options:

Making better use of information by:

- applying a trusted regulator's information during assessments and reassessments
- being more responsive to substances that pose the greatest risk
- applying a trusted regulator's decision to change a hazard classification.

Other improvements to reassessments:

- streamlining consultation by:
  - improving the quality of information
  - using targeted processes.
- avoiding duplication by:
  - streamlining the early stage of reassessment
  - removing replication where substances contain the same active ingredient
  - updating controls on existing substances, based on a recent EPA assessment.

What this document does not cover

This discussion document does not propose which options we prefer. Before we identify these, we are anticipating public feedback, which will inform a cost-benefit analysis. However, please see the accompanying Regulatory Impact Assessment for an analysis of each option, based on current information. This sets out the relative strengths of the options.

Changes to assessments of new hazardous substances are limited to applying a 'trusted regulator' approach. A broader review of the assessment process and changes to principles in the HSNO Act are outside the scope of this consultation. Workplace controls on hazardous substances will continue to be made and updated separately under the Health and Safety at Work Act 2015 (HSWA). WorkSafe New Zealand will be involved during HSNO processes, to ensure appropriate workplace controls are in place.

Section 1: Introduction

1.1 Purpose of this consultation

Chemicals are an important part of our modern lives. Chemicals are used in many places, from homes to workplaces, on fields, in factories, and even on our bodies. Given the potential risks to human health and the environment from exposure to chemicals, the Government is responsible for managing their importation, manufacture, distribution and use. The management also ensures that communities derive benefits from the use of chemicals.

Hazardous substances are chemicals or mixes of chemicals that can be explosive, flammable, oxidising, corrosive or toxic to people and the environment. New Zealand gives approvals to hazardous substances which contain one or more components (chemicals). However, for easy reading, the terms 'chemicals' and 'hazardous substances' are sometimes used interchangeably here except as otherwise explicitly indicated.

The Government is considering ways to make better use of international information for assessments and reassessments of hazardous substances and other improvements to the reassessment process under the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The purpose of this consultation is to ensure we:

- make better use of international information
- make appropriate decisions to protect people and the environment, and derive benefits from chemicals
- manage existing substances with the most appropriate controls
- review the most harmful substances as efficiently as possible
- incentivise the substitution of high-risk substances for safer alternatives.

The outcome of this consultation must serve the original purpose of the HSNO Act, which 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".

This document will take you through the problems that have been identified, and options for improvements.

For information on how to make a submission, see section 4.

We welcome your views on these proposals.

Submissions close on 30 September 2019 at 5pm.

1.2 Assessments and reassessments under the HSNO Act

In New Zealand, the Environmental Protection Authority (EPA) is responsible for managing more than 150,000 hazardous substances under the HSNO Act. The EPA works alongside WorkSafe New Zealand (WorkSafe), which administers and enforces rules for the use of hazardous substances in the workplace.

The HSNO Act

The HSNO Act came into force for hazardous substances on 2 July 2001. Under the HSNO Act, new hazardous substances that have not been legally present must be assessed and approved with appropriate controls before being introduced (imported or manufactured) into New Zealand.

Before 2001, most hazardous substances were notified, not assessed. Some were assessed and approved, with limited controls to manage their effects. From 2001 to 2006, substances legally present in New Zealand were transferred to the new regime and became subject to the controls of the HSNO Act.

Group Standards and individual approvals

To aid the transfer, Group Standards were introduced in 2005 to set controls for substances of similar nature, type or use. There are 208 Group Standards. This mechanism is not used for higher-risk substances (explosives, pesticides, wood preservatives, and chemicals toxic to vertebrates). These require individual approval for use, with specifically assigned risk management measures (controls). There are about 9350 individual approvals.

To obtain an approval, an application process is required.

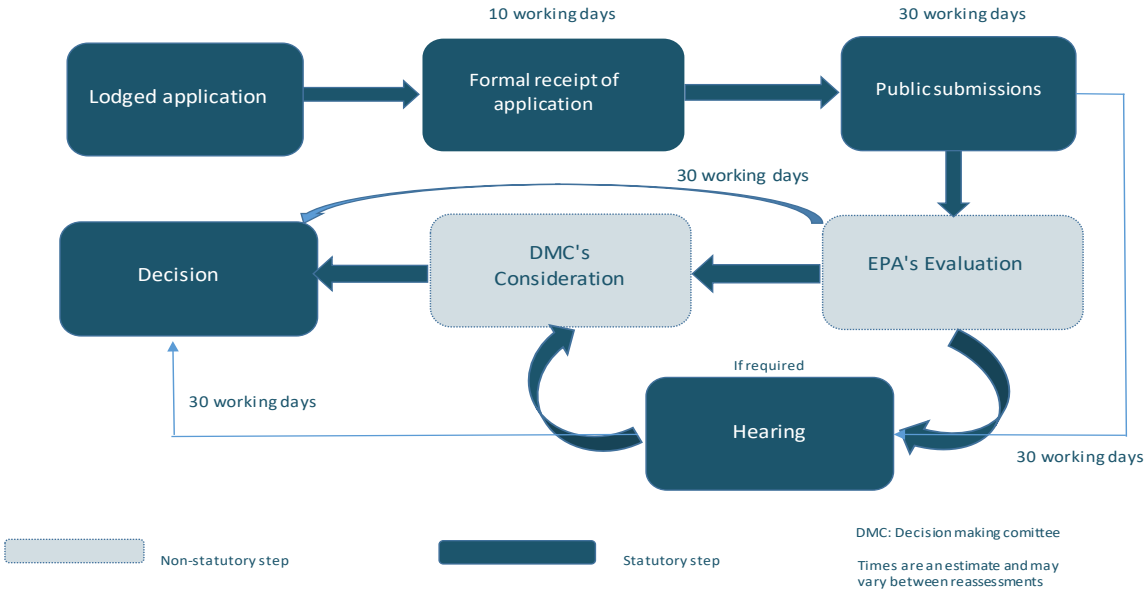
For higher-risk substances, the EPA's assessment of a new hazardous substance takes at least five months (for one that is publicly notified). The process includes a public consultation (30 working days), a hearing if requested within 30 working days after the close of submissions, and a decision-making process within 30 working days of the close of the hearing (see figure 1). The timing of the process largely depends on the quality of application's information. The EPA may request further information during the process.

When undertaking assessments, the HSNO Act requires the EPA to take into account:

- the need for caution in managing adverse effects where there is scientific and technical uncertainty
- the Treaty of Waitangi (Te Tiriti o Waitangi)
- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga
- the economic and related benefits and costs of using a particular substance
- New Zealand's international obligations.

WorkSafe can be involved in the process if the use of the substance requires workplace controls under the Health and Safety at Work Act 2015 (HSWA). WorkSafe may initiate a Safe Work Instrument process alongside the EPA assessment to add or vary workplace controls if needed. These controls need to be in place for the EPA to make a final decision on an application.

Figure 1: Application process



Note: WorkSafe will be involved during the process to ensure appropriate workplace controls are in place.

Reassessment

Chemicals already legally approved can be reassessed when new information or other circumstances indicate the need for a review of the controls or the approval itself.

Who can request a reassessment?

Anyone can approach the EPA to request a reassessment. The EPA's Chief Executive can also initiate reassessments.

Two-step process

A reassessment has two stages:

1. determining the grounds
2. applying for reassessment.

There may also be a non-statutory 'call for information' before the application is lodged.

Determining the grounds

Under section 62 of the HSNO Act, the EPA can decide that grounds exist, after taking into account the following mandatory considerations:

- significant new information about the effects of the substance
- a significant change in the use and quantity of the substance
- a better alternative for the substance
- changes to controls under the HSWA.

Applying for reassessment

A reassessment application is deemed to be an application and follows all steps of the above application process (see figure 2).

Types of reassessment

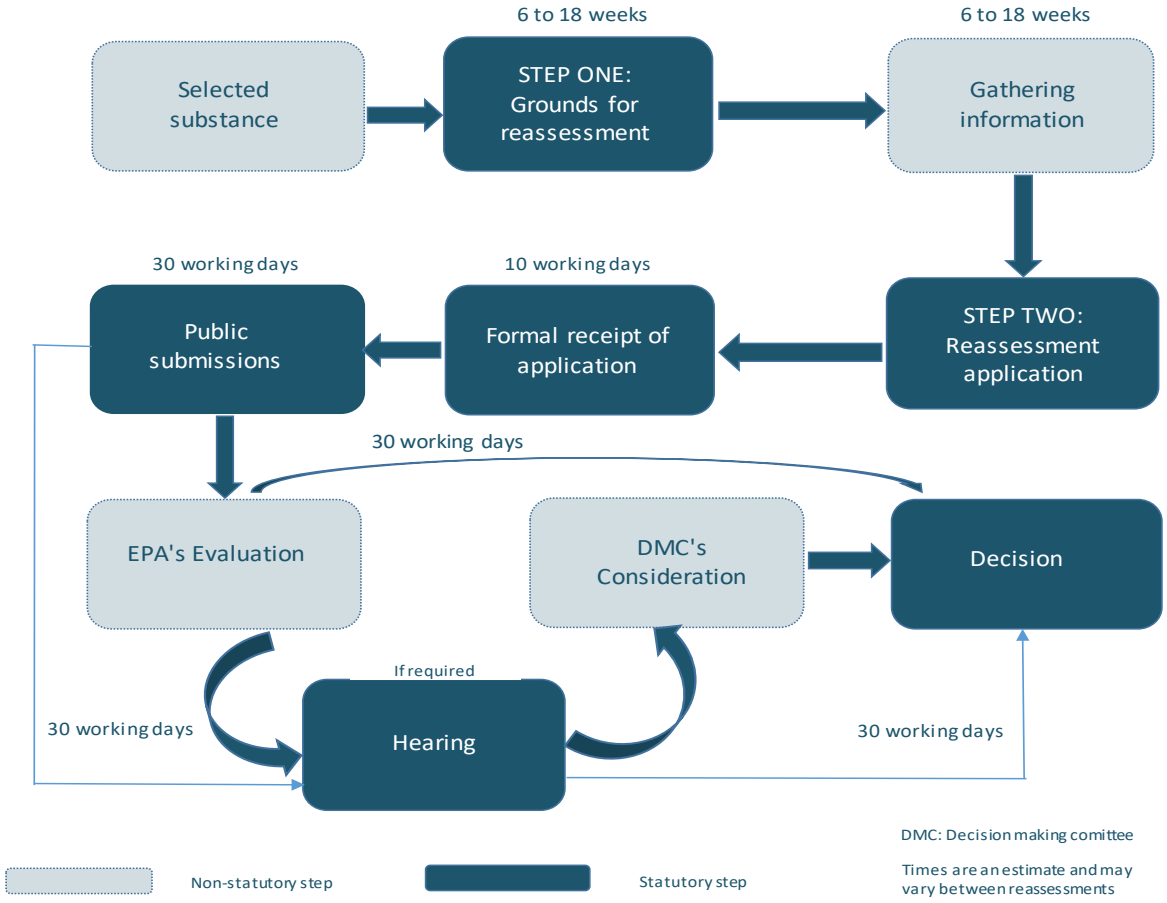
There are two types of reassessment:

1. Modified reassessments change part of an existing approval. For example, the application may be to review a specific hazard classification as the applicant has additional data which they consider supports changing the classification.
2. Full reassessments consider varying any part of an existing approval, including the approval being declined. These applications are typically complex, and may often cover multiple approvals.

Reassessment decision

Reassessment involves evaluating all the effects of an approved substance and the controls on it. This includes reviewing the risks, costs and benefits. A reassessment may result in revocation, restriction of certain uses, changes to controls, change of hazard classification, or no change at all.

Figure 2: Full reassessment process



Note: WorkSafe will be involved during the process as appropriate to ensure timely update to workplace controls.

Section 2: The need for change

2.1 Making better use of information

New Zealand has a low profile in chemical manufacture. We mostly import chemicals which have been approved and used in other countries. Much of the data on hazard characteristics and exposure of chemicals used by the Environmental Protection Authority (EPA) during assessments and reassessments has been produced and used overseas.

Currently, international information, including the assessments and decisions of other regulators, has the same priority as other types of information when the EPA performs assessments and reassessments. The Hazardous Substances and New Organisms Act 1996 (HSNO Act) requires the EPA to consider, review and verify all types of information. In many cases, this means the EPA must repeat technical work already done overseas, which may cause delays in processes. There is no discretion for the EPA to apply reliable information to save resources and time for both the regulator and industry.

Delays in assessing new substances means, in some cases, delays in introducing beneficial substances, including safer alternatives to existing ones, and delays in reassessments can pose risks to people and the environment.

Currently, average costs to the EPA for assessing new applications are $19,500, $54,000, and $111,000 for applications of category A, B, and C[1] respectively. Application fees contribute about 11 per cent of the total costs of HSNO applications (EPA, 2017).

It takes at least five months for the EPA to process a publicly notified application. Some applications can take more than two years. In 2017 and 2018, the EPA received 41 and 30 applications, respectively, for hazardous substances approvals (categories A-C) (excluding other hazardous substances applications).

The current reassessments are comprehensive, time-consuming, and resource-heavy, especially when they cover multiple chemicals and approvals. Average costs of establishing grounds for reassessment is $16,000 and of reassessment processes is $111,000 (EPA, 2017). Some reassessments can take up to two years and cost more than $1 million.

We are considering how the EPA could better use international information by adopting a trusted regulator approach during assessments of new hazardous substances and reassessments of existing ones. This is to save time and resources for both the regulator and industry. In addition, we are proposing making better use of information to suspend or temporarily restrict an approval, and to facilitate the timely change of hazard classifications.

2.1.1 Trusted regulators

Trusted regulators approach relates to a relationship between select trusted regulators, who recognise and share information to the benefit of one or more parties.

[1] The EPA categorises applications based on the level of complexity of the applications.

Information for use from international regulator

The information includes:

- scientific information, data or hazard assessments generated by industry or a regulator
- risk assessment reports by industry or a regulator
- decisions made by a regulator or a political decision-making authority.

New Zealand's assessments and reassessment are unique in that the EPA assesses both hazards and risks, and makes the final decision. For domestic processes, scientific information, data and hazard assessments are provided by applicants. Hazard assessments provided by applicants are sometimes not complete therefore the EPA, at times, obtains this information to ensure a robust assessment.

If a reassessment is initiated by the EPA's Chief Executive, the EPA prepares this information. In some cases, this information of existing substances can be easily accessed. In other cases, there are constraints on sharing because of confidentiality requirements. The trusted regulator's approach could help facilitate the sharing to some extent.

Risk assessments can be provided by applicants. The EPA must evaluate these. A trusted regulator could provide risk assessments if there is an established relationship between the EPA and the regulator. These could be used to complement or evaluate the assessments provided by applicants.

Chemical management decisions are often freely available, but they can be influenced by risk appetites, political or commercial biases, and local context.

Choosing a trusted regulator

The criteria might include:

- reliability, for example agencies that:
  - follow a quality, transparent and robust chemical assessment process
  - have assessment reports accessible to the EPA
- the quality and relevance of information.

Using information from a trusted regulator

Using a trusted regulator's information should follow the purpose and principles of the HSNO Act and be guided by other principles, such as:

- promoting the sharing and use of scientific information, data and assessment reports
- being cautious when adopting decisions, to align different risk appetites, eliminate any biases or influences from a local context, and ensure the situations are comparable
- incentivising the replacement of harmful substances with safer alternatives.

Other considerations include:

- not every jurisdiction may allow another jurisdiction to use information, due to confidentiality and protection of intellectual property rights or caveats on the use of data
- shared information may still include withheld information, requiring the EPA to fill in the gaps or decide to trust information that was not provided

- risk of unknown political influence
- differences in chemical management systems (eg, other countries manage chemicals while New Zealand manages substances (formulations of chemicals)).

International cooperation in chemical management

Internationally, regulators are seeking to use data and assessments from others to increase efficiency. The sharing of information can be supported by memoranda of understanding (MOUs) or similar agreements. Some examples are given below.

Australia

Three arrangements enable Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to consider overseas assessments when receiving an application:

- Approved Foreign Scheme (Canada)
- modular notification (comparable agency) – Canada/ United States/ European Union
- OECD parallel process.

NICNAS and Health Canada have an Approved Foreign Scheme, which allows NICNAS Australia to use a Canadian hazard assessment, as long as it assesses Australian risk (Richarchs, 2019). This scheme only applies to chemicals in a comparable category.

Under the Approved Foreign Scheme and the modular notification arrangements, an applicant will request the comparable agency to release information or assessment reports for NICNAS.

The OECD parallel process facilitates multilateral arrangements for notifying and assessing new industrial chemicals. This allows the sharing of hazard assessments based on agreements between an applicant and participating jurisdictions on a volunteer basis (OECD, 2012).

Canada and the European Union

Canada and the European Chemicals Agency (ECHA) signed an MOU focusing on technical cooperation (the ECHA and Environment Canada/Health Canada, 2010).

The MOU enables:

- scientific collaboration and information exchange on hazard and risk assessment of chemicals
- exchange of operational experience
- communication of non-confidential information
- other information exchange.

New Zealand's experience of using trusted international information

Other government agencies are making good use of international information, with special pathways for evaluation and registration. Examples include:

- MedSafe's shorter process using evaluation reports by recognised regulatory authorities
- Agricultural Compounds and Veterinary Medicines registration, referring to Australian Pesticides and Veterinary Medicines Authority registration.

2.1.2 Suspending an approval to protect people and the environment

Sometimes international or domestic information would signal a need for immediate response, such as when an international regulator bans or revokes the approval of a chemical because of new information about the high risk to human health. Currently section 64 of the HSNO Act does not make it easy for the EPA to immediately react in these situations. We are looking at options to suspend or temporarily restrict an approval when needed.

2.1.3 Using a trusted regulator's decision to change a classification

Under the HSNO Act, if an overseas regulator changes a hazard classification, the only way New Zealand can also make the change is through a 'modified reassessment' (see section 3.2.2) – which largely repeats the international work. Because such a change might not be on the EPA's priority list for reassessments, inappropriate classification and controls could remain in place for a long time. We are considering how to allow more timely changes to classifications.

2.2 Other improvements to reassessments

Hazardous substances approvals do not expire. Many existing substances were transferred from the previous regime, with outdated controls for safe use. In light of new information, they are in need of review.

In 2018, the EPA developed the Flexible Reassessment Categorisation Screening Tool (FRCaST) to identify 39 high-priority chemicals for review.[2] The tool was internationally peer-reviewed[3] and the prioritisation process is on-going.

Since 2001, the EPA has only been able to complete 31 Chief Executive-initiated reassessments and 20 external reassessments. This means that risks to human health and the environment may not be managed appropriately.

Slow assessment and reassessment is a common issue in many OECD countries.

The EPA recently looked at ways to improve the process. One initiative was reassessment of a wider group of related substances (historically, EPA reassessments focused on individual substances).

In addition to adopting the trusted regulator approach, there are other opportunities to improve reassessments (described below).

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2 https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/priority-chemicals-list/.

3 FRCaST was peer-reviewed by Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS), and by Environment Canada. See more information about FRCaST: https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/screened-chemicals-list/.

2.2.1 Streamlining consultation

Collecting quality information

There are currently no incentives for the chemical industry to provide quality information for reassessments. The EPA generally uses a 'call for information', which is a non-statutory process, to collect information. This means it cannot use the HSNO Act to require further information from interested parties at the right time. As a result, it often takes a long time or even becomes impossible to collect quality information. We are looking at ways to encourage the industry and others to provide better data.

Improving targeted consultations

The current modified reassessment process allows the EPA to reassess a specific aspect of an approval (excluding minor or technical amendments). This process is not used to revoke a substance's approval. The targeted consultation process for a modified reassessment is intensive and requires almost full public notification, making it as time consuming and resource intensive as a full reassessment. We are considering changes to that requirement.

2.2.2 Avoiding duplication of work

Avoiding duplication for substances on the Priority Chemicals List

Although the EPA uses a screening tool FRCaST to identify chemicals it considers most in need of review, the HSNO Act still requires formal grounds for reassessments of these chemicals, that is, determining there is enough information to trigger a reassessment. We are looking at ways to avoid duplication of work in the early stage of reviewing priority substances.

Removing duplication for substances with the same active ingredient

There is currently duplication of work when concurrently assessing and reassessing substances with the same active ingredient. At present the two processes must run in parallel. We are looking at more efficient options.

Updating controls on related substances

Assessing a new substance may suggest the controls on existing relevant substances with the same active ingredient are out of date or not fit for purpose. This applies to many substances that were approved several decades ago, with controls that are no longer fit for purpose. We are looking at options to quickly update these controls.

Section 3: Options for improvements

3.1 Making better use of information

3.1.1 Making better use of international information

The problem

The Hazardous Substances and New Organisms Act 1996 (HSNO Act) allows the Environmental Protection Authority (EPA) to obtain any relevant information on a substance from any source when undertaking assessments and reassessments.

Section 28 of the HSNO Act requires applicants to provide information on whether the substance has been considered by other agencies and the results of such consideration. The Hazardous Substances and New Organisms (Methodology) Order 1998 further requires the EPA to review and verify or engage experts to review and verify this information.

The Methodology Order 1998 explains that the EPA can take into account information produced for or by other agencies in New Zealand and overseas, but must assess:

- its quality and reliability
- the status of the relevant agency
- the rigour and completeness of the decision-making if the information is in the form of an approval
- relevance to New Zealand and the requirements of the HSNO Act.

These requirements mean the EPA cannot treat information from overseas regulators as being any more reliable than other sources of evidence. The HSNO Act also requires the EPA to further assess all evidence (no matter what the source) to make a decision.

There are opportunities for the EPA to better use international information to:

- conduct assessments and reassessments more efficiently
- better manage hazardous substances to protect people and the environment and derive benefits from the substances
- save time and resources for both the regulator and industry
- contribute to international alignment in chemical management.

Options

Option 1: Status quo

Currently the EPA must consider all types of information equally, without placing greater weight on any source. The EPA currently has no discretion in applying any source of information, which means it has to duplicate work done elsewhere.

This may delay the introduction of new substances which are highly beneficial to New Zealand, including safer alternatives to existing substances.

Slow reassessments mean potentially high-risk substances, with inappropriate controls, can stay in use for longer than desired. The existing process takes considerable time and resources.

Also, the time taken to assess and reassess substances could mean there is little incentive to replace existing substances with safer alternatives.

Option 2: Apply trusted regulator's information

Option 2A: Apply in part

Consider and apply available information (data, scientific information, assessments) from trusted regulators, along with the EPA's own research or applicant's information.

It would require changes to the HSNO Act to allow the EPA to substitute parts of the EPA assessments with information from a trusted regulator.

For assessments of new substances, applicants are responsible for providing this information. The EPA can use a trusted regulator's information to complement or evaluate the information provided by applicants. Applicants could also request a trusted regulator to provide this information to the EPA to support the application, provided there is an established relationship between the EPA and that regulator, which enables the regulator to release the information upon a request from applicants.

For reassessments, using trusted regulator's information could save the time and resources for the EPA and applicants in preparing parts of applications and for the EPA in reviewing and verifying the information. Data on existing substances is often more freely available than that of new substances.

Option 2B: Apply full risk assessments with New Zealand lens

Changes to the HSNO Act would allow the EPA to apply risk assessments from trusted regulators. It would then consider the relevance to New Zealand, and the requirements of the HSNO Act, to make a final decision.

This option would not require the EPA to obtain all data underpinning the assessments. This would help mitigate the effects of confidentiality requirements in other jurisdictions.

This option would save time and resources for both the EPA and industry in obtaining and assessing data. As in Option 2A, applicants may request trusted regulators' to provide risk assessments to the EPA to support the application.

Option 2C: Apply full assessments or decisions with New Zealand lens

Changes to the HSNO Act would allow the EPA to trust both assessments and decisions from trusted regulators. It would then consider the relevance to New Zealand, and the requirements of the HSNO Act, to make a final decision.

Trusted regulator's decisions can be influenced by risk appetites, political or commercial biases, and local context. Based on the same risk assessments different regulators may make different decisions because of differences in use pattern, applicable risks, and the formulation of substances.

As for Option 2B, this option would not require the EPA to obtain all data underpinning the assessments and decisions.

These options would require additional regulations or guidelines to specify trusted regulators, which information can be trusted, and other matters. It is worth noting that these options would provide the EPA discretion to better use international information. The EPA would retain the power to undertake full assessments or reassessments when needed to protect people and the environment.

These proposals strike a balance between protecting New Zealanders' health and the environment, and making assessments and reassessments more efficient. They also align with international and domestic best practice (see section 2.1.1 and box 1).

Workplace controls will continue to be set and updated under the Health and Safety at Work Act 2015 (HSWA). WorkSafe New Zealand would be involved in the processes to ensure appropriate workplace controls are in place.

These options would require the EPA to consider the New Zealand context to make final decisions for applications and reassessments. This is because:

- The HSNO Act requires the EPA to take a precautionary approach and take into account the Treaty of Waitangi (Te Tiriti o Waitangi). The Treaty provides an obligation on the New Zealand Government to recognise and provide for the customary interests and rights of Māori. In making decisions, the EPA must take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga.
- The EPA also needs to consider our specific environmental and economic context. New Zealand has a unique ecology with a range of endemic plants, animals, and fungi having developed due to our specific geographic characteristics. An overseas decision cannot consider the intrinsic value of our ecosystems. New Zealand also has special economic benefits to be protected, which can affect the consideration of costs and benefits of using a particular substance.
- The EPA also needs to consider technical issues when applying trusted regulators' decisions. As the EPA regulates substances while overseas authorities regulate chemicals, it is sometimes necessary for the EPA to consider the applicability of a trusted regulator decision on a chemical for the application of a related substances. Differences in use patterns also require the EPA's final check. For example, a substance is approved to be used with ground-based spray methods by an overseas regulator. An application is made to the EPA to import and use the same substance but including both aerial and broadcast methods, higher application rate, more application frequency, and shorter minimum interval between each application. Any of these changes can increase the total level of risk to New Zealanders and the environment, and thus requires the EPA's consideration.

Internationally, no jurisdiction yet allows an automatic adoption of others' decisions without considering their local context (see section 2.1.1 and box 1). Both MedSafe and the Ministry for Primary Industries require the provision of a comprehensive package of data from overseas agencies for consideration during their shorter processes. They also undertake technical appraisal and risk assessment based on the international information provided (MedSafe, 2016, Ministry of Agriculture and Forestry, 2011). Similarly, the EPA should be able to retain the power to make a final decision, and be accountable for its role as an independent regulator of hazardous substances in New Zealand.

Box 1: International approaches to banning chemicals

European Union (EU)

- EU Plant Protection Directive (The European Parliament and of the Council, 2009):

Article 44 and 46 of the directive provide for the removal of authorisation from plant protection chemicals (agrichemicals that are not fertilisers or vet medicine).

Article 44 allows for the authorisation holder to provide information/comment before a decision. The period is not specified. Once made it can take effect immediately or after a grace period (Article 46).

If a member state withdraws or amends an authorisation, other members in the same zone shall withdraw or amend the authorisation accordingly, taking into account national conditions and risk mitigation measures (Article 44) (The European Parliament and Council, 2009).

- European Chemicals Agency (ECHA)'s Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (European Chemicals Agency, 2007)

A process is in place to restrict a substance that poses unacceptable risk to human health and the environment. This can take about 15 months. It includes notifying the public of the intention to restrict, as a public warning; preparing a dossier; a six-month public consultation; a risk assessment; a socio-economic assessment; an enforcement consideration; and decision-making.

Canada

Canada's legislation (Canadian Environmental Protection Act, 1999) provides for short-term bans on chemicals. This is a ministerial power to deal with a significant danger to the environment or human health based on information from other OECD jurisdictions (Section 75 and 94). The minister must consult with all affected governments and other ministers, and apply for an approval by Governor in Council. The suspension order must be published in the Canada Gazette and any contravention due to being not notified is not convicted. The minister's interim order has effect for less than two years.

Australia

Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) established the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework to speed the assessment of risks to human health and the environment from existing chemicals.

According to the IMAP review in 2016, data from international sources has been fundamental to the assessments process. However, the review also recognised that it takes substantial effort to extract and evaluate the relevance of the information for the Australian context (NICNAS, 2016).

Under the NICNAS legislation there is no scope for immediate bans. The quickest process in the NICNAS bill is for at least 20 days' notice before a ban takes effect, after a re-evaluation or a decision that the original measure was based on incorrect information.

The United States

The Toxic Substances Control Act (United States Environmental Protection Authority, 2019) regulates chemicals in the United States. This includes the process for reassessment. Reassessments of the First Ten Priority List follow a three-step process with extensive public consultation.

World Trade Organisation (WTO) obligations

Article 2 of the WTO Agreement on the Technical Barriers to Trade requires 60 days' notice of proposed technical regulations decisions, so that offshore traders and countries can make submissions. HSNO Group Standards and Part 5 HSNO approvals fall within the scope of technical regulations.

An exception is where “urgent problems of safety, health, environmental protection or national security arise or threaten to arise” (Article 2.10).

Newer trading agreements add more requirements than the WTO agreement.

We seek your views on the extent to which the HSNO Act should regulate use of international information:

1. Do you agree that the EPA should make better use of international information during assessments and reassessments of hazardous substances? If so, how?
2. Do you agree with the criteria for defining who is a trusted regulator (see section 2.1.1 of the discussion document)? What other criteria should we consider?
3. Do you agree with the proposed principles and considerations of using information from trusted regulators (see section 2.1.1 of the discussion document)? What other principles should we consider?
4. Which jurisdictions/agencies do you think we should regard as trusted regulators? Why?
5. What information should we regard as trusted?
6. Which options do you support for using information from trusted regulators for assessments of new hazardous substances? Why?
7. Which options do you support for using information from trusted regulators for reassessments of existing hazardous substances? Why?
8. Should the requirements for applying trusted regulators' information for the initial assessment to introduce a chemical to the New Zealand market be any different to a reassessment (see section 1.2 and 2.1 of the discussion document)?
9. Do you suggest another option? If so, please explain.
10. When applying information from a trusted regulator, should the New Zealand context always be considered? (This is currently a requirement in the HSNO Act).
11. Are there any other issues with using information from international regulators that the discussion document has not covered?

3.1.2 Immediate suspension based on trusted information

The problem

Section 64 of the HSNO Act allows the EPA to suspend approvals during the reassessment of a substance, if there is significant actual or imminent danger to human health or safety or the environment from its continued use. However, there are four issues:

1. The criterion of “significant actual or imminent danger to human health or safety or the environment” sets a high threshold that the EPA has never been able to use to suspend a substance. This definition requires the EPA to prove an active risk or one that is very likely in the near future, or that it is serious or notable, yet the negative effects of hazardous substances can take time to appear.
2. The focus on human health and the environment is quite broad and can be difficult for testing and proving the danger of a substance.
3. The suspension power only applies after public notification of an application for reassessment, which is generally within 10 working days of receipt. The actual waiting

time can be much longer. It takes time to establish the grounds for reassessment, call for information, and prepare the application.

4. Section 64 only allows a complete suspension of an approval, yet sometimes there is a need for temporary restrictions on a substance.

There are situations where overseas regulators ban, revoke an approval, restrict the uses, or significantly tighten controls on a chemical, indicating there might be an increased risk from the chemical and relevant substances. Currently the HSNO Act does not allow the EPA to respond to this information in a timely way. This might cause risks to people and the environment (see box 2 for an example).

Box 2: Reassessment of organophosphate and carbamate insecticides

Organophosphate and carbamate insecticides (OPCs) have been widely used in New Zealand and internationally for many decades. They control a broad range of insect pests for a variety of purposes (plant protection, veterinary medicine, public health, and industrial uses).

Concerns about the use of some OPCs were identified by international regulators between 2000 and 2010. For example:

- Chlorpyrifos: Canada restricted this in 2003, followed by the US Environmental Protection Authority in 2006
- Diazinon: Canada restricted it in 2009
- Benomyl: last legal use in Canada was in 2003; in Australia it became illegal to supply or use in 2006
- Dichlorvos: Canada restricted it in 2008 and Australia in 2011 (EPA, 2012).

However, in New Zealand reassessment of OPCs only began in 2012, with a decision in 2013 (the real-time preparation was seven years). Between 2003 and 2012, there was no suspension or restriction of the most harmful OPCs.

The EPA's reassessment shows that some OPCs are very harmful. It revoked a number of approvals, including benamyl and diazinon (with a 15-year phase-out). It also added stricter controls on others, including chlorpyrifos and dichlorvos (EPA, 2013).

At times, domestic information, such as an assessment of a related substance, could also indicate the risks of continued use of a substance.

Options

Option 1: Status quo

Currently, there could be a risk to people and the environment because the EPA cannot be responsive to the greatest risks.

Option 2: Temporary action and reassessment

This would require changes to the HSNO Act to address the issues with Section 64 to allow the EPA to suspend or temporarily restrict an approval to protect people or the environment. The EPA would have discretion and be accountable for this decision, including the rationale and scope.

This option would require the EPA to reassess a suspended or restricted substance within a set period, for example within six months of the temporary measure.

This option might reduce the time and resources for collecting information. The assumption is that the industry would be more motivated to give information to maintain the existing approval after the EPA has taken this action. The measure might also foster innovation to introduce lower-risk substances.

There might be an impact on commercial sales of a substance, as the action sends a warning to end-users. There could also be negative effects on the industry if the reassessment shows that revoking the approval is unnecessary. However, the benefits to people and the environment could outweigh the cost. There could also be incentives for the industry and the public to provide information to speed up decisions.

We seek your views:

12. Do you think the current threshold for suspension is appropriate (that is, significant actual or imminent danger to human health or safety or the environment from the continued use of the substance – see section 3.1.2 – 'The problem')? Why/why not?
13. Does the current suspension apply at the right time in the process (that is, after a reassessment decision has been publicly notified – see section 3.1.2 – 'The problem')? Why/Why not?
14. Do you agree in addition to a suspension, a temporary restriction is also needed?
15. Which option do you support? Why?
16. If you choose Option 2, do you have any suggestions on change to the criteria or threshold for the EPA to suspend or temporarily restrict an approval?
17. If you choose Option 2, what are the potential impacts of a temporary restriction or suspension?
18. If you choose Option 2, what can be done to reduce the negative impacts of a temporary suspension or restriction on the industry and end-users?
19. Do you suggest another option? If so, please explain.

3.1.3 Using a trusted regulator's decision to change a hazard classification

The problem

Currently, the HSNO Act only allows a change of hazard classification following a modified reassessment. In this process, the EPA must follow all the steps of a full reassessment (with modification, for example a targeted consultation instead of a full public notification), including establishing grounds for reassessment (see box 3).

Changing a hazard classification is a technical decision the EPA can adopt. By comparison, a modified reassessment is, in many cases, regarded as unnecessary because a risk assessment is not required. This is because hazard classifications set out the intrinsic properties and the degree of hazard of a chemical or substance. They are based on data and scientific information. Changing a classification is unlikely to be affected by political or commercial interests. Nor are New Zealand specific matters of relevance at this point in the process.

The EPA is planning to update the HSNO classification system to align with the Globally Harmonized System of Classification and Labelling (GHS). This is an internationally agreed system for classifying chemicals based on their physical, health and environmental hazards. A

full adoption of GHS would allow using a trusted regulator's decision to change a classification, without the need to verify the equivalent HSNO classification.

A classification change leads to a change of the default controls on a related substance. Local context, such as use scenarios, could be used to substitute, add, combine, or delete controls (section 77(3) to 77(5)).

Box 3: Time taken to change a hazard classification

- 4,4'-Methylenediphenyl diisocyanate (MDI) – adding a 6.7B carcinogenicity classification

This new classification was based on the harmonised classification listed by the European Chemicals Agency (ECHA) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Registration dossier for MDI.

2005: The classification appears to have been adopted in Europe after a 2005 EU review.

April 2014: An EPA toxicologist noted the 2005 EU classification change.

- Copper (II) carbonate hydroxide – revising the 6.1C (oral, dermal and inhalation) classifications to 6.1D (oral and inhalation) ['No' for acute toxicity – dermal]

2011: The classifications were changed in EU based on information in the 2011 EU Biocides report.

An external applicant raised the issue with the EPA in September/October 2011.

2013: The applicant raised it formally in May 2013 and an EPA toxicologist reviewed the classifications.

2012–2014: The changes of MDI's and Copper (II) carbonate hydroxide's classifications were considered in New Zealand during the EPA's Chemical Review programme 2012–2014. They still had to go through a full reassessment process: grounds and reassessment application (including public notification and submissions). The size of the reviews and inclusion of multiple chemicals (with knock-on effects on multiple formulated substances) add to the time taken.

2015–2016: The key dates for this reassessment were:

- January 2015: Grounds application – formal receipt
- February 2015: Decision date for grounds application
- June 2015: Formal receipt of application
- June 2016: Decision date for reassessment application.

In summary, the classifications of MDI and copper (II) carbonate hydroxide were amended by the EU in 2005 and 2011, but could only be changed in New Zealand in 2016.

Options

Option 1: Status quo

The current situation does not allow the EPA to use international information efficiently, to save costs and time.

This option keeps out-of-date classifications and controls in place for a long time, especially when external parties and the EPA's Chief Executive cannot start a reassessment because of priorities in reassessments. This has a negative impact on the industry and the public.

It could also cause inconsistent management of hazardous substances, when new substances are approved using the new classification but old approvals cannot be readily updated.

Option 2: Adopting a trusted regulator's decision following an internal process

This measure assumes the EPA has a relationship with one or more trusted regulators overseas.

The EPA could adopt a trusted regulator's decision to change the hazard classification of a chemical or substance. It may need to verify the equivalence of the new classification to the HSNO system, depending on whether the GHS update is complete.

The change would lead to the change of default controls on related substances, to align with the new classification. This change would be recorded on a reissued approval by the EPA.

Some cases would require consideration of information, to substitute, add, combine, or delete controls. The EPA would only include the public if further information was needed. These controls would also be included on the reissued approval.

This internal process would be similar to reissuing approvals, covered in Schedule 7 of the HSNO Act. The new controls would take effect after the EPA publicly notified the re-issued approvals, with updates on the EPA websites, potentially with a transitional timeframe to comply with changes to controls.

If the change of classification leads to a need for changes to workplace controls, these will follow the HSWA.

This option would:

- allow more timely decisions to change a classification, based on trusted information
- save time and costs as the EPA would not require a modified reassessment.

Option 3: Adopting a trusted regulator's decision following an controls updating process

This is similar to Option 2 for the classification and default controls, but the EPA would set up a process of updating controls to substitute, add, combine, or delete controls. This process would be similar to the modified reassessment under section 63C, where the 'grounds' step is omitted and a targeted consultation replaces public notification. The EPA would have the discretion to include the targeted consultation.

This option would:

- allow more timely decisions to change a classification based on trusted information
- save time and costs as the EPA would not need to determine the grounds for a modified reassessment, and would have more discretion on consultation.

As with Option 2, if the change of classification leads to a need for changes to workplace controls, these will follow the HSWA.

We are seeking your views:

20. Do you agree with the description of this issue (that is, it is not necessary for the EPA to always follow a modified reassessment process to change a hazard classification based on trusted information – see section 3.1.3 – 'The problem')? Why/why not?

21. Should the EPA be able to adopt a trusted regulator's decision to change a hazard classification? Why/why not?
22. Which option to change a classification based on trusted information do you support? Why?
23. (If you choose Option 2 or 3) The EPA is planning to update the HSNO classification system to align with the Globally Harmonized System of Classification and Labelling (GHS). While this update is taking place, the EPA needs to verify the GHS classification with an HSNO classification. Should the EPA be able to adopt a trusted regulator's classification change before the update is complete? Why/why not?
24. Do you suggest another option to change a classification based on trusted information? If so, please explain.

3.2 Streamlining consultations during reassessments

3.2.1 Better consultation process to collect quality information

The problem

The HSNO Act places the burden of proof for reassessments on applicants. In practice, the EPA has taken considerable responsibility both in preparing Chief Executive-initiated reassessments and in helping applicants prepare applications.

Chief Executive-initiated reassessments

Most reassessments have been initiated by the EPA's Chief Executive, to set stricter controls or remove approval of substances of concern.

When the Chief Executive initiates a reassessment, the EPA prepares an application by calling for information. As this is not a statutory step for reassessments, responding is voluntary. The EPA cannot use the HSNO Act to request further information before formally receiving an application.

The EPA faces difficulties in collecting information, especially about the use of substances, when this is voluntary.

Reassessments initiated by an external applicant

In some cases, external applicants apply for reassessments (for less restrictive controls or extending the uses of a substance) but do not give enough information. For a robust review, the EPA has, at times, taken on the burden of proof and cost.

In both the above cases, less engagement from the chemical industry and users extends the time for collecting information and increases costs for the regulator. For substances of most concern, this may cause risks to people and the environment, because of the time taken.

Why would the EPA not receive quality information?

By using both the non-statutory call for information and the public notification, the EPA still, in many cases, cannot receive quality information at the right time and from the right people. This is partly because of the industry's low interest in maintaining some approvals.

Experiences of other countries and agencies

Internationally, some jurisdictions have shifted to a new regime where the industry is responsible for generating and assessing data, and assessing risks of a chemical. This has helped to streamline the reassessment process (OECD, 2015).

The OECD's 2015 report indicates that putting more responsibility on the industry makes the assessment process more efficient.

Options

Option 1: Status quo

The HSNO Act does not encourage the industry to get involved in reassessment. The resulting lack of information lengthens the process. This could cause risks to people and the environment because of inappropriate management of substances.

As higher-risk substances are still available, the *status quo* does not motivate the industry to introduce safer alternatives.

The time-consuming call for information also affects the transparency of reassessment. People might question why a reassessment cannot be undertaken if grounds have been established.

End-users are the most disadvantaged as they might be using substances with inappropriate controls, or using chemicals with greater health and environmental risks than viable alternatives.

Option 2: Making the call for information statutory, and then revoke an approval because of the lack of information

This option would require changes to the HSNO Act to make reassessment a three-step process. The call for information would come before officially receiving an application, and would be a statutory process. The EPA could use existing mechanisms in the HSNO Act to collect information on use scenarios of substances.

This option might motivate applicants and others to engage and provide quality information. Even though the changes would create one more step, they would reduce the time for the call for information.

Chief Executive-initiated: If the call for information still cannot collect enough information, the EPA would be able to revoke relevant approvals. This would assume the substances were not in use, and the industry had no interest in maintaining the approvals. The EPA would not need to take further steps for reassessment.

External-applied: If there is still a lack of information, the application would lapse (similar to the consequence of failure to provide further information under Section 52 of the HSNO Act).

This option would save time and resources for the EPA in collecting information and making a decision. Reassessing existing substances would be quicker. However, the EPA could revoke an approval without taking the reassessment step, so there would be no notification for the public to have a say.

This would affect the chemical industry and users because it would require them to provide information, and could take some substances off the shelves very quickly.

This option would only allow the EPA to use existing mechanisms under the HSNO Act to request information, if the call for information becomes statutory. No direct consequences will be imposed on those withholding information. The indirect impact would be that an approval could be revoked due to the lack of information for a reassessment.

We have considered more protection of data to encourage people to provide information. However, we considered the current HSNO data protection mechanism is appropriate to manage hazardous substances in New Zealand.

Option 3: Making the call for information statutory, then reassessing to revoke an approval

This option is similar to Option 2, but does not allow the EPA to revoke an approval until after a reassessment.

If the call for information was statutory, there would be more incentive to give quality information. If this still does not yield enough information, the EPA could consider to suspend the approval. It would then make a reassessment to consider the:

- lack of information on the benefits of a substance
- available information from trusted sources on the negative effects of the substance.

This would inform a final decision on whether to revoke or restrict the approval.

As for Option 2, this option would only allow the EPA to use existing mechanisms under the HSNO Act to request information. No direct consequences will be imposed on those withholding information. The indirect impact would be that an approval could be revoked due to the lack of information on the benefits of a substance.

We seek your views:

25. Do you agree with the description of this issue (that is, the current voluntary mechanism cannot help the EPA collect quality information for reassessments – see section 3.2.1 – 'The problem'?) If not, why not?
26. What would motivate people to give more comprehensive information for a reassessment?
27. Which option do you support? Why?
28. Do you suggest another option to collect quality information? If so, please explain.
29. Should the EPA have the discretion to decide what a 'lack of information' means or this needs to be prescribed in the HSNO Act/regulations? Why/why not?
30. Do you find there are barriers when applying for a reassessment? If so, what are they?

3.2.2 Amending modified reassessments for a more targeted consultation

The problem

Section 63A of the HSNO Act provides for a modified reassessment, in which the EPA reviews only a specific aspect of an approval, excluding minor or technical amendments. This can result in a change in hazard classification or description of a substance, or a change in the controls.

A modified reassessment cannot revoke an approval.

The current process consists of all steps of a full reassessment with a modified consultation. The Act requires the EPA to:

- do everything reasonably practicable on its part to consult with all persons who, in its opinion, may be affected by the reassessment
- give those persons a reasonable opportunity to make submissions and comments to the Authority on the reassessment
- consider all submissions and comments received.

In practice, this modified version does not differ from a full public consultation. There is also a risk of missing some consultation, as the EPA does not have all contacts of affected people, especially end-users. This requirement makes a modified reassessment as time consuming and resource heavy as a full one.

Options

Option 1: Status quo

This option does not allow an efficient modified reassessment process. It does not allow a faster process when the reassessment is straightforward, with quality information available. As a result, there may be negative impacts on people or the environment.

Option 2: Amending the HSNO Act

This would give more flexibility in targeted consultation for a modified reassessment process, instead of a public notification. The changes would reduce the risk of legal challenges because of inadequate consultation.

This option is expected to benefit the EPA, the industry and end-users. It would save time and resources as the EPA could use the new process more frequently and effectively, and raise the reassessment rate.

We seek your views:

31. Do you agree that the current modified reassessment process does not allow flexibility in consultation? If you don't agree, why not?
32. One option is to allow the EPA more flexibility in consultations, that is, a more targeted consultation. Would you support this?
33. Do you suggest another option? If so, please explain.

3.3 Avoiding duplication of work during reassessments

3.3.1 Avoiding duplication when reassessing priority chemicals

Background

Grounds for reassessment

Under section 62(2) of the HSNO Act, the EPA can decide there are grounds for a reassessment after taking into account:

- significant new information about the effects of the substance
- a significant change in the substance's use and quantity
- a better alternative for the substance
- changes to controls under the HSWA.

Currently, it takes the EPA around 6-18 weeks to determine grounds, which are decided by an EPA committee. The average estimated cost to process a grounds application is $16,000. However, applicants are only charged $1,000.

The Priority Chemical List

In 2018, the EPA used the FRCaST screening tool to identify 39 chemicals in the Priority Chemical List (PCL) which the EPA considers are most in need of review in New Zealand. Screening, which is ongoing, is intended to allow comparison between chemicals, and to enable the EPA to prioritise chemicals and develop a work plan for reassessments.

The PCL is approved by the EPA's Chief Executive.

The problem

The EPA is looking at new or updated information when prioritising chemicals for reassessment. This work will ensure that reassessments for PCL chemicals are warranted. There is an opportunity to consider ways to avoid duplication of work in determining grounds for reassessing those substances.

Internationally, there are priority lists of chemicals for reassessments in the United States, Canada and Japan. These countries often set a deadline for reassessments of these chemicals.

Options

Option 1: Status quo

The original drafting of the HSNO Act envisaged the need for a priority list of substances for reassessments. However, at that time there was no priority list available so the process is universal for all substances.

The EPA's recent prioritisation process has established the need for a review of prioritised chemicals. Determining the grounds for reassessment of these chemicals can be inefficient if it is done in the same way as for other chemicals. This costs the EPA unnecessary time and resources in replicating its own work.

The longer a reassessment takes, the more risks there are to people and the environment. Also, the longer these substances are available or not adequately controlled, the less incentive there is for the industry to introduce lower-risk alternatives. This option does not promote innovation or encourage competition.

Duplication can also undermine the integrity of the reassessment process, and does not meet public expectations of lower-risk alternatives. End-users might have to keep using a high-risk substance rather than 'safer' ones.

Option 2: Giving the Priority Chemical List statutory status and skipping grounds for reassessment

This amendment to the HSNO Act would require the EPA to make minor changes to the screening process.

With a statutory status for the PCL, the EPA could omit the grounds and avoid spending unnecessary time and resources.

This might create some uncertainty for the industry and the public, as the 'grounds' step serves as a signal about upcoming reassessments. A solution is to indicate the order of PCL reassessments, and promote communication between the EPA and industry about the work programme.

Option 3: Including the Priority Chemical List in the grounds for reassessment

This amendment to the HSNO Act would still require the EPA to determine the grounds. However, the determination would be more straightforward because the PCL would be on the list of factors to consider for grounds.

We seek your views:

34. Do you agree that it is likely the EPA encounters a duplication of work in determining the grounds for reassessment of priority chemicals given that these chemicals have been screened using the FRCaST tool and appear on the Priority Chemicals List (PCL)? If you don't agree, why not?
35. Which option do you support? Why?
36. If you choose Option 2 (giving the PCL a statutory status, and skipping grounds for reassessment of these chemicals), how would you like the EPA to inform the public about the planned timing of PCL reassessments?
37. (For those who have technical knowledge about the FRCaST) How do you think the prioritisation process should be improved to allow the skipping of grounds?
38. If you choose Option 3 (adding the PCL to the HSNO list of grounds for reassessment, to streamline the process)? What are the implications to consider?
39. Do you suggest another option? If so, please explain.

3.3.2 Avoiding duplication when assessing new and existing substances

The problem

New Zealand gives approvals to hazardous substances which are formulations of one or more components (chemicals).

The EPA may receive an application for a substance with an active ingredient that is currently being reassessed. Regardless of whether the reassessment is complete, the EPA is still required to accept the application alongside the reassessment.

There are then options for progressing the application, depending on the progress of the reassessment and its scope.

The EPA can put the application on hold. However, legal advice is needed to clarify whether waiting for the reassessment decision is reasonable and the applicant is not unduly prejudiced.

In other cases the EPA assesses the application alongside the reassessment. A decision can be made on the new substance even though the reassessment is not complete. The new approval must then be reviewed, to reflect the reassessment decision (see box 4 for an example). Two reassessments take more time, and can lead to inconsistent control of substances while the second reassessment is under way.

Box 4: Reassessment of organophosphates and carbamates

In 2012, the EPA reviewed the approvals for a group of chemicals called organophosphates and carbamates (OPCs), and the hazardous substances that contain them. The reassessment covered 128 substances.

In late 2012, two new OPC-containing substances were approved (Maldi-Shield 50EW and Diazinon 800EC NF). At the same time, the reassessment of their ingredients for the same use patterns was in progress. The decision was made in June 2013.

The decisions for both substances noted the need to update the controls on them after the reassessment. The decision on Diazinon 800EC NF stated, "Following the completion of the organophosphate and carbamate reassessment, the approval of this substance may be subject to reassessment. This may result in additional controls being applied and the availability of the substance being phased out."

All diazinon-containing plant insecticides that were identified in the reassessment, will cease to be approved from 1 July 2028. The approval for Diazinon 800EC NF does not specify this phase-out date. This requires a second reassessment for Diazinon 800EC NF.

Options

Option 1: Status quo

The HSNO Act provides approval in perpetuity and does not allow full recovery of cost. Lengthy and costly reassessment is the mechanism for the EPA to revoke an approval.

At times, the EPA can anticipate the need for a reassessment before granting an approval. However, it still has to assess and reassess in tandem, and cannot avoid the second reassessment. This could cause inconsistent substance management, at least in the short term.

If the EPA chooses to put the application on hold, legal discussion is needed. This takes time and resources.

Option 2: Combining assessment and reassessment of substances with the same active ingredient

This amendment to the HSNO Act would align the processing timeframes. The EPA would save time and resources, and manage relevant substances consistently.

This option might extend the time for assessing a new substance because it coincides with a related reassessment. However, the saving on resources and the benefits of consistency could outweigh the cost. This could have negative effects for the applicant of the new assessment, but increased benefits for human health, the environment and end-users.

Option 3: Declining or postponing an application, pending a reassessment

This amendment to the HSNO Act would allow the EPA to decline or postpone an application while waiting for a reassessment decision on related substances. It would then assess the new application based on the decision, for consistent controls.

This option means a potentially late access to market for the new substance. The benefits are saving the time and resources needed for a second reassessment, and for the legal advice for putting an application on hold.

We seek your views:

40. Do you agree there can be duplication of work in assessing and reassessing related substances with the same active ingredient (see section 3.3.2 – 'The problem')? If not, why not?
41. What option do you support? Why?
42. If you choose Option 2 (combining processes), what are the implications of the proposed combination?
43. If you choose Option 3 (postponing/declining an application, pending a reassessment), what are the implications of this option?
44. Do you suggest another option? If so, please explain.
45. Are there any other ways to promote innovation in the chemical industry, to replace chemicals being reassessed or on the Priority Chemicals List?

3.3.3 Updating controls of existing substances

The problem

Assessing a new substance sometimes requires updates to the controls on existing substances with the same active ingredient. In this case, the EPA has to review the previously approved substances.

This creates inconsistent control of the new and existing substances. It removes the level playing field for related substances during the reassessment and probably longer, as the reassessment might not be initiated (because of a priority issue).

Transferred substances are likely to fall into this situation, as controls from the previous regime can be obsolete in light of new information. For example, with new information available, the EPA may place stricter controls on some herbicides, such as restricting their domestic uses, limiting use to ground-based methods only, or extending buffer zones and wind speed conditions.

These stricter controls may not apply for old substances with the same active ingredient, concentration and use scenarios, which were approved several decades ago.

Options

Option 1: Status quo

The *status quo* would not allow faster update of controls on existing substances, and would create inconsistency in managing hazardous substances. It is likely that minor updates will not happen, given the time and costs of a reassessment.

Option 2: Combined process

This option would allow the EPA to combine assessing a new substance and reassessing existing substances with the same active ingredient. This might be difficult if the EPA has no reassessment plan for the existing substances, or is not certain if a reassessment is needed, for example, where the discrepancies in controls are not significant. The applicant for the new substance could have a long wait.

Option 3: Aligning controls with new approvals

This option would allow the EPA to use the assessment of a recent application to quickly update controls on approvals of related existing substances, for consistent management.

This would involve updating existing approvals to align with the new approval. Updating process would be similar to the modified reassessment under section 63C of the HSNO Act, where no 'grounds' step is needed and public notification is replaced by targeted consultation. The EPA would have discretion on whether to hold a targeted consultation.

This option would shorten the application waiting time, but would not avoid inconsistency between the new approval and the update decision.

We seek your views:

46. Do you agree that controls on existing substances should be updated quickly, to align with a more recent assessment? Why?
47. Which option do you support, and why?
48. Do you suggest another option? If so, please explain.

3.4 Other considerations to enable change

Some of the proposed improvements require consideration of two other issues:

1. Adopting a process for updating controls. This would be similar to the modified reassessment process under section 63C of the HSNO Act. Controls would be updated based on:
   - a new hazard classification based on a trusted regulator's decision
   - a recent EPA assessment of a substance with the same active ingredient as existing substances.
2. Amending the HSNO Act to delegate some decision-making to EPA staff, for a purely technical change (currently, the HSNO Act requires that all reassessment decisions must be made by a decision-making committee). For example, adopting a trusted regulator's decision to change the hazard classification, and the default controls.

We seek your views:

49. Should a process for updating controls be introduced as described in this section? Why/why not?

50. Should EPA staff (rather than a decision-making committee) have the power to make decisions, if the change is purely technical? Why/why not?

3.5 Conclusion

We have proposed new ways to assess and reassess hazardous substances, to enable beneficial substances to be introduced and ensure the appropriate and timely protection of people and the environment. Table 1 sets out these options.

Table 1: Summary of options for change

	Option 1: *Status quo*	Option 2	Option 3
Making better use of information			
Making better use of international information for assessments and reassessments	Taking into account international information, review and verify this	**Option 2A:** Apply in part + the EPA's assessment **Option 2B:** Apply full risk assessments with New Zealand lens **Option 2C:** Apply full assessments or decisions with New Zealand lens	
Suspending an approval to protect human health and the environment	High threshold for suspension	New threshold for suspension or restriction	
Changing the hazard classification of a chemical or substance	Modified reassessment process	Internal process (similar to the reissue process in Schedule 7 of the HSNO Act)	Controls updating process (similar to that provided for in section 63C of the HSNO Act)
Streamlining consultation during reassessments			
Collecting quality information for reassessments	Voluntary provision of information	Statutory call for information + revocation	Statutory call for information + new modified reassessment
Enabling a new modified reassessment process	Current targeted consultation (almost full public notification)	New targeted consultation	
Avoiding duplication of work during reassessment			
Avoiding duplication early in the reassessment of PCL substances	Grounds step for PCL reassessments	Statutory recognition of PCL + no grounds step for reassessments	Include the PCL in the list of grounds
Avoiding duplication in assessing and reassessing substances with the same active ingredient	Two separate processes	Combined process of the new assessment and concurrent reassessment	Decline/postpone an application pending a reassessment decision
Updating existing controls based on a recent assessment of a substance with the same active ingredient	Full reassessments or modified reassessments	Combined process	Apply a controls updating process to existing substances (similar to that in section 63C of the HSNO Act)

Section 4: Next steps

4.1 Your feedback is valuable

The Government welcomes your responses to this consultation document. The questions asked in this document are a guide only, and all comments are welcome. You do not have to answer all the questions.

We encourage your submissions to help us fully understand:

- the use of international information during assessments and reassessments
- how the reassessment process is working
- the impact they have on you
- which proposals to adopt, to achieve the objectives
- the implications to consider.

To ensure others clearly understand your point of view, you should explain the reasons for your views and provide supporting evidence where appropriate.

4.2 How to make a submission

You can make a submission in two ways.

- Use our online submission tool, available at https://www.mfe.govt.nz/consultations/hazardous-substances.

  This is our preferred way to receive submissions.

- Write your own submission.

If you are posting your submission, send it to: Environmental Risk and Innovation, Ministry for the Environment, PO Box 10362, Wellington 6143. Include:

- the title of the consultation
- your name or organisation
- your postal address
- your telephone number
- your email address.

If you are emailing your submission, send it to HSNOsubmissions@mfe.govt.nz as a:

- PDF
- Microsoft Word document (2003 or later version).

Submissions close on 30 September 2019 at 5pm.

4.3 Contact for queries

Please direct any queries to:

- Email: HSNOsubmissions@mfe.govt.nz
- Postal: Environmental Risk and Innovation, Ministry for the Environment, PO Box 10362, Wellington 6143

4.4 Consultation questions

Proposal 1: Making better use of international information

1. Do you agree that the EPA should make better use of international information during assessments and reassessments of hazardous substances? If so, how?
2. Do you agree with the criteria for defining who is a trusted regulator (see section 2.1.1 of the discussion document)? What other criteria should we consider?
3. Do you agree with the proposed principles and considerations of using information from trusted regulators (see section 2.1.1)? What other principles should we consider?
4. Which jurisdictions/agencies do you think we should regard as trusted regulators? Why?
5. What information should we regard as trusted?
6. Which options do you support for using information from trusted regulators for assessments of new hazardous substances? Why?
7. Which options do you support for using information from trusted regulators for reassessments of existing hazardous substances? Why?
8. Should the requirements for applying trusted regulators' information for the initial assessment to introduce a chemical to the New Zealand market be any different to a reassessment (see section 1.2 and 2.1)?
9. Do you suggest another option? If so, please explain.
10. When applying information from a trusted regulator, should the New Zealand context always be considered? (This is currently a requirement in the HSNO Act).
11. Are there any other issues with using information from international regulators that the discussion document has not covered?

Proposal 2: Immediate suspension based on trusted information

12. Do you think the current threshold for suspension is appropriate (that is, significant actual or imminent danger to human health or safety or the environment from the continued use of the substance – see section 3.1.2 – 'The problem')? Why/why not?
13. Does the current suspension apply at the right time in the process (that is, after a reassessment decision has been publicly notified – see section 3.1.2 – 'The problem')? Why/Why not?
14. Do you agree in addition to a suspension, a temporary restriction is also needed?
15. Which option do you support? Why?
16. If you choose Option 2, do you have any suggestions on change to the criteria or threshold for the EPA to suspend or temporarily restrict an approval?

17. If you choose Option 2, what are the potential impacts of a temporary restriction or suspension?
18. If you choose Option 2, what can be done to reduce the negative impacts of a temporary suspension or restriction on the industry and end-users?
19. Can you suggest another option? If so, please explain.

Proposal 3: Using a trusted regulator's decision to change a hazard classification

20. Do you agree with the description of this issue (that is, it is not necessary for the EPA to always follow a modified reassessment process to change a hazard classification based on trusted information – see section 3.1.3 – 'The problem')? Why/why not?
21. Should the EPA be able to adopt a trusted regulator's decision to change a hazard classification? Why/why not?
22. Which option to change a classification based on trusted information do you support? Why?
23. (If you choose Option 2 or 3) The EPA is planning to update the HSNO classification system to align with the Globally Harmonized System of Classification and Labelling (GHS). While this update is taking place, the EPA needs to verify the GHS classification with an HSNO classification. Should the EPA be able to adopt a trusted regulator's classification change before the update is complete? Why/why not?
24. Do you suggest another option to change a classification based on trusted information? If so, please explain.

Proposal 4: Better consultation process to collect quality information

25. Do you agree with the description of this issue (that is, the current voluntary mechanism cannot help the EPA collect quality information for reassessments – see section 3.2.1 – 'The problem'?) If not, why not?
26. What would motivate people to give more comprehensive information for a reassessment?
27. Which option do you support? Why?
28. Do you suggest another option to collect quality information? If so, please explain.
29. Should the EPA have the discretion to decide what a 'lack of information' means or this needs to be prescribed in the HSNO Act/regulations? Why/why not?
30. Do you find there are barriers when applying for a reassessment? If so, what are they?

Proposal 5: Amending modified reassessments for a more targeted consultation

31. Do you agree that the current modified reassessment process does not allow flexibility in consultation? If you don't agree, why not?
32. One option is to allow the EPA more flexibility in consultations, that is, a more targeted consultation. Would you support this?
33. Do you suggest another option? If so, please explain.

Proposal 6: Avoiding duplication when reassessing priority chemicals

34. Do you agree that it is likely the EPA encounters a duplication of work in determining the grounds for reassessment of priority chemicals given that these chemicals have been

screened using the FRCaST tool and appear on the Priority Chemicals List (PCL)? If you don't agree, why not?

35. Which option do you support? Why?
36. If you choose Option 2 (giving the PCL a statutory status, and skipping grounds for reassessment of these chemicals), how would you like the EPA to inform the public about the planned timing of PCL reassessments?
37. (For those who have technical knowledge about the FRCaST) How do you think the prioritisation process should be improved to allow the skipping of grounds?
38. If you choose Option 3 (adding the PCL to the HSNO list of grounds for reassessment, to streamline the process)? What are the implications to consider?
39. Do you suggest another option? If so, please explain.

Proposal 7: Avoiding duplication when assessing new and existing substances

40. Do you agree there can be duplication of work in assessing and reassessing related substances with the same active ingredient (see section 3.3.2 – 'The problem')? If not, why not?
41. What option do you support? Why?
42. If you choose Option 2 (combining processes), what are the implications of the proposed combination?
43. If you choose Option 3 (postponing/declining an application, pending a reassessment), what are the implications of this option?
44. Do you suggest another option? If so, please explain.
45. Are there any other ways to promote innovation in the chemical industry, to replace chemicals being reassessed or on the Priority Chemicals List?

Proposal 8: Updating controls of existing substances

46. Do you agree that controls on existing substances should be updated quickly, to align with a more recent assessment? Why?
47. Which option do you support, and why?
48. Do you suggest another option? If so, please explain.

Proposal 9: Other considerations to enable change

49. Should a process for updating controls be introduced as described in this section? Why/why not?
50. Should EPA staff (rather than a decision-making committee) have the power to make decisions, if the change is purely technical? Why/why not?

4.5 Publishing and releasing submissions

All or part of any written submission (including names of submitters) may be published on the Ministry for the Environment's website, www.mfe.govt.nz. Unless you clearly specify otherwise in your submission, the Ministry will consider that you have agreed to have your submission and your name posted on its website.

Contents of submissions may be released to the public under the Official Information Act 1982, if requested. Please let us know if you do not want some or all of your submission released, stating which parts you consider should be withheld and the reasons for withholding the information.

Under the Privacy Act 1993, people have access to information held by agencies about them. Any personal information you send to the Ministry with your submission will only be used in relation to matters covered by this document. In your submission, please indicate if you prefer we do not include your name in the published summary of submissions.

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