Coversheet: Releasing a discussion document on proposed improvements to assessments and reassessments of hazardous substances

Advising agencies	Ministry for the Environment
Decision sought	Releasing a discussion document on proposed improvements to assessments and reassessments of hazardous substances.
Proposing Ministers	Minister for the Environment

Summary: Problem and Proposed Approach

Problem Definition **What problem or opportunity does this proposal seek to address? Why is Government intervention required?**
Summarise in one or two sentences
Currently, international information has not been used effectively during assessments and reassessments of hazardous substances. This causes delays in introducing new beneficial substances and discourages innovation to replace existing harmful substances. Especially, the reassessment process is proved to be lengthy and expensive while there is a long list of substances that need to be reviewed. We have identified policy problems relating to the inefficient use of information during assessments and reassessments, and ineffective consultation processes and duplication of work during reassessments.

Proposed Approach **How will Government intervention work to bring about the desired change? How is this the best option?**
Summarise in one or two sentences
We are looking at options to apply a 'trusted regulator' approach to make better use of international information during assessments and reassessments. We are also proposing other improvements to the reassessment process by streamlining consultation and avoiding duplication of work. We are seeking feedback from the public to achieve the desired improvements.

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?
Monetised and non-monetised benefits
Some proposals provide the Environmental Protection Authority (EPA) with more flexibility and discretion in decision-making, which may allow the regulators to improve decision-making in managing hazardous substances. The proposals are expected to facilitate the

introduction of beneficial substances and incentive the replacement of harmful substances. They could also save time and resources for the regulator and industry.

More effective and efficient processes also benefit the chemical industry and the general public as they ensure appropriate on-going chemical management and allow communities to derive benefits from the use of chemicals.

Where do the costs fall?

Monetised and non-monetised costs; for example, to local government, to regulated parties

The 'trusted regulator' approach may risk adopting inappropriate decisions from 'trusted regulators' to manage chemicals. We clearly raise this in the discussion document and emphasise that the EPA needs to consider the New Zealand context when applying 'trusted regulators' decisions.

While the proposal could bring benefits to the EPA's process, it may have operational and resource implications on WorkSafe's process in setting and updating workplace controls on chemicals. This may require operational solutions or similar changes under the Health and Safety Act 2015 (HSWA).

The Government may incur costs for implementing the 'trusted regulator' approach. These include costs of introducing regulations/guidelines on 'trusted regulator' approach and the costs of establishing relationships with 'trusted regulators'.

Another proposal requires more engagement of the chemical industry and the public in providing quality information for reassessments. Failure to provide quality information may result in an approval being revoked, which may have impacts on the chemical industry and end-users. We seek the public input on the costs of providing information and the implications of the proposal on the chemical industry and the public.

One proposal suggests replacing a nearly public notification process with a targeted consultation for the modified reassessment process. This means the public will not be consulted during a modified reassessment. The EPA would have discretion in deciding who will be consulted.

Some proposals suggest giving the EPA more discretion in targeted consultation and skip the 'grounds' step[1] to allow faster updating of controls based on trusted information. These proposals would not affect industry and the public as these changes are technical in nature and would not require the participation of the public.

We will seek the public's input about the cost of these proposals.

What are the likely risks and unintended impacts, how significant are they and how will they be minimised or mitigated?

Options for making better use of information from 'trusted regulators' range from cautious consideration of the information to adoption of 'trusted regulators' decisions without consideration of the New Zealand context. The latter option is considered inappropriate

[1] 'Grounds' step determines if there is information to trigger a reassessment

because it is inconsistent with the principles of the Hazardous Substances and New Organisms (HSNO) Act 1996 and potentially affects the independent role of the EPA. We discuss this option in this assessment to provide the public with evidence on why it is not a preferred option. The Government is seeking public opinion on the most appropriate option. The Government is also seeking feedback from the chemical industry and the general public on potential impacts of the proposals and how to mitigate them.

Identify any significant incompatibility with the Government's 'Expectations for the design of regulatory systems'.
There is no significant incompatibility with the Government's expectations in these proposals.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?
How confident are you of the evidence base?
The problem definition and development of options are supported by data and evidence provided by the EPA: the independent regulator of hazardous substances in New Zealand. The discussion document is aimed to collect more evidence from the chemical industry and the general public to help finalise the proposals.

To be completed by quality assurers:

Quality Assurance Reviewing Agency:
Quality Assurance Assessment:
Reviewer Comments and Recommendations:

Section 1: General information

Purpose

1. The Ministry for the Environment (MfE) is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. The analysis and advice have been produced for the purpose of informing stakeholders to be consulted on a government discussion document.
2. The purpose of the project is to make assessments and reassessments of hazardous substances more efficient, and to improve reassessment process to the most possible extent. 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.
3. The outcome of this project must serve the original purpose of the Hazardous Substances and New Organisms Act 1996 (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".

Key Limitations or Constraints on Analysis

4. This analysis is limited to policy problems relating to inefficient use of international information during assessments and reassessments of hazardous substances and some other issues of reassessments. A broader review of the assessment process is out of the scope of this analysis.
5. The analysis has not included proposals to make changes to the cost recovery mechanism under the HSNO Act.
6. Workplace controls on hazardous substances will continue to be set and updated separately under the Health and Safety at Work Act 2015 (HSWA). WorkSafe New Zealand (WorkSafe) is facing a similar quality information issue during its own process to set and update workplace controls on hazardous substances. If the Environmental Protection Authority (EPA) is able to apply 'trusted regulator' information, it would be more difficult for WorkSafe to collect data and assess evidence for workplace controls. This is because, currently, WorkSafe's process relies on information from HSNO applications. This may require operational solutions, for example including WorkSafe in establishing relationships with 'trusted regulators' for sharing information, or similar changes under the HSWA.
7. Evidence of policy problems have been provided by the EPA. This include average costs and time of assessments and reassessments, how the processes could be benefited from the use of information provided by trusted regulators, and evidence of inefficiency and duplication of work during the reassessment process.

8. Time and costs for assessments and reassessments vary, depending on the complexity of the substance(s), and the number of relevant approvals. The number of applications for new substances depends on the demand from the chemical industry. The number of reassessments depend on the available budget and other resources, and also the demand from the chemical industry and the public. There is some uncertainty in estimating the monetised costs and benefits of proposed options.
9. We are assuming the nature of costs and benefits of applying 'trusted regulator' approach to assessments of new substances would be similar to that of reassessments, as the HSNO Act clarifies that a reassessment is deemed to be an (new) application and thus follows the same procedure and requirements of evaluation and consideration. The chemical industry may benefit more from the proposal for assessments than that for reassessments as they are the main applicants for new substances while the EPA is the main applicant of complicated reassessments.
10. We anticipate public feedback on this assumption.
11. We would like to test our understanding of the policy problems with the public and how appropriate are the proposed options. We also seek information on the costs of providing information for reassessments and impacts of our proposed options on industry and the public as well as how to mitigate the impacts.
12. We have worked closely with the EPA in analysing policy problems and proposing options for improvements. WorkSafe has also provided feedback on the proposals.
13. Policy problems and proposed options have not been tested with any stakeholders except some government agencies, including Department of Internal Affairs, Department of Conversation, Ministry of Business, Innovation and Employment, Ministry of Health, Ministry of Primary Industries, Ministry of Justice, Te Puni Kōkiri, and Treasury.

Glenn Wigley
Director
Natural and Built Systems
Ministry for the Environment

Section 2: Problem definition and objectives

2.1 What is the context within which action is proposed?

Hazardous substances are managed under the HSNO Act

14. In New Zealand, the EPA is responsible for managing more than 150,000 hazardous substances under the HSNO Act. The EPA works alongside WorkSafe, which administers and enforces rules for the use of hazardous substances in the workplace.
15. The HSNO Act came into force for hazardous substances on 2 July 2001. The Act's purpose 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.
16. Under the Act, new hazardous substances that have not been legally present must be assessed and approved with appropriate controls before being introduced into New Zealand.
17. Hazardous substances legally present in New Zealand prior to 2001 were transferred to the new HSNO Act. Many substances are managed by Group Standards,[2] other higher risk substances (explosives, pesticides, wood preservatives and chemicals toxic to vertebrates) require individual approvals[3] for use with specifically assigned risk management measures (controls).
18. HSNO Act approvals do not expire and reassessments are a mechanism for the EPA to change or revoke existing approvals. Any person, including the Chief Executive of the EPA can apply for a reassessment if there is new information on the effect or use of a substance.

Assessment under the HSNO Act

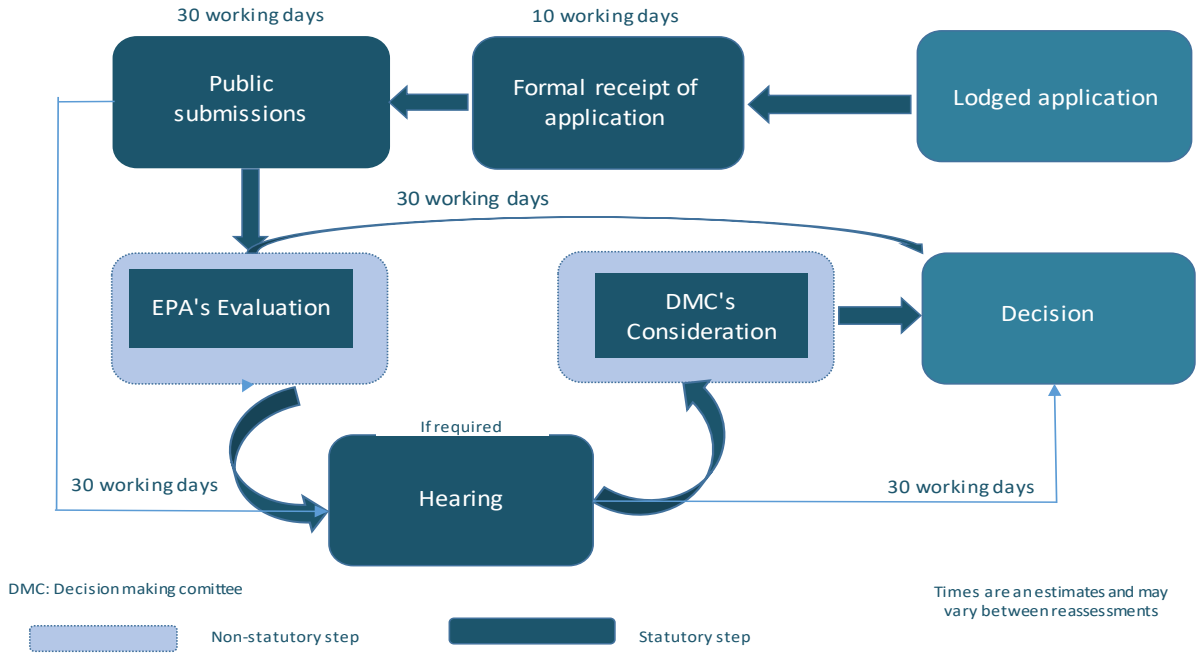
19. The EPA's assessment of a new hazardous substance takes at least five months (for one that is publicly notified). The process includes a public consultation (30 working days), a hearing if requested within 30 working days after the close of submissions, and a decision-making process within 30 working days of the close of the hearing (see Figure 1).
20. The timing of the process largely depends on the quality of application's information. The EPA may request further information during the process. Requesting and processing additional information can delay following steps.
21. The HSNO Act requires the EPA, when undertaking assessments, to take into account: the need for caution in managing adverse effects where there is scientific and technical uncertainty, the Treaty of Waitangi (Te Tiriri o Waitangi), and:
    - the sustainability of all native and valued introduced flora and fauna
    - the intrinsic value of ecosystems
    - public health

[2] Group Standards are approvals for a group of hazardous substances of similar nature, type, or use. Group Standards were introduced in 2005 and re-issued in 2017 to set controls for substances of relatively low risk. There are 208 Group Standards.
[3] There are about 9,350 individual approvals.

- 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.

22. WorkSafe can be involved in the process if the use of the substance requires workplace controls under the HSWA. WorkSafe may initiate a Safe Work Instrument process alongside the EPA assessment to add or vary workplace controls if needed.

Figure 1: Application process



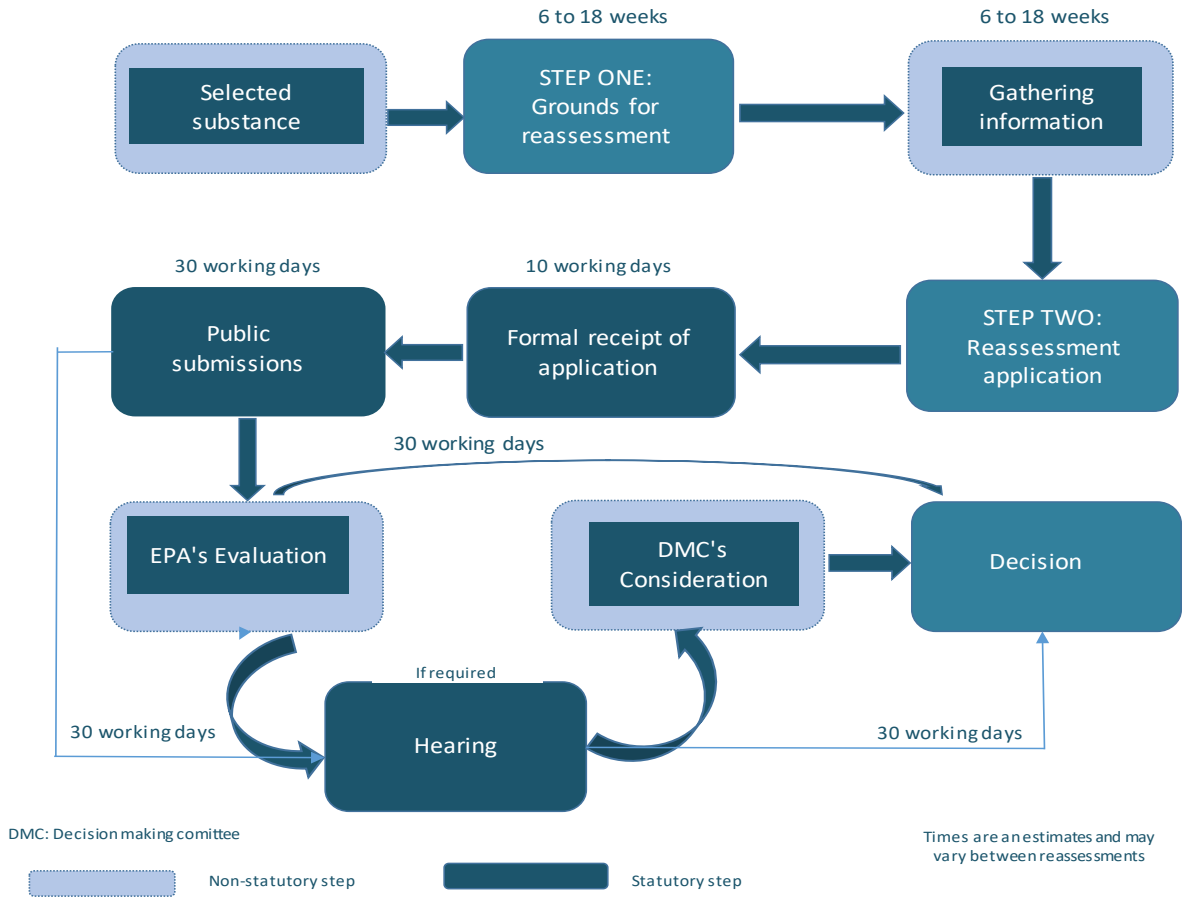
Note: WorkSafe will be involved during the process as appropriate to ensure appropriate workplace controls are in place

Reassessment under the HSNO Act

23. Under the HSNO Act, a reassessment is deemed to be an application. It is a two-step process: determination of grounds and reassessment application.
24. The 'grounds' step determines if there is information to trigger a reassessment.
25. The reassessment application process follows the same procedure of the application process. There may also be a non-statutory call for information before the application is lodged (See Figure 2).
26. All reassessment decisions, including determining the grounds for reassessments, must be undertaken by an EPA decision making committee.
27. There are two types of reassessment: modified and full. Modified reassessments change part of an existing approval while full reassessments consider varying any part of an existing approval, including the revocation of the approval. Full reassessment applications are typically complex, and may often cover multiple approvals.

28. The 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

The need for change

29. 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 EPA during assessments and reassessments has been produced and used overseas.
30. 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 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 costs and time for both the regulator and industry.

31. Delays in assessing new substances defers the introduction of beneficial substances, including 'safer' alternatives to existing chemicals, and delays in reassessments can pose risks to people and the environment.
32. 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, respectively. In 2017 and 2018, the EPA received 41 and 30 applications, respectively, for hazardous substances approvals (categories A-C) (excluding other hazardous substances applications).
33. It takes at least five months for the EPA to process a publicly notified application. Some applications can take more than two years.
34. Particularly, the current reassessments are comprehensive, time-consuming and resource-heavy, especially when they cover multiple chemicals and approvals. Average costs of a 'grounds' step for reassessment is $16,000 and of a reassessment is $111,000 (EPA, 2017). Some reassessments can take up to two years and cost more than $1 million.
35. Since 2001, the EPA has completed 31 Chief-Executive-initiated reassessments and 20 external reassessments. Low rates of assessment and reassessment of existing chemicals are a common issue in many of the OECD countries.
36. There are a significant number of priority substances that need to be reassessed. In 2018, the EPA identified 39 chemicals that it considers are most in need of review in New Zealand. Timely reviews of these chemicals would ensure appropriate management of chemicals to protect human health and the environment.
37. The EPA has recently undertaken an operational review to improve reassessments but there are legislative opportunities for further improvements to the assessment and reassessment process.

2.2 What regulatory system, or systems, are already in place?

38. Our 2017 regulatory stewardship strategy expressed an intention to improve the system for monitoring hazardous substances, to better identify more long-term effects on the environment.
39. The EPA is undertaking a modernisation project to improve the way chemicals are managed and regulated in New Zealand by different operational initiatives, including updating and streamlining processes; aligning technologies with international partners, and developing a chemical map in New Zealand.
40. A Technical Working Group was also set up to review the compliance and enforcement of hazardous substances.
41. This project is looking at potential improvements to the assessment and reassessment processes to better manage hazardous substances.
42. Most provisions relating to these processes under the HSNO Act have not been reviewed for more than 20 years. This project is an opportunity to consider legislative changes and other improvements to the processes to enhance the effectiveness and efficiency of the system.
43. The EPA is an independent regulator of hazardous substances in New Zealand and the only agency empowered with approving new hazardous substances and reassessing existing ones. Its operation must be in accordance with the HSNO Act. Potential changes to the system would likely require changes to the legislation.

44. Some proposals would incentive more engagement of the chemical industry and other people. We intend to seek feedback from them on the proposed changes.

2.3 What is the policy problem or opportunity?

45. MfE has identified eight policy problems which can be grouped in three categories.

2.3.1. Inefficient use of information

Policy problem 1: Inefficient use of international information during assessments and reassessments

46. International information, including the assessments and decisions of international regulators, is given the same priority as other types of information when the EPA performs assessments and reassessment. Currently, the EPA can only consider but not apply any of this information. In many cases, this means the EPA must repeat technical work that has already been done overseas.
47. Internationally, regulators are seeking to use international data and assessments from other regulators in order to create efficiencies to reduce the regulatory burden for industry and build a global approach to chemical regulation. Given New Zealand's low profile in chemical manufacture industry, it is inefficient if New Zealand cannot make good use of international information.
48. Other government agencies that consider medicines and agricultural compounds are making good use of international information by using special pathways for evaluation and registration.
49. A lengthy assessment process of new substances may delay the introduction of highly beneficial substances, 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 processes take considerable time and resources.
50. Also, the lengthy time taken to assess and reassess substances could mean there is little incentive to replace existing substances with 'safer' alternatives. This discourages innovation and causes frustration to industry.

Policy problem 2: Difficulties in suspending an approval

51. Section 64 of the HSNO Act allows the EPA to suspend an approval to protect people and the environment. However, the threshold to immediately suspend a chemical from sale is very high and difficult to exercise. The provision requires the EPA to prove that there is a "significant actual or imminent danger to human health or safety or the environment."
52. The suspension power only applies once an application for reassessment has been publically notified, 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. There is also no provision for a temporary restriction.
53. There are circumstances when international or domestic information indicates a need for immediate response, such as when an international regulator bans or revokes the approval of a chemical because of new information on its high risk to human health. The

current section 64 does not allow the EPA to immediately react in these circumstances to protect human health and the environment.

54. Some insecticides, such as benomyl, were banned by international regulators from 2003 but the EPA could only ban this substance in 2013 because it took time for the EPA to be aware of the ban, then prepare for a reassessment application (which was about 7 years) and undertake the reassessment process (which was about 2 years). The EPA was unable to place a suspension on relevant approvals during the preparation time.

Policy problem 3: Unable to apply a trusted regulator decision to change a hazard classification

55. Hazard classification describes the hazardous properties of a substance. The EPA is planning to update the current classification system to align with a recent version of the Globally Harmonized System of Classification and Labelling (GHS), an internationally agreed system for classifying chemicals based on their physical, health, and environmental hazards. Once this update is complete, the EPA should be able to trust and apply a decision to change a hazard classification by certain international regulators.
56. Currently, under the HSNO Act, if an overseas regulator changes the hazard classification of a chemical, the only way New Zealand can follow suit is to undertake a modified reassessment process. The current modified reassessment is as time-consuming and resource-heavy as a full reassessment. This work is unnecessary as the EPA just repeats the work done overseas.
57. In many cases, changes to the hazard classification might not be in the EPA's priority list of reassessments. This means the inappropriate classification and its controls will be in place for a very long time.
58. This situation also creates inconsistency in hazardous substance management where new substances are approved using the new classification but old approvals cannot be readily updated.
59. There were cases the EPA could only change the classification of a substance after a very long time, following an international regulator's decision. For example, 4,4'-Methylenediphenyl diisocyanate was added the carcinogenicity classification in 2005, but the EPA could only change the classification in 2016 after an EPA Chemical Review and a full reassessment process.

2.3.2. Streamlining consultation

Policy problem 4: Difficulties in collecting quality information for reassessment

60. The HSNO Act as it is written, does not allow the EPA to request industry to provide quality information for reassessments before a reassessment is publicly notified. As a result, the EPA cannot collect quality information to prepare for a reassessment application.
61. 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.

62. 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.
63. 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 human health and the environment, because of the time taken.

Policy problem 5: The current modified reassessment process is time-consuming and as resource-heavy as a full reassessment.

64. Section 63A of the HSNO Act provides for a modified reassessment process intended to allow for a more efficient review of controls, but cannot be used to revoke an approval.
65. However, the targeted consultation process for a modified reassessment requires the EPA to do everything reasonably practicable to consult with all persons who, in its opinion, may be affected by the reassessment, and give those persons a reasonable opportunity to make submissions and comments. This is unrealistic in some circumstances as the EPA does not hold a database of all affected persons.
66. This situation does not allow for a faster process when the reassessment is straightforward and quality information has been obtained.

2.3.3. Duplication of work during reassessment

Policy problem 6: Duplication of work when reassessing priority chemicals

67. Under section 62(2) of the HSNO Act, the EPA can decide that grounds for a reassessment exist after taking into account the following:
    - 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.

68. In 2018, the EPA used the FRCaST screening tool[4] to identify 39 chemicals in the Priority Chemicals List (PCL) that the EPA considers are most in need of review. The screening process is based on new information in New Zealand and overseas. It ensures reassessments of these substances are warranted and most needed.
69. 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 screening and grounds for reassessment have the same activities of considering new information on the use and effect of substances that warrants the need of a reassessment.
70. However, currently, it still takes about 6-18 weeks and costs about $16,000 to establish the grounds for reassessment of these substances. If an applicant applies for the grounds for a reassessment, he/she is only charged $1,000.

[4] https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/screened-chemicals-list/

71. 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.
72. It is inefficient to determine the grounds for reassessment of PCL substances in the same way as other substances. This costs the EPA unnecessary time and resources in replicating its own work. Consequently, this situation unnecessarily lengthens the reassessment process of chemicals on the PCL, potentially poses risk to people and the environment and discourages innovation to replace the substances of greatest concern.

Policy problem 7: Duplication of work in the assessment and reassessment of substances with the same active ingredient

73. There is currently duplication of work when a substance is being reassessed and an application is made for a substance that contains an active ingredient that is being reassessed. The two processes are currently required to continue alongside each other.
74. It is possible to put an application on hold but it would need legal advice on a case by case basis and the new application will still need to be assessed at some point.
75. Sometimes the approval for the new substance is given before the reassessment decision is made, and thus that approval needs to be reassessed in light of the reassessment decision. This costs the EPA time and resources and potentially creates inconsistencies in substances management at least in the short term.
76. This situation happened in the case of the reassessment of organophosphates and carbamates (OPCs) and the applications of two new OPC-containing hazardous substances (Maldi-Shield 50EW and Diazinon 800EC NF). The reassessment decision states that 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.

Policy problem 8: Updating controls on existing substances

77. Assessment of a new substance sometimes requires that controls on existing substances with the same active ingredient need to be updated.
78. 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.
79. This creates discrepancies between the controls on the existing substances and the new substances. If the existing substances are not prioritised for reassessment by both the EPA and industry, it is unlikely that their controls will be updated, given the time and costs of undertaking a reassessment.

2.4. Are there any constraints on the scope for decision making?

80. The analysis is limited in making better use of international information during assessments and reassessments of hazardous substances as well as other improvements of the reassessment process. It does not cover any aspect of the cost

recovery mechanism which might involves a consideration of a fair distribution of the burden of costs for reassessments.

81. Workplace controls on hazardous substances will continue to be set and updated separately under the HSWA and are not directly affected by these proposals.
82. This analysis does not include consideration of the recommendations of the Technical Working Group and the outcomes of the EPA's hazardous substances modernisation project. They will be addressed in other policy projects.

2.5 What do stakeholders think?

83. In March, the project team engaged informally with a brief survey on targeted stakeholders and iwi, inviting their views on the early policy direction. The survey focused mainly on the reassessment process.
84. Approximately half the respondents (57 per cent) had negative experience with the current reassessment process because of many reasons, including the timeframe and slow process, the way the EPA is using international information, the difficulties of applying for small changes. Respondents are keen to provide input into reassessments, and expected changes in engagement, consultation, timeframe, using international information, and other issues. They also emphasised the need to consider the New Zealand context when applying international information.
85. We expect the public consultation process will gather more comprehensive feedback from industry and the public about the policy problems and proposed changes.
86. MfE has also engaged with other government agencies about options for changes and receive support from agencies for the release of the discussion document.

Section 3: Options identification

87. MfE has identified some options to address those policy problems explained in Section 2. We seek the public's views on whether any of these options are appropriate. We also expect to receiv suggestions on other viable options.
88. Integral to some of the proposals is the use of information provided by 'trusted regulators', which will be explained below.

'Trusted regulator' approach

89. The 'trusted regulator' approach relates to a relationship between selected 'trusted' international regulators, which allows for the recognition and sharing of information to the benefit of one or more parties. A trusted regulator might be chosen based on criteria such as the reliability[5] of the regulator, and the quality and applicability of information.
90. The information referred to here includes scientific information, data, hazard assessments, risk assessments and decisions. Note however that data is not always available for sharing between regulators because of confidentiality requirements. Some risk assessments and decisions can be influenced by local context, risk appetites, and political or commercial biases.
91. Internationally, no jurisdictions automatically apply the decisions of another regulator. However, some regulators are seeking to use international data and assessments from others. Domestically, other agencies are also making good use of international information by using special pathways for evaluation and registration of agricultural compounds and medicines.
92. Options for applying information provided by trusted regulators to assist the domestic processes have taken into consideration the purpose and principles of the HSNO Act, international and domestic best practices, and matters such as risk appetite, biases, local context, and differences in chemical management systems.
93. Using information provided by trusted regulators is included in different proposals below.

3.1. Making better use of information

Policy problem 1: Inefficient use of international information

94. **Option 1** is the status quo, which has been discussed in Section 2. There are two other options for better use of international information.
95. **Option 2** would allow the EPA to apply in part or whole trusted regulator's information to substitute part of the EPA's own assessment and then consider the New Zealand context and the requirements of the HSNO Act to make a final decision. There are several sub-options:
96. **Option 2A:** Apply in part: This option would require changes to the HSNO Act to allow the EPA to apply available data and assessment information from trusted regulators in combination with the EPA's own research and applicant information at various stages throughout the reassessment process.
97. For assessments of new substances, applicants are responsible for providing data and assessments. The EPA can use a trusted regulator's information to complement or

[5] A reliable regulator can be one that follows a quality, transparent and robust chemical assessment process, and has assessment reports accessible to the EPA.

evaluate the information provided by applicants. Applicants may also request ‘trusted regulators’ to provide this information to the EPA to support the application.

98. 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 of existing substances is often more freely available than that of new substances.
99. **Option 2B:** Apply full risk assessments: This option would require changes to the HSNO Act to allow the EPA to ‘trust‘ risk assessments from trusted regulators and then consider the relevance to the New Zealand context and the requirements of the HSNO Act to make a final decision.
100. 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.
101. 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.
102. **Option 2C:** Apply full assessments or decisions: This option would require changes to the HSNO Act to allow the EPA to ‘trust’ both assessments and decisions (which can be influenced by local context and political or commercial biases) from trusted regulators and then consider the relevance to the New Zealand context and the requirements of the HSNO Act to make a final decision.
103. 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.
104. These options would require the regulations or guidelines to specify trusted regulators, which information can be trusted, and other matters. The regulations or guidelines must ensure the information we trust would be quality, robust and transparent; would not carry any political or commercial biases or other local influences and would align with our risk appetite.
105. It is worth noting that these options would provide the EPA discretion to make better use of international information. The EPA would retain the power to undertake full assessments or reassessments when needed to protect human health and the environment.
106. Workplace controls will continue to be set and updated under the HSWA. WorkSafe would be involved in the processes to ensure appropriate workplace controls are in place.
107. These proposals strike a balance between protecting New Zealanders’ health and the environment, and making reassessments more efficient. They align with international and domestic best practice.
108. **Option 3** would allow the EPA to apply trusted regulators’ decisions to immediately approve or ban a substance, without considering any New Zealand context. Analysis shows that no jurisdictions provide an automatic adoption of other regulators’ decision without consideration of local context. The option would compromise the EPA’s independence in making decisions on chemical management in New Zealand and might risk adopting inappropriate decisions influenced by political and commercial biases.
109. Option 3 is inconsistent with the principles of the HSNO Act. This option is included in this assessment to demonstrate the range of applications of trusted regulators’ information and to provide evidence on why this is not a preferred option.

Policy problem 2: Difficulties in suspending an approval

110. **Option 1** is the status quo, which has been discussed in Section 2. There are two other options for more EPA's responsiveness to protect human health and the environment.

111. **Option 2** would amend Section 64 of the HSNO Act by:

- lowering the threshold of danger
- narrowing down the protected target, ie, instead of proving the danger to the environment in general, the EPA might prove the danger to a specific species,
- changing the timing of the suspension, ie can be before a reassessment application is submitted
- allowing a temporary restriction in addition to a complete suspension.

These changes are to allow the EPA to quickly react if international or domestic information indicates that there is a high risk for people and the environment from a certain substance.

112. This option would require the EPA to undertake a reassessment process within a set time, ie, in six months since the suspension or restriction has taken effect. This requires the EPA to prioritise reassessment of the substance.

113. The temporary suspension or restriction may help to reduce the time and resources for collecting information for reassessment based on an assumption that industry would be more incentivised to provide information relating to the substance (to maintain the existing approval) after the EPA taking the temporary action. It can also encourage industry to innovate and introduce lower-risk substances.

114. 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 industry if the reassessment shows that revoking the approval is unnecessary. However, the benefits to human health and the environment could outweigh the cost. There could also be incentives for industry and the public to provide information to speed up decisions.

115. **Option 3** would allow the EPA to immediately revoke an approval using a trusted regulator decision. Similarly to option 3 of policy problem 1 this option would compromise the EPA's independence in making decisions and might risk adopting inappropriate decisions influenced by political and commercial biases.

Policy problem 3: Unable to apply a trusted regulator decision to change a hazard classification

116. **Option 1** is the status quo, which has been explained in Section 2. There are two other options for better use of trusted regulator decision to change the hazard classification of a chemical/substance.

117. **Option 2** would allow the EPA to adopt a trusted regulator decision to change the hazard classification of a chemical or substance. This change could be notified on the EPA website. The change would lead to the change of default controls on related substances for alignment with the new hazard classification. An internal process is undertaken to decide substituting, adding or combining controls on substances in related approvals. This process would be similar to the reissue process provided for in

Schedule 7 of the HSNO Act. The new controls take effect after the EPA re-issue related approvals with updated controls.

118. Change of a classification is an exception of using international regulators' decisions where the EPA could directly adopt the decision without the need to consider the New Zealand context.

119. **Option 3** is similar to Option 2 for changes to the hazard classification and default controls but instead of using a reissue process, the EPA would undertake a process of updating controls to calculate substituting, adding or combining controls. This process would be similar to the modified reassessment provided for in section 63C of the HSNO Act where the 'grounds' step is omitted and a targeted consultation replaces public notification. The EPA would have the discretion to include the targeted consultation or not.

120. Both options would allow more timely decisions to change a classification based on trusted information. They allow the change to happen faster than the status quo, which could save the time and resources for both the EPA (if there is an increase in the classification) and industry (in case of a decrease). However Option 2 would allow the change to happen faster than Option 3.

3.2. Streamlining consultation

Policy problem 4: Difficulties in collecting quality information for reassessment

121. **Option 1** is the status quo, which has been discussed in Section 2. There are two other options to make changes to the consultation process of reassessments.

122. **Option 2** 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.

123. 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.

124. This option would allow the EPA to revoke an approval due to the lack of information for the reassessment. This means after the first consultation process, if the EPA cannot collect quality information for the reassessment, it is able to revoke the approval.

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

126. **Option 3** would be similar to Option 2 but does not allow the EPA to revoke an approval until after a reassessment process is complete.

127. 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 suspend the approval.

128. The EPA would then make a reassessment, to consider the lack of information on the benefits of a substance and the available information from trusted sources on the negative effects of the substance to decide whether to revoke or restrict the approval.

Policy problem 5: The current modified reassessment process is time-consuming and resource–heavy as a full reassessment.

129. We propose options to provide more flexibility in ways the EPA can consult. We seek public views on whether the HSNO Act should allow the EPA to undertake a targeted consultation process instead of a nearly public notification for the modified reassessment process.
130. If the public supports the change, we will further work on new wordings of Section 63A to reduce the risk of the EPA being legally challenged because of missing consultation.
131. The change is expected to benefit the EPA, 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.

3.3. Avoiding duplication of work during reassessment

Policy problem 6: Duplication of work when reassessing priority chemicals

132. **Option 1** is the status quo, which has been discussed in Section 2. There are two other two options to save time and resources for determining the grounds for reassessments of the priority chemicals.
133. **Option 2** would amend the HSNO Act to give the PCL a statutory status and clarify that the chemicals in the PCL would meet the grounds threshold.
134. This option would require the EPA to make some minor changes to the screening process for adopting the PCL.
135. This option could reduce the time and resources needed to reassess prioritised substances. It would also help to accelerate the reassessments of the chemicals of greatest concern.
136. This might create some uncertainty for 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.
137. **Option 3** would amend the HSNO Act to include the PCL into the list of grounds for reassessment in Section 62. This means the EPA still has to determine the grounds, however the determination would be more straightforward than it currently is.

Policy problem 7: Duplication of work in the assessment and reassessment of substances with the same active ingredient

138. **Option 1** is the status quo, which has been discussed in Section 2. There are two other options to avoid duplication of work in the assessment and reassessment of relevant substances which contain the same active ingredient.
139. **Option 2** would allow the combination of the two processes so that they are decided together with consistent controls (ie, amend legislation to align processing timeframes).
140. 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.

141. **Option 3** would amend the HSNO Act to allow the EPA to decline or postpone an application 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.
142. This option means potentially late access to the market for the new substance. The benefit is saving the time and resources needed for a second reassessment.

Policy problem 8: Updating controls on existing substances

143. **Option 1** is the status quo, which has been discussed in Section 2. There are two other options to address this policy problem:
144. **Option 2** 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, eg, where the discrepancies in controls are not significant. The applicant for the new substance could have a long wait.
145. The benefit of this option is the consistency in controls of the new and existing substances.
146. **Option 3** would allow the EPA to use a process of updating controls to change existing approvals to align with the new approval.
147. This process would be similar to the modified reassessment process provided under section 63C of the HSNO Act where no 'grounds' step is needed and the EPA would have more discretion in undertaking a targeted consultation.
148. This option would shorten the waiting time for the new application but would not avoid the inconsistency during the time between the new approval and the update decision.

3.4. Other considerations to allow options to be adopted

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

- 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.
- Amending the HSNO Act to delegate some decision-making to EPA staff, for a purely technical change. For example, adopting a trusted regulator's decision to change the hazard classification, and the default controls.

Section 4: Impact Analysis

150. Based on the purpose and principles of the HSNO Act, the purpose of this project, and our policy analysis, we assessed the proposed options against six policy criteria:

- appropriate management of substances to protect human health and the environment
- time saving
- cost effectiveness
- promote innovation and encourage competition
- integrity, clarity, certainty, and transparency of the assessment and reassessment process
- stakeholders' satisfaction.

4.1. Making better use of information

Policy problem 1: Inefficiency in using of international information

Key:

++ much better than doing nothing/the status quo

+ better than doing nothing/the status quo

0 about the same as doing nothing/the status quo

- worse than doing nothing/the status quo

- - much worse than doing nothing/the status quo

Table 1: Assessment of options for better use of international information during assessments and reassessments

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1: Status quo- Taking into account international information	0 Delay in introducing beneficial substances Lengthy reassessment means inappropriate management might be in place	0 Slow processes	0 Not a good use of international information	0 No incentive for innovation and competition	0 Lengthy process and inefficient use of international information	0 Likely to have negative impacts on most stakeholders
Option 2A **Apply a part of trusted regulator's information**	++ Trusted regulator's information supports the EPA processes + a consideration of the NZ context would allow an appropriate management decision	+ Better use of international information but the EPA still needs to undertake its own assessment → save some time for the processes	+ Better use of international information but the EPA still needs to undertake its own assessment → save some costs for the processes	+ Beneficial substances can be available faster than currently possible High risk substances would be reviewed faster → would encourage the introduction safer alternatives	++ If there are guidelines or regulations on trusted regulators and the EPA still undertakes its assessment	++ Likely to have positive impacts on most stakeholders
Option 2B: Apply full assessments + consider NZ context	++ A consideration of the NZ context would allow an appropriate management decision	+ Better use of international information → save more time for the processes	+ Better use of international information → save more costs for the processes	+ Beneficial substances can be available faster than currently possible High risk substances would be reviewed faster → would encourage the introduction safer alternatives	++ If there are guidelines or regulations on trusted regulators	++ Likely to have positive impacts on most stakeholders
Option 2C: Apply full assessments or decisions + consider the NZ context	++ Trusted regulator's decision may contains biases thus require a thorough consideration of the NZ context to allow an appropriate management decision	++ Better use of international information → save more time for the processes	++ Better use of international information → save more costs for the processes	++ Beneficial substances can be available faster than currently possible High risk substances would be reviewed faster → would encourage the introduction safer alternatives	++ If there are guidelines or regulations on trusted regulators and the EPA undertakes a thorough consideration of the NZ context and understands embedded biases in trusted regulator's decision	++ Likely to have positive impacts on most stakeholders
Option 3-Immediate adoption of a trusted regulator's decision	-- Without a consideration of the NZ context, the appropriate management of substances cannot be achieved	- Unknown costs to people and the environment	-- Unknown costs to people and the environment	0 Might promote innovation in some cases but with an unknown cost	-- Compromising the integrity, clarity, and transparency of the EPA's decision-making process.	-- All stakeholders have no chances to have a say on the decisions.

Policy problem 2: Difficulties in suspending an approval

Table 2: Assessment of options for more responsiveness

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-Status quo-High threshold for suspension	0 Unable to immediately react to risks to human health and the environment	0 Very slow rate of reassessment	0 Potentially cause cost to human health and the environment	0 No incentives for innovation and competition	0 Lengthy process and inefficient use of information	0 Likely to have negative impacts on most stakeholders
Option 2-Feasible suspension or restriction	++ The suspension power protects human health and the environment	++ Industry will be incentivised to provide information	+ Benefits from better management of substances Potentially saves cost for human health and the environment	+ The suspension encourage the introduction of safer alternatives	+ More applicable power of suspension	+ Likely to have positive impacts on most stakeholders Minor negative impacts on the introducers/users of the suspended substances but the benefits outweigh the costs
Option 3-Immediate adoption of a trusted regulator's decision to revoke an approval	-- Without a reassessment, the appropriate management of substances cannot be achieved	- No reassessment process happens with this option	- Unknown costs of a revocation in case there is no alternatives or inheritance of foreign biases	0 Might promote innovation in some cases but with unknown costs	-- Compromising the integrity, clarity, and transparency of the EPA's decision-making process.	-- Substances are to be taken off the shelves without a reassessment All stakeholders have no chances to have a say on the EPA's decisions of revocation

Policy problem 3: Unable to apply a trusted regulator decision to change a hazard classification

Table 3: Assessment of options for changing the hazard classification

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-Status quo-Modified reassessment process	0 Inappropriate management of substances Risks to human health and the environment in some cases	0 Very low rates of reassessment	0 Potentially cause costs to human health and the environment Or costs to industry and end-users for unnecessary controls	0 No incentives for innovation and competition	0 Lengthy process and inefficient use of information	0 Likely to have negative impacts on most stakeholders
Option 2- adopting a trusted regulator's decision + internal process (similar to the reissue process in Schedule 7 of the HSNO Act)	++ Appropriate management of substances	++ No reassessment happens but still achieve desirable management outcomes	++ Big benefits from not undertaking unnecessary reassessments Potentially saves costs for human health and the environment Potentially save costs for industry and end-users	+ Appropriate management encourages innovation and competition	+ Increase certainty of changes in hazard classifications	+ Likely to have positive impacts on most stakeholders
Option 3- adopting a trusted regulator's decision + controls updating process (similar to that provided for in section 63C of the HSNO Act)	+ Appropriate management of substances can be achieved faster than the status quo but not as fast as in Option 2 Appropriate management might not be achievable if the EPA or industry does not initiate/apply for a modified reassessment due to priority.	+ Reassessment could happen faster than the status quo because the 'grounds' step is not needed and the EPA has more discretion in consultation	+ Some savings from a new modified reassessment process	+ Depending on how the new modified reassessment is implemented	+ Depending on how the new modified reassessment is implemented,	+ Depending on how the new modified reassessment is implemented,

4.2. Streamlining consultation

Policy problem 4: Difficulties in collecting quality information

Table 4: Assessment of options for collecting quality information

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-Voluntary provision of information	0 Difficult to collect quality information → lengthy reassessment → inappropriate management of substances	0 Lengthy reassessment	0 Burden of costs on the regulator	0 High risk substances cannot be reassessed on time	0 Long reassessment process	0 Likely to have negative impacts on most stakeholders
Option 2-Statutory call for information + revocation before a reassessment	0 More incentives for industry to provide information → better management decision The revocation might be a too cautious decision	++ Reassessment can be completed very quickly	+ Fair distribution of costs between the regulator, industry and end-users	+ Potentially encourages innovation and competition	0 The Act must be changed to allow the EPA to revoke an approval because of the lack of information for reassessment	- Industry and end-users might be negatively affected by the revocation
Option 3- Statutory call for information + revocation after a reassessment	++ More incentives for industry to provide quality information → better management decision	+ Can expedite the reassessment thanks to quality information	+ Fair distribution of costs between the regulator, industry and end-users	+ Potentially encourages innovation and competition	+ The EPA can review whatever available evidence to make an appropriate decision, including the revocation	+ Industry and end-users have a second chance to provide information

Policy problem 5: The current modified reassessment process is time-consuming and resource –heavy as a full reassessment

Table 5: Assessment of options for a new modifies reassessment process

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-current targeted consultation	0 Time-consuming modified reassessment process Limited applicability → Inappropriate management	0 Low rates of reassessment	0 More costs for the regulator	0 No incentives for innovation and competition	0 Time-consuming process	0 Likely to have negative impacts on most stakeholders
Option 2-New targeted consultation	++ A more applicable modified reassessment process to achieve appropriate management	++ A faster reassessment process → would increase reassessment rates	++ Potentially saves costs for the regulators and costs for the human health and the environment	++ Potentially encourages innovation and competition	++ A more applicable modified reassessment process	++ Likely to have positive impacts on most stakeholders

4.3. Avoiding duplication of work during reassessment

Policy problem 6: Duplication of work in reassessing priority chemicals

Table 6: Assessment of options for avoiding duplication of work in assessing priority chemicals

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-grounds step for PCL reassessments	0 More lengthy reassessment that it could be	0 Slower reassessments	0 More costs for the regulator	0	0	0
Option 2-Statutory recognition of PCL + no grounds step for PCL reassessments	+ Shorter time for reassessments of PCL	++ Saves the time for grounds → increase reassessment rate	++ Save the costs of grounds	+ Encourage innovation	+ If there are minor changes to the prioritisation process	+ If there are ways to signal industry about the upcoming reassessment
Option 3-Include the PCL in the list of grounds	+ Shorter time for the reassessments of PCL	+ There is a small saving of the time for the grounds step	+ Small saving of the costs of the grounds step	+ Encourage innovation	++ The 'grounds' step maintains but is more straightforward	++ Industry is signalled about the upcoming reassessment

Policy problem 7: Duplication of work in the assessment and reassessment of substances with the same active ingredient

Table 7: Assessment of options for assessment and reassessment of substances with the same active ingredient

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1: Status quo- Two separate processes	0 Inconsistency in management decisions	0 Creates more reassessments Cannot save time when possible	0 Heavily ineffective as more reassessments are needed Cannot save costs when possible	0 Does not encourage innovation as applicants still can apply for an approval of a substance with an active ingredient being reassessed	0 Uncertainty as the EPA have options to progress with more costs on the regulator	0 Benefits for the applicant but not for human health and the environment
Option 2-Combined process of the new assessment and concurrent reassessment	+ More consistencies in management decisions	++ Saves time for unnecessary reassessments Potentially saves time from a combined process	++ Saves costs for unnecessary reassessment Potentially saves costs from a combined process	+ Potentially promote innovation and competition	+ Might need works on how to undertake a combined process	++ Benefits from the consistencies for all stakeholders The applicant might have to wait longer for the regulator's decision but the benefits outweigh the costs
Option 3- Decline/Postpone an application, pending a reassessment decision	+ More consistencies in management decisions	+ Saves time for unnecessary reassessments	+ Saves costs for unnecessary reassessments	+ Potentially promote innovation and competition	+ If there are criteria for the decline/postpone	+ Uncertainty for industry because an application can be declined or postponed but a legislative change could clarify when it can happen Longer wait for access to market for new substances

Policy problem 8: Updating existing controls based on a recent assessment

Table 8: Assessment of options for updating controls on existing substances

	Appropriate management of substances to protect human health and the environment	**Time saving**	**Cost effectiveness**	**Promote innovation and encourage competition**	**Integrity, clarity, certainty, and transparency of the processes**	**Stakeholders' satisfaction**
Option 1-Status quo	0 Inconsistency in management decisions	0	0	0 Does not encourage innovation and competition	0	0
Option 2-Combined process	+ More consistencies in management decisions	+ More reassessments could be done	+ Can save cost of gathering information for reassessment	+	0 Creates uncertainty for new application	- Applicant of the new substance might be negatively affected by the combination
Option 3: Controls updating process	++ More consistencies in management decisions	+ Save time of a full reassessment	+ Save costs of a full reassessment	+ Promote innovation and competition	+ If a controls updating process is well developed	++ Likely to have positive impacts on most stakeholders

Section 5: Conclusion

151. Based on the impact analysis in Section 4 we found some options are more preferable than others (see below). However, this assessment is based on current information. We are expecting public feedback to inform a formal cost-benefit analysis, which will be used to identify preferred options to report to Cabinet.

152. The preferable options are aimed to reduce costs, speed up processes and reduce regulatory burden on the regulator and industry.

5.1. Making better use of information

Policy problem 1: Inefficiency in using of international information

Table 9: Option 2C: Applying trusted regulators' information and then consider the New Zealand context and the requirements of the HSNO Act to make a final decision during assessments of new hazardous substances and reassessments of existing substances.

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	No	
Regulators	Costs of providing regulations/guidelines on the trusted regulator approach (one-off cost) Costs of establishing relationships with trusted regulators (one-off cost) Risks of adopting inappropriate decision is managed by regulations/guidelines about trusted regulator and the consideration of the New Zealand context	Low
Wider government	Currently WorkSafe relies on information from the EPA to set and update workplace controls. If the EPA is able to apply a trusted regulator's information, changes may be required to how WorkSafe obtain information for its own process.	Not identifiable
Other parties	Risks of adopting inappropriate decision is managed by regulations/guidelines about trusted regulator and the consideration of the New Zealand context	
Total Monetised Cost		Low
Non-monetised costs		None
Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Benefits of not re-producing data/information for applications (on-going benefits)	High
Regulators	Benefits of not re-producing data/information and not verifying and reviewing some data/information (on-going benefits)	High

	Average costs of an assessments range from $19,500 to $111,000, depending on the categories of the applications. A notified assessments can take at least 5 months. Costs of a reassessment vary depending on the scale of the reassessment. Some can take up to $1 million, others can be about $25,000. Better use of international information can save time and resources for the regulator when assessing new substances and reassessing existing substances.	
Wider government	Depending on how WorkSafe and MBIE response to the change, there may be benefits from sharing information.	Not identifiable
Other parties	On-going benefits of a faster assessments and reassessments which allows for more appropriate chemical management. On-going benefits of beneficial substances being available for use and high risk substances being removed from market, which could encourage innovation and competition.	High
Total Monetised Benefit		High
Non-monetised benefits		High

Policy problem 2: Difficulties in suspending an approval

Table 10: Option 2: Amending the HSNO Act to allow for a more feasible suspension or temporary restriction

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	The temporary suspension or restriction can sometimes be a too cautious decision and might impact the commercial sales of the substance Risk of a too cautious decision can be managed by criteria of applying the suspension based on trusted information	Low
Regulators	Costs of making the suspension/restriction decision (on-going costs) and identifying trusted sources of information (one-off cost)	Low
Wider government	No	
Other parties	End-users might not be able to use a substance for a short period of time in very rare cases when the suspension is a too cautious decision	Low

	Risk of a too cautious decision can be managed by criteria of applying the suspension based on trustworthy sources of information	
Total Monetised Cost		Low
Non-monetised costs	The suspension/restriction is a too cautious decision in rare cases	Low

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	On-going benefits of not importing, manufacturing, using a very high risk substance	High
Regulators	On-going benefits of being more responsive in chemical management	High
Wider government		
Other parties	On-going benefits of appropriate chemical management On-going benefits of high risk substances could be removed from the market which could encourage innovation and competition	High
Total Monetised Benefit		High
Non-monetised benefits		High

Policy problem 3: Unable to apply a trusted regulator decision to change a hazard classification

Table 11: Option 2: Applying a trusted regulator's decision to change the hazard classification of a chemical following an internal process

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*

Additional costs of proposed approach, compared to taking no action		
Regulated parties	No	
Regulators	Costs of providing regulations/guidelines on the trusted regulator concept (one-off cost) No risks have been identified	Low
Wider government	No	
Other parties	No	
Total Monetised Cost		Low
Non-monetised costs		None

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Benefits of faster changes of hazard classifications	High

Regulators	On-going benefits of not assessing the changes of hazard classification in some cases. On-going benefits of faster changes of hazard classifications to lead to appropriate chemical management	High
Wider government		
Other parties	On-going benefits of faster changes of hazard classifications which allow for more appropriate chemical management	High
Total Monetised Benefit		High
Non-monetised benefits		High

5.2. Streamlining consultation

Policy problem 4: Difficulties in collecting quality information

Table 12: Option 3: Giving 'the call for information' a statutory status and allow the EPA to revoke an approval due to the lack of information on the benefits of a substance

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	On-going costs for providing quality information for reassessments. However the cost can be insignificant because industry and end-users are holding the information. Some manufacturers/importers might not want to share sensitive information to maintain an approval because competitors might be benefited from the information. It is difficult to estimate the costs in this case	Low/Medium Not identifiable
Regulators	No	
Wider government		
Other parties	Un-known costs if manufacturers decide to withhold information to maintain an approval, and there is no available alternatives	Not identifiable
Total Monetised Cost		Low/ Not identifiable
Non-monetised costs		Not identifiable
Expected benefits of proposed approach, compared to taking no action		
Regulated parties	On-going benefits from faster reassessments	High
Regulators	On-going benefits from quality information for reassessments and faster reassessments	High

Wider government		
Other parties	On-going benefits from faster reassessments	High
Total Monetised Benefit		High
Non-monetised benefits		High

Policy problem 5: The current modified reassessment process is time-consuming and resource-heavy as a full reassessment.

Table 13: Option: 2: Amending the HSNO Act to provide more flexibility in ways the EPA can consult during the modified reassessment process.

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	Might lose an opportunity to submit if the EPA consider they are not affected by the reassessment. However, as modified reassessments only change an aspect of an approval this cost is considered insignificant.	Low
Regulators		
Wider government		
Other parties	No more opportunities to submit because there is no public notification. As above, this cost can be insignificant.	Low
Total Monetised Cost		Low
Non-monetised costs		
Expected benefits of proposed approach, compared to taking no action		
Regulated parties		
Regulators	On-going benefits of avoiding the risk of missing consultation On-going benefits of shorter targeted consultation and faster reassessment	High Medium
Wider government		
Other parties		
Total Monetised Benefit		Medium
Non-monetised benefits		High

5.3. Avoiding duplication of work during the reassessment process

Policy problem 6: Duplication of work in reassessing priority chemicals

Table 14: Option 2: Giving the PCL a statutory recognition and skipping the grounds for reassessments of PCL.

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	No	
Regulators	One-off costs of minor changes to the EPA's screening tool No risks have been identified	Low
Wider government	No	
Other parties	No	
Total Monetised Cost		Low
Non-monetised costs		None
Expected benefits of proposed approach, compared to taking no action		
Regulated parties	On-going benefits of faster reassessments of the most concerned chemicals	High
Regulators	On-going benefits of faster reassessment of the most concerned chemicals The saved costs of determining the grounds for one reassessment is about $16,000 There are currently 39 chemicals in the PCL list. The list is a living document and will be updated periodly.	High
Wider government		
Other parties	On-going benefits of faster reassessments of the most concerned chemicals	High
Total Monetised Benefit		High
Non-monetised benefits		High

Policy problem 7: Duplication of work in the assessment and reassessment of substances with the same active ingredient

Table 15: Option 2: Combining the two processes so that they are decided together with consistent controls

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
Regulated parties	Applicants of new substances might have to wait longer for the reassessment decision	Medium
Regulators		
Wider government		
Other parties		
Total Monetised Cost		Medium
Non-monetised costs		
Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Avoiding the reassessment of the new approval if controls on the reassessment decision are more lenient than those in the new approval Level playing field	High High
Regulators	Avoiding the reassessment of the new approval if controls on the reassessment decision is stringent than those in the new approval Consistency in chemical management	High High
Wider government		
Other parties	Consistency in chemical management	High
Total Monetised Benefit		High
Non-monetised benefits		High

Policy problem 8: Updating controls on existing substances

Table 16: Option 3: Using a controls updating process to change existing approvals to align with the new approval.

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		

Regulated parties	Costs to apply for a controls updating process	Medium
Regulators	One-off cost to identify the new controls updating process	Low
Wider government		
Other parties		
Total Monetised Cost		Medium
Non-monetised costs		

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Consistency in chemical management Shorter controls updating process, easier to apply for minor changes	High Medium
Regulators	Consistency in chemical management, easier to undertake a small review for minor changes in controls	High
Wider government		
Other parties	Consistency in chemical management Easier for minor changes in controls	High
Total Monetised Benefit		**Medium**
Non-monetised benefits		**High**

Section 6: Implementation and operation

153. Based on feedback from the public on policy problems and proposed options, we will continue our policy analysis to propose preferred options for changes. We will identify the most appropriate approach to give effect to the proposed changes in a subsequent cabinet policy paper later in 2019.
154. It is likely that the EPA and chemical industry will be required to implement the changes. Some proposed changes would provide the EPA with more flexibility and discretion in its decision-making. We will carefully consider them against the EPA's accountability and function as an independent regulator of hazardous substances.
155. There may be operational and resources implications on WorkSafe from the trusted regulator approach.
156. We will seek input from industry and the public about the proposals and how they can be implemented.
157. We also seek submissions from all stakeholders about the proposed changes.
158. We expect the changes to be adopted and implemented in mid-2021.

Section 7: Monitoring, evaluation and review

7.1 How will the impacts of the new arrangements be monitored?

159. The impacts of the proposed changes could be measured by the saving from using trusted regulators' information when assessing and reassessing hazardous substances and other improvements. The ultimate impacts of the proposals is better management of hazardous substances to protect human health and the environment.

160. Feedback from the EPA, chemical industry, and the public is important for evaluating the impacts of changes.

7.2 When and how will the new arrangements be reviewed?

161. We do not anticipate any foreseeable review of the proposed changes unless there is feedback from the EPA or stakeholders about issues relating to the implementation of the changes.