

**Regulatory Impact Assessments on proposed amendments to the Hazardous Substances and New Organisms Act 1996**

Advising agencies	Ministry for the Environment
Decision sought	Policy decisions on proposed improvements to the assessments and reassessments of hazardous substances.
Proposing Ministers	Minister for the Environment

**Section A - Summary: Problem and Proposed Approach**

<p><b>Problem Definition</b></p> <p><b>What problem or opportunity does this proposal seek to address? Why is Government intervention required?</b></p>
<p><i>Summarise in one or two sentences</i></p>
<p>In New Zealand, the Environmental Protection Authority (EPA) is responsible for managing more than 150,000 hazardous substances under the HSNO Act. The EPA approves new hazardous substances and sets controls over them, and also reassesses hazardous substances to ensure the existing controls are fit for purpose.</p> <p>The assessment and reassessment of hazardous substances can be time-consuming and resource-intensive. The consequence of slow and costly processes is inadequate incentives for the introduction of new, beneficial hazardous substances, and for the replacement of old, harmful ones.</p> <p>The EPA has been making operational improvements through their hazardous substances modernisation programme to better manage hazardous substances in New Zealand. The programme includes updating the hazardous substance classification system and upgrading its hazardous substances database. Effort has also been made to increase funding for assessments and reassessments.</p> <p>The EPA sought Ministerial approval to investigate options for legislative changes to achieve more improvements to the processes. Enabling the EPA to make better use of international information is a potential way to increase the process' efficiency. This approach was also supported by a Technical Working Group's independent report on hazardous substances compliance system. Other policy issues of reassessments could also be addressed through this legislative change.</p>

<p><b>Proposed Approach</b></p> <p><b>How will Government intervention work to bring about the desired change? How is this the best option?</b></p>
<p><i>Summarise in one or two sentences</i></p>
<p>We are proposing enabling the EPA to apply information from international regulators that it trusts as having a reliable and similar approach (trusted regulators). The EPA will continue to consider the New Zealand context and the requirements under Part 2 of the Hazardous Substances and New Organisms (HSNO) Act 1996 when applying information</p>

from trusted regulators, but will have discretion over consultation, except in particular circumstances.

We are also proposing enabling the EPA to react to potential actual or imminent danger to protect human health, safety, and the environment. Other improvements to reassessments will contribute to streamline the process and avoid duplication of work.

## 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 would provide the EPA with more flexibility and discretion in decision-making. The proposals are expected to incentivise the introduction of beneficial substances and replacement of harmful substances. This will support the appropriate management of hazardous substances to protect human health, safety, and the environment. They could also save time and resources for the EPA and industry.

One proposal would enable the EPA to temporarily restrict certain uses of a hazardous substance to better protect human health, safety, and the environment.

More effective and efficient processes also benefit industry and the general public as they would support timely and appropriate hazardous substances management and allow communities to derive benefits from the use of those hazardous substances.

It is difficult to accurately quantify the benefits of these proposals. A cost benefit analysis commissioned by MfE showed the monetised benefit from these proposals could be less than \$10 million to the economy over 10 years. However, the non-monetised benefits to human health, safety, and the environment from more timely and a greater number of assessments and reassessments will generate positive effect.

### Where do the costs fall?

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

Feedback from the public showed that it is important for the EPA to consider the applicability of information from trusted regulators to the New Zealand context to ensure appropriate hazardous substances management. The EPA will continue to do so and meet the requirements under Part 2 of the HSNO Act.

We are proposing the EPA's discretion over consultation in three proposals. The discretion may limit the public's ability to submit on some applications. Changes to the Hazardous Substances and New Organisms (Methodology) Order 1998<sup>1</sup> will set criteria for the EPA's discretion to ensure that affected parties are consulted where appropriate.

<sup>1</sup> The HSNO Methodology Order contains regulations on making decisions during assessments and reassessments under Part 5 of the HSNO Act. The Methodology Order is made by Order in Council following a regulatory process (which includes a public consultation led by the EPA) under section 9 of the HSNO Act

Proposals on applying information from trusted regulators may have operational and resource implications on WorkSafe if the number of assessments and reassessments involving workplace controls would increase, or if information used by the EPA would not be sufficient for WorkSafe to set workplace controls under the Health and Safety at Work Act 2015, and thus require WorkSafe to collect further information itself. The EPA and WorkSafe are expected to work on cooperation arrangements for hazardous substances assessments to achieve full benefits from these proposals.

The Government may incur costs for implementing the 'trusted regulator' approach. These include costs of amending the HSNO Act and the Methodology Order, and the costs of identifying and establishing relationships with 'trusted regulators'.

One proposal would enable the EPA to temporarily restrict certain uses of a hazardous substance if there would be potential actual or imminent danger to human health, safety, or the environment. This may cause significant impacts on the chemical industry and end-users if the restricted hazardous substances are important to their businesses and there are no suitable alternatives. We recommend the EPA engages with directly affected stakeholders to inform the decision in advance. We also set other conditions, including ensuring the highest priority for reassessment of restricted hazardous substances to reduce any unintended impacts of the restriction.

Another proposal would enable the EPA to align the timeframes of assessments and reassessments of hazardous substances containing related chemical or substance (such as the same active ingredient), in a specific situation to achieve efficiency and consistency. This may have impacts on applicants of new hazardous substances while waiting for a reassessment decision. However we consider the benefits would outweigh the cost.

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

These changes will effectively create a more dynamic hazardous substances regime, where assessments and reassessments will happen more quickly. This requires the EPA to be more transparent and responsive in its engagement with applicants and the public regarding its assessment and reassessment programme and processes.

Risks from applying information from trusted regulators will be managed through changes to the Methodology Order, which will specify the implementation of trusted regulator proposals. In addition, the decisions of the EPA continue to be subject to judicial review proceedings, which can consider a decision made under statutory powers. An affected party could also potentially seek an injunction through the courts if their business or undertaking was likely to be substantially impacted by an EPA decision and there were grounds for such a proceeding.

Ongoing operational improvements and increased budget and funding for assessments and reassessments of hazardous substances could also help address the backlog of reassessment and incentivise the introduction of safe, beneficial substances.

To manage potential risk from the proposed temporarily restriction of certain uses of a hazardous substance, we propose specific requirements for the implementation of the power.

**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?*

Our analysis is based on information from the EPA, public submissions, cost benefits analysis and interdepartmental consultation.

*To be completed by quality assurers:*

**Quality Assurance Reviewing Agency:**

The Ministry for the Environment's Regulatory Impact Analysis Panel has reviewed the RIA.

**Quality Assurance Assessment:**

The panel considers that the RIA partially meets the quality assurance criteria.

**Reviewer Comments and Recommendations:**

The RIA contains required information, and clearly sets out objectives and criteria. There is evidence of consultation on the proposals and consideration of feedback from consultation. The analysis is constrained by a narrow problem definition relating to "trusted regulator" proposals, although this scope is clearly described. A range of impacts have been identified but may be incomplete. Implementation relies on development of a secondary instrument (Methodology Order), and the RIA indicates that further implications will be assessed as part of that process.

## 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 Assessment (RIA), except as otherwise explicitly indicated. The analysis and advice have been produced for the purpose of obtaining Government decisions on proposed improvements to the assessments and reassessments of hazardous substances.
2. The purpose of the project is to make assessments and reassessments of hazardous substances more efficient so that we can better protect human health, safety, and the environment. The aim is to:
  - improve the efficiency of assessments and reassessments by making better use of international information
  - make appropriate decisions to protect human health, safety, and the environment, and to enable communities to derive benefits from hazardous substances
  - manage existing hazardous 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" (section 4).

### Key Limitations or Constraints on Analysis

4. This analysis is limited to policy problems relating to the use of international information during assessments and reassessments of hazardous substances, and some other issues with the reassessment process. A broader review of the initial 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 and the existing mechanisms that protect confidential information under the HSNO Act.
6. The proposed amendments to the HSNO Act and the HSNO Methodology Order are part of initiatives to better regulate and manage hazardous substances in New Zealand. The Environmental Protection Authority (EPA) has been working on its chemical modernisation programme, which is updating the hazardous substances classification system and upgrading the EPA's hazardous substances database. The EPA has also sought budget funding to support its assessment and reassessment programme in the financial year 2020/2021. Work has also been started to look at the cost recovery mechanism (see more in figure 3).
7. In addition, an independent Technical Working Group reported in 2019 on its evaluation of the hazardous substances compliance system in New Zealand.<sup>2</sup> MfE and the EPA are working on the recommendations of the report. One of the report findings was that the trusted regulator concept could speed up the reassessment process and help achieve

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<sup>2</sup> [https://www.epa.govt.nz/assets/Uploads/Documents/EPA-Publications/Hazardous\\_Substances\\_Compliance\\_System\\_Findings\\_Report\\_2019.pdf](https://www.epa.govt.nz/assets/Uploads/Documents/EPA-Publications/Hazardous_Substances_Compliance_System_Findings_Report_2019.pdf)

- international alignment of standards. The report recommended the EPA continues to pursue the introduction of the trusted regulator mechanism.
8. Since December 2017, as a result of the 2015 Health and Safety at Work reforms, WorkSafe New Zealand (WorkSafe) has been involved in the EPA's hazardous substances assessment and reassessment processes. Workplace controls on hazardous substances are set and updated under the Health and Safety at Work Act 2015 (HSWA). WorkSafe is facing a similar issue regarding quality information for its own process to set and update workplace controls on hazardous substances.
  9. If the EPA was able to apply information from trusted regulators, it would share the information with WorkSafe. In some circumstances, because of the different requirements under the two legislation, WorkSafe may require further information that is not available from the EPA. These different requirements require full and early information sharing and cooperation between the two regulators to achieve the full benefits of the proposals.
  10. The proposals could also have operational and resource impacts on WorkSafe if the number of assessments and reassessments involving workplace controls were to increase, or if information used by the EPA were not sufficient for WorkSafe to set workplace controls under the HSWA, and thus required WorkSafe to collect further information itself. The EPA and WorkSafe are expected to work on cooperation arrangements for hazardous substances assessments.
  11. We received information and evidence for our analysis from the EPA, feedback from public consultation, interdepartmental consultation and a cost benefit analysis commissioned by MfE.
  12. Time and costs for assessments and reassessments vary, depending on the complexity of the hazardous substance(s), and the number of related approvals. The number of applications for new hazardous substances depends on the demand from the chemical industry and end-users. The number of reassessments depends on the available budget and other resources, as well as the demand from the chemical industry and the public.
  13. It is difficult to accurately quantify the monetary benefits of these proposals. A cost benefit analysis commissioned by MfE showed the monetised benefit from these proposals could be less than \$10 million to the economy over 10 years. However, the non-monetised benefits to human health, safety, and the environment from more timely and a greater number of assessments and reassessments will generate positive effect.
  14. The cost benefit analysis identifies three key features of assessments that may limit possible benefits from changes. They are the relatively low number of assessments and reassessments, the relatively high fixed costs of the processes, and the high level of expertise required.
  15. There is a need for further engagement on the criteria and process for identifying trusted regulators and how their information could be used, including criteria for the EPA's discretion over consultation and increased transparency in the EPA's work plan. We propose changes to the Methodology Order to stipulate these matters in detail. As the Methodology Order is made by regulations, the proposed changes require public consultation led by the EPA.
  16. We have worked closely with the EPA in finalising policy problems and proposing options for improvements. WorkSafe has also provided feedback for the cost benefit analysis.

17. Policy problems and proposed options have been consulted with the chemical industry, end-users, iwi/Māori, NGOs, central and local government agencies, and the public. Feedback from consultation have been used in proposing preferred options.



Glenn Wigley

**Director**

**Natural and Built Systems**

**Ministry for the Environment**

Proactively released

## 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

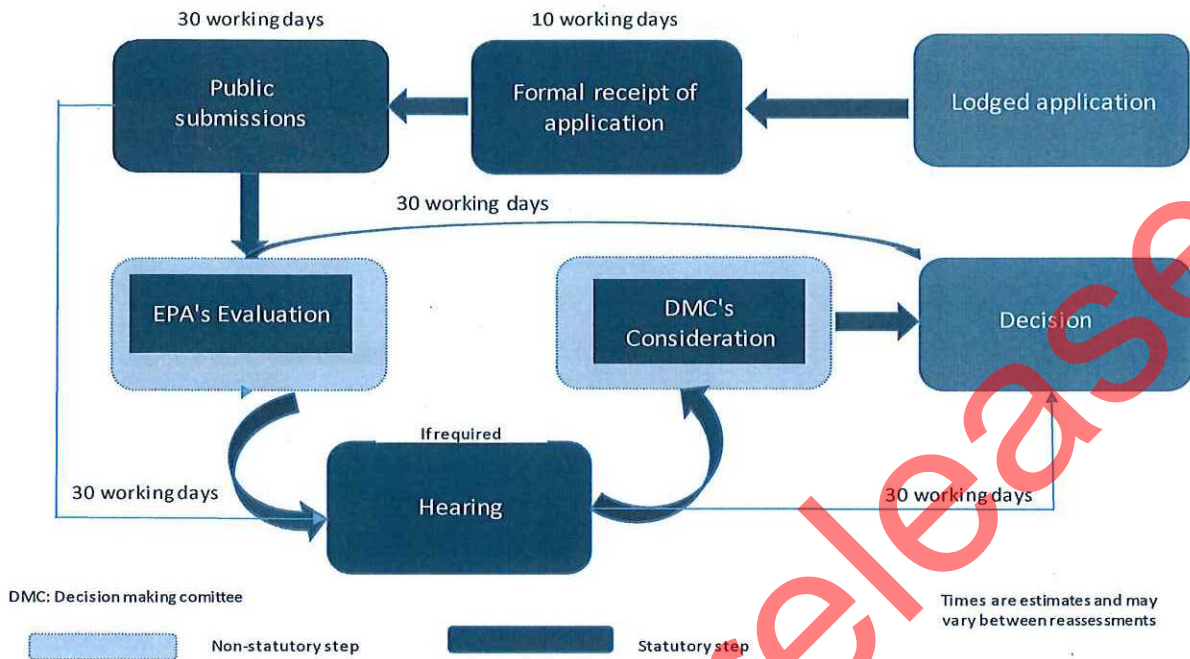
18. The Hazardous Substances and New Organisms (HSNO) Act came into force for hazardous substances on 2 July 2001. The Act's purpose is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.
19. The Environmental Protection Authority (EPA) is responsible for managing more than 150,000 hazardous substances under the HSNO Act. The EPA approves new hazardous substances and sets controls over them, and also reassesses hazardous substances to ensure the existing controls are fit for purpose. WorkSafe New Zealand (WorkSafe) provides the EPA with advice on workplace controls for hazardous substances and enforces rules for the use of hazardous substances in the workplace.
20. Under the HSNO Act, new hazardous substances that have not been legally present in New Zealand must be assessed and approved with appropriate controls before being manufactured or imported. Hazardous substances legally present in New Zealand prior to 2001 were transferred to the new Act.

#### Assessment under the HSNO Act

21. 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), hearings 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).
22. 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 subsequent steps.
23. 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 Tiriti o Waitangi), and:
  - 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.
24. WorkSafe can be involved in the process if the use of the hazardous substance requires workplace controls under the HSWA 2015. WorkSafe may initiate a Safe Work Instrument process alongside the EPA assessment to add or vary workplace controls if needed. This process includes public consultation.



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

25. Under the HSNO Act, a reassessment is deemed to be an application. It is a two-step process: formal justification for reassessment (grounds step) and reassessment application. The formal justification for reassessment determines if there is new significant information to trigger a reassessment.<sup>3</sup>

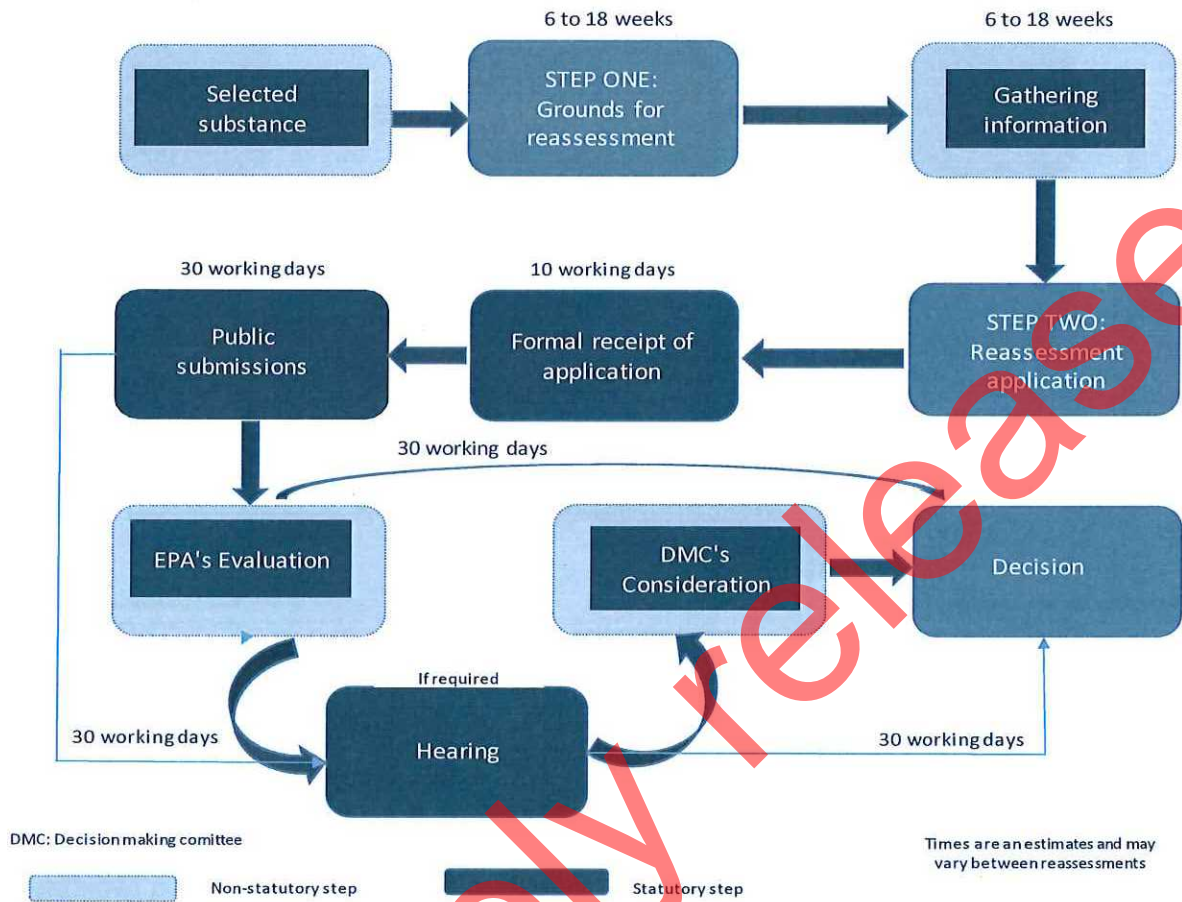
26. The reassessment application process follows the same procedure of the application process. There may also be a non-statutory call for information before the application is lodged (see figure 2). All reassessment decisions, including determining the grounds for reassessments, must be undertaken by 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. Reassessments involve evaluating all the effects of an approved hazardous 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.

<sup>3</sup> Note that grounds for reassessments of some hazardous substances have been established but reassessment applications for them have not been proceeded because of different reasons including the cost and time of the process and the backlog of reassessments.

Figure 2: Full reassessment process



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

29. 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,<sup>4</sup> 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). It takes at least five months for the EPA to process a publicly notified application. Some applications can take more than two years.

30. Reassessments are currently comprehensive, time-consuming and resource-heavy, especially where they cover multiple chemicals and approvals. Average costs of a formal justification for reassessment (grounds step) 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.

31. Since 2001, the EPA has completed 31 Chief-Executive-initiated reassessments and 20 external reassessments. In 2018, the EPA identified 39 chemicals that it considers are in need of review in New Zealand. This prioritisation process is ongoing and new chemicals could be added to the list. Timely reviews of hazardous substances containing these chemicals would support the appropriate management of hazardous substances to protect human health, safety, and the environment.

<sup>4</sup> The EPA categorises applications based on the level of complexity of the applications.

32. 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?

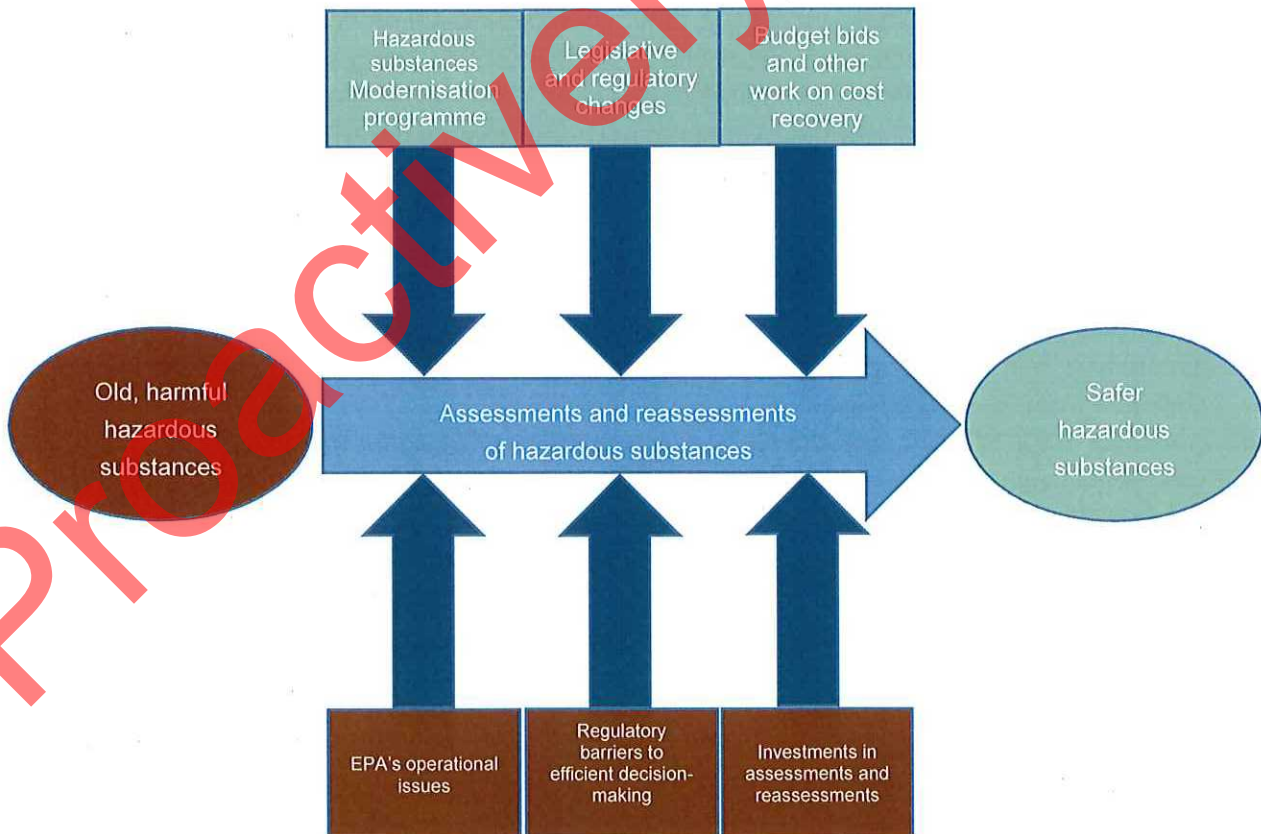
33. Our 2017 regulatory stewardship strategy expressed an intention to improve the system for monitoring hazardous substances, to better identify more long-term effects on the environment.

34. This project is looking at potential improvements to the assessment and reassessment processes to better manage hazardous substances. 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.

35. The EPA is an independent regulator of hazardous substances in New Zealand and the only agency empowered with approving new hazardous substances and reassessing substances already in the market. Its operation must be in accordance with the HSNO Act. Potential changes to the system would require changes to the legislation and its Methodology Order.

36. These proposed amendments to the HSNO Act and the Methodology Order are part of a broader work programme to better regulate and manage hazardous substances in New Zealand (see paragraphs 6, 7 and figure 3).

Figure 3: Appropriate management of hazardous substances.



## 2.3 What is the policy problem or opportunity?

### 2.3.1. Making better use of information from trusted regulators

*Policy problem 1: Enabling the EPA to apply data, information, assessments, and decisions from trusted regulators*

37. Currently, the assessment and reassessment of hazardous substances in New Zealand can be time-consuming and resource-intensive. The consequence of slow and costly processes is inadequate incentives for the introduction of new, beneficial hazardous substances, and for the replacement of old, harmful ones.
38. The EPA has been making operational improvements through their hazardous substances modernisation programme to better manage hazardous substances in New Zealand. The programme includes updating the hazardous substance classification system and upgrading its hazardous substances database. Effort has also been made to increase funding for assessments and reassessments (see Appendix 1).
39. The EPA sought and gained Ministerial approval to investigate options for legislative changes to achieve more improvements to reassessments. Enabling the EPA to make better use of international information is a potential way to increase the process' efficiency. During the policy development, we received direction from Ministers to extend the scope of this project to enable the EPA to make better use of international information to the initial assessments of new hazardous substances.
40. Making better use of international information through a trusted regulator approach was also supported by a Technical Working Group's independent report on hazardous substances compliance system.<sup>5</sup>
41. New Zealand does not manufacture many chemicals. 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 of hazardous substances<sup>6</sup> has been produced and used overseas.
42. Currently the HSNO Act and the Methodology Order requires the EPA to carry out an assessment of all information from all sources, and decision-making processes, which may include consultation and hearing(s). In many instances, however, the information from international regulators, in combination with the applicant's information and the EPA's existing databases would be sufficient to make satisfactory decisions. Undertaking a public notification and holding hearing(s) can be very costly and time-consuming, and sometimes disproportionate with the level of further information collected from these processes.
43. Currently, the HSNO Act provides a rapid assessment process for new hazardous substances with components that have already been assessed by a previous EPA assessment subject to specific conditions (section 28A). However, there is currently no simplified process for applying information and assessments from international regulators that the EPA trusts. This does not enable New Zealand to take advantage of international intellectual property, and to save time and resources in evaluating hazardous substances.

<sup>5</sup> [https://www.epa.govt.nz/assets/Uploads/Documents/EPA-Publications/Hazardous\\_Substances\\_Compliance\\_System\\_Findings\\_Report\\_2019.pdf](https://www.epa.govt.nz/assets/Uploads/Documents/EPA-Publications/Hazardous_Substances_Compliance_System_Findings_Report_2019.pdf)

<sup>6</sup> A hazardous substance can be a chemical or a formulation of different chemicals that meets hazardous classification criteria.

44. 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.<sup>7</sup> Other government agencies that consider medicines and agricultural compounds are making good use of international information by using special pathways for evaluation and registration.<sup>8</sup>
45. There is an opportunity to streamline assessments by making better use of international information following a simplified process.

*Policy problem 2: Providing a simplified process for updating hazard classifications of hazardous substances and corresponding controls based on information from trusted regulators*

46. Currently, change to a hazard classification and corresponding controls of existing hazardous substances must be undertaken through a modified reassessment, which includes the formal justification for reassessment (grounds step) and a reassessment application process with consultation and hearings if requested.
47. 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 would be in place for a longer time. This situation also creates inconsistency in hazardous substances management where new hazardous substances are approved using the new classification but old approvals are not readily updated.
48. In 2005, the carcinogenicity classification was added to 4,4'-Methylenediphenyl diisocyanate, but the EPA only made similar changes in 2016 after an EPA Chemical Review and a full reassessment process. There could have been an opportunity to undertake the update earlier if there had been a simplified process available for this type of change, and no backlog of reassessments.

*Policy problem 3: Enabling the EPA to temporarily restrict certain uses of a hazardous substance*

49. Currently the HSNO Act allows the EPA to suspend approvals during a reassessment process if there is reasonable cause to believe there is significant actual or imminent danger to human health, safety, or the environment from the continued use of the hazardous substance (section 64). The current threshold of "significant" actual or imminent danger is a very high and difficult bar to reach in practice.
50. The suspension power only applies after 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.
51. There are circumstances when international or domestic information indicates a need for immediate response, such as when an international regulator bans a chemical or revokes the approval of a chemical because of new information on its high risk to human health. In another situation, a recent EPA assessment of a hazardous substance may

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<sup>7</sup> For example, Australia's Approved Foreign Scheme with Canada, and modular notification with Canada, the US and the EU, or the OECD's parallel process.

<sup>8</sup> For example, Ministry for Primary Industries' Agricultural Compound and Veterinary Medicine Registration by Reference to Australia Pest and Veterinary Medicines Authority's registrations, and MedSafe's abbreviated evaluation process using evaluation reports from recognised regulatory authorities.

require the restriction of certain uses of related hazardous substances.<sup>9</sup> The current section 64 does not allow the EPA to immediately react in these circumstances to protect human health, safety, and the environment.

52. During the development of a reassessment application of chlorothalonil, a fungicide to control fungal leaf diseases in vegetables, turf and ornamental crops, the EPA had significant concern about its domestic uses. The concern was triggered following an EPA declined approval for a related substance and the overseas prohibition of domestic uses of chlorothalonil. A temporary restriction before the reassessment completed would have provided earlier protections to human health, safety, and the environment.

### 2.3.2. Other improvements to the reassessment process

#### *Policy problem 4: Enabling more targeted consultation during modified reassessments*

53. The HSNO Act allows the EPA to undertake a modified reassessment where it reviews only one or some specific aspects of an approval, excluding minor or technical amendments (section 63A). A modified reassessment cannot revoke an approval.
54. The current wording of section 63A 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”. This effectively means the EPA has to publicly notify modified reassessments in most cases because the EPA does not hold a database of all affected persons.
55. This situation does not allow for a faster process when the reassessment is straightforward and quality information has been obtained.

#### *Policy problem 5: Requiring the EPA to develop a publicly available work plan for reassessments, with items on this work plan deemed to meet the reassessment criteria*

56. Under section 62(2) of the HSNO Act, a decision making committee can decide that grounds for a reassessment exist after taking into account new information on the use, effect or management of existing hazardous substances. A decision making committee only considers if there exists new information for reassessment. The consideration does not guarantee that changes should be made to existing approvals.
57. The EPA undertakes an on-going prioritisation process to identify chemicals of current concern and in need of a review. This prioritisation process helps the EPA create a work plan for reassessment and will serve to improve transparency in the EPA work plan and decision-making. There are some duplication of work between the prioritisation process and the formal justification for reassessment (grounds step) of hazardous substances containing these chemicals.
58. Currently, to undertake a reassessment of priority hazardous substances, the EPA still have to carry out a formal justification process before the reassessment itself (see figure 2). The original intention of the formal justification was to prevent unfounded reassessment requests from externals. The HSNO Act drafters envisaged the need for a priority list of hazardous substances for reassessments. However, at that time there was no priority list available so the process was set universal for all hazardous substances.
59. Even though the formal justification step is not the major cause of the backlog of reassessments, there is an opportunity to save administrative cost and time for the EPA in preparing applications for formal justification for reassessments of priority hazardous

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<sup>9</sup> Related hazardous substances can be hazardous substances with the same active ingredient or the same component that provides the hazardous substances’ desired chemical or biological action on target organisms.

substances. There are no risks if hazardous substances containing priority chemicals are deemed to meet the grounds criteria for reassessment and can skip the formal justification step. This also helps save the cost and time for decision making committees to convene and consider the applications.

*Policy problem 6: Enabling the EPA to align the timeframes of the assessments and reassessments of related hazardous substances*

60. There is currently duplication of work where an application is made for a new hazardous substance with an active ingredient or a component that is already being reassessed. Currently, the EPA is required to process the new application separately from the reassessment.
61. It is possible to put an application on hold but it would need legal advice on a case by case basis and the EPA must ensure that the applicant is 'not unduly prejudiced'.
62. In some circumstances, a decision can be made on the new hazardous substance even though the reassessment is not complete. The new approval would then likely be reviewed, to reflect the reassessment decision. This costs the EPA time and resources and potentially creates inconsistencies in hazardous substances management at least in the short term.
63. 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 because there was not enough information to do so at the time of the approval. This requires a second reassessment for Diazinon 800EC NF.
64. Aligning the timeframe of an application for a new hazardous substance with that of an ongoing reassessment of related hazardous substances is desirable to achieve consistency. We consider that the EPA should be entitled to do so by changes to the HSNO Act.

*Policy problem 7: Providing a simplified process for updating controls on existing hazardous substances in a situation where the EPA has undertaken a recent assessment of a related hazardous substance*

65. Assessment of a new hazardous substance sometimes requires that controls on existing related hazardous substances, including hazardous substances with the same active ingredient, need to be updated.
66. Transferred hazardous substances<sup>10</sup> 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 hazardous substances, such as restricting their domestic uses, limiting use to ground-based methods only, or extending buffer zones and wind speed conditions. These controls may have not been applied for other related hazardous substances.
67. This creates discrepancies between the controls on the existing hazardous substances and the new hazardous substances. If the existing hazardous substances are not

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<sup>10</sup> Hazardous substances that were legally present in New Zealand before 2001.

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?

68. The analysis is limited in making better use of international information during assessments and reassessments of hazardous substances as well as other improvements for the reassessment process. It does not cover any aspect of the cost recovery mechanism and the existing mechanisms that protect confidential information under the HSNO Act.
69. This analysis does not include a consideration of all 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?

70. In March 2019, the project team engaged informally using a brief survey to targeted stakeholders and iwi, inviting their views on the early policy direction. The survey focused mainly on the reassessment process.
71. 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, and 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.
72. During policy development, we consulted the Ministry of Foreign Affairs and Trade and Ministry of Business, Innovation and Employment on international obligations regarding intellectual property policy when applying information from other regulators.
73. In July 2019, Cabinet agreed for the Ministry for the Environment to consult on proposed improvements to the assessments and reassessments of hazardous substances under the HSNO Act [CAB-19-MIN-0362]. The proposed improvements were set out in a discussion document *Hazardous substances assessments – Improving decision-making: proposed improvements to the assessments and reassessments of hazardous substances*.<sup>11</sup>
74. We consulted on the proposals during August and September 2019. We received 44 submissions from a range of individuals and groups, including iwi/Māori, NGOs, the chemical industry, primary industry sectors, local government and health agencies.
75. Most submitters supported making better use of international information, but also emphasised the importance of the New Zealand context. Submitters suggested in addition to international information, the EPA ought to consider potential impacts on access to some vital chemicals, financial impacts on industry, our native species and the unique environment, the importance of Māori knowledge, and obligations in Treaty of Waitangi settlements.
76. Feedback on other proposed improvements to reassessments of hazardous substances were mixed. Generally, submitters supported initiatives to reduce duplication of work

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<sup>11</sup> <https://www.mfe.govt.nz/publications/hazards/hazardous-substances-assessments-improving-decision-making-%E2%80%93-discussion>



and increase efficiency but also raised concerns about the workability and impacts of the proposals. Some submitters requested greater transparency of the EPA's work plan for reassessments and improved engagement practices.

77. In November 2019, we commissioned a cost benefit analysis to inform our final advice on the policy package.
78. Taking into consideration feedback from the public and the cost benefit analysis, we propose non-regulatory solutions for one proposal regarding the EPA's call for information. For the other seven proposals, we propose legislative and regulatory changes (sections 3-5).
79. In February 2020, we consulted with other government agencies on a draft Cabinet paper outlining our policy proposals and received support from agencies.

Proactively released

### Section 3: Options identification

80. In the discussion document, we identified potential options for improvements to the assessments and reassessments of hazardous substances.
81. Based on the feedback from the public and other government agencies, we worked with the EPA to develop preferred options to address policy problems explained in Section 2.
82. Integral to some of the proposals is the use of information provided by 'trusted regulators', which is explained below.

#### 'Trusted regulator' approach

83. 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<sup>12</sup> of the regulator, and the quality and applicability of information.
84. The information referred to here includes data, information, 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 consideration.
85. Internationally, no jurisdictions automatically apply the decisions of another regulator. However, some regulators are seeking to use international data and assessments from others.<sup>13</sup> Domestically, other agencies are also making good use of international information by using special pathways for evaluation and registration of agricultural compounds and medicines.<sup>14</sup>
86. Options for applying information from 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 appetites, biases, local context, and differences in chemical management systems.
87. Using information from trusted regulators is included in different proposals below.

#### 3.1. Making better use of information from trusted regulators

*Policy problem 1: Enabling the EPA to apply data, information, assessments, and decisions from trusted regulators*

##### Proposed options in the discussion document

88. Option 1 was the status quo, which has been discussed in Section 2. We proposed two other options for better use of international information.
89. Option 2 would allow the EPA to apply in part or whole information from trusted regulators 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:

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<sup>12</sup> A reliable regulator can be one that follows an independent, transparent and robust chemical assessment process, and has assessment reports and other information accessible to the EPA. The criteria of trusted regulators will be further developed through the regulatory process of amending the Methodology Order.

<sup>13</sup> For example, Australia's Approved Foreign Scheme with Canada, and modular notification with Canada, the US and the EU, or the OECD's parallel process.

<sup>14</sup> For example, Ministry for Primary Industries' Agricultural Compound and Veterinary Medicine Registration by Reference to Australia Pest and Veterinary medicines Authority's registrations, and MedSafe's abbreviated evaluation process using evaluation reports from recognised regulatory authorities.

90. 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 application's information.
91. 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.
92. 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 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.
93. These options would not require the EPA to obtain all data underpinning the assessments. This would help mitigate the effects of confidentiality requirements in other jurisdictions.
94. These options would require regulations or guidelines to set criteria and process for identifying trusted regulators, and how the information could be used.
95. These options would provide the EPA with discretion to make better use of international information. The EPA would retain the power to undertake full assessments or reassessments where needed to protect human health, safety, and the environment.
96. There was also an Option 3, which would allow the EPA to apply trusted regulators' decisions to immediately approve or ban a hazardous substance, without considering any New Zealand context. Analysis showed that no jurisdictions provide an automatic adoption of other regulators' decisions without a consideration of the local context. The option would compromise the EPA's independence in making decisions on hazardous substances management in New Zealand and might risk adopting inappropriate decisions influenced by political or commercial consideration.
97. Option 3 was inconsistent with the purpose and principles of the HSNO Act. This option was not included in the discussion document but mentioned in the preliminary RIA to demonstrate the range of options, and to provide evidence on why it was not a preferred option at that time.

#### Feedback from the public

98. Submitters generally supported making better use of international information, but were concerned that the New Zealand context needed to be maintained. Some submitters from the chemical industry and end-users asked to be involved in developing the criteria for selecting trusted regulators and applying their information. Submitters also queried how the EPA might deal with conflicting information from different regulators or important information withheld by trusted regulators because of confidentiality requirements. They were concerned whether stakeholders would still have an opportunity to submit their feedback during assessment and reassessment processes.

#### Preferred option after consultation

99. Taking into consideration feedback from the public, we propose amendments to the HSNO Act to:
- i. enable the EPA to apply data, information, assessments, and decisions from trusted regulators with a consideration of the New Zealand context (with consultation in its discretion, except in particular circumstances)
  - ii. specify that when the EPA decides not to consult, or is not required to consult, it will

follow a process specified by amendments to the Methodology Order, and the decision-making power will be delegated to the EPA's Chief Executive.

- iii. specify that when the EPA decides to consult, or is required to consult, it will follow the full assessment, or the full or modified reassessment processes provided under the current sections 28, 63, 63A, and 63C of the HSNO Act. The decision-making power will be delegated to an EPA decision making committee in this circumstance.
100. To implement the above changes, we also propose amendments to the Methodology Order to:
- i. set the criteria and process for identifying international regulators whom the EPA can trust (trusted regulators)
  - ii. specify the assessment and reassessment processes when the EPA applies information from trusted regulators<sup>15</sup>
  - iii. specify other requirements on the way the EPA applies information from trusted regulators, including how the EPA will apply a part or the whole package of information
  - iv. set the criteria for the EPA's discretion over consultation<sup>16</sup>
  - v. require the EPA to be more transparent about its work plan and decisions.
101. The EPA's Chief Executive will make decisions on the appropriate process for each assessment or reassessment applying information from trusted regulators in accordance with amendments to the Methodology Order.
102. The proposed amendments to the HSNO Act will only take effect after the proposed amendments to the Methodology Order have taken effect.
103. As the Methodology Order is made by regulations, the proposed changes require public consultation (led by the EPA). This will provide additional opportunity for stakeholders to be involved in developing the criteria and process.
104. Following changes to the HSNO Act being made, the Minister for the Environment will invite the EPA to start the regulatory process to amend the Methodology Order. The proposed changes to the Methodology Order will be brought to Cabinet for approval following the EPA's consultation.
105. We do not propose any amendments to the existing mechanism that protects confidential information under the HSNO Act. This is outside the scope of this project. While applying information from trusted regulators, the EPA will continue to comply with any relevant confidentiality requirements.

*Policy problem 2: Providing a simplified process for updating hazard classifications of hazardous substances and corresponding controls based on information from trusted regulators*

#### Proposed options in the discussion document

106. Option 1 was the status quo, which has been explained in Section 2. We proposed two other options.

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<sup>15</sup> These processes will have some similarities with the existing rapid assessment process provided under the current section 28A of the HSNO Act where certain information from a previous EPA assessment is applied for a new assessment.

<sup>16</sup> Consultation may be required, for example, if there were important gaps in information or the assessments would be complex (including situation where there is conflicting conclusions from different trusted regulators), or the application would have substantial impacts to human health, safety, and the environment or to New Zealand's economy and international obligations.

107. Option 2 would allow the EPA to follow an internal process to make change to hazard classifications and corresponding controls of a hazardous substance by applying a trusted regulator's decision to change the hazard classification of a related chemical.
108. Option 3 was similar to Option 2, however, the EPA would undertake a simplified process to make change to hazard classifications and corresponding controls of a hazardous substance. This process would not require the EPA to undertake the formal justification for reassessment (grounds step) and the EPA would have the discretion over consultation.
109. Both options would allow more timely decisions to change a hazard classification and corresponding controls based on an assessment and decision from trusted regulators. They would 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.
110. We also sought feedback on whether the EPA staff should be delegated to make purely technical decisions during a simplified process of updating hazardous substances controls.

#### Feedback from the public

111. Submitters generally supported the proposal but noted these processes may require targeted consultation. Submitters also supported the delegation of decision-making power but some raised concerns about the definition of 'technical decisions' and asked for a mechanism to appeal the decisions of the EPA's staff.

#### Preferred option after consultation

112. We propose amendments to the HSNO Act to:
- i. allow the EPA to follow a simplified process ('a process of updating hazardous substances controls') to make these changes when a trusted regulator decides to change the hazard classifications of a related chemical.<sup>17</sup>
  - ii. specify that the process of updating hazardous substances controls will not require the formal justification for reassessment
  - iii. allow the EPA to have discretion over consultation when making these changes
  - iv. specify that when the EPA decides not to undertake a consultation, the decision-making power will be delegated to the EPA's Chief Executive.
113. To implement the above amendments to the HSNO Act, we also propose amendments to the Methodology Order to:
- i. set the criteria for the EPA's discretion over consultation and the extent of consultation
  - ii. require the EPA to be more transparent about its work plan for these updates and resultant decisions with underpinning evidence and rationale.
114. The proposed amendments to the HSNO Act will only take effect after the proposed amendments to the Methodology Order have taken effect.

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<sup>17</sup> A hazardous substance can be a chemical or a formulation of different chemicals that meets hazardous classification criteria.

115. The EPA's Chief Executive will make decisions on the appropriate process for changes to hazard classifications and corresponding controls in accordance with amendments to the Methodology Order.

### *Policy problem 3: Enabling the EPA to temporarily restrict certain uses of a hazardous substance*

#### Proposed options in the discussion document

116. Option 1 was the status quo, which has been discussed in Section 2. We proposed another option for more responsiveness.
117. 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.
118. This option would require the EPA to undertake a reassessment process within a set time, for example, within six months since the suspension or restriction has taken effect. This would require the EPA to prioritise reassessment of the hazardous substance that has been suspended or restricted.
119. The action may encourage the provision of information from industry for the reassessment of the hazardous substance that has been suspended or restricted. It may also encourage industry to innovate and introduce lower-risk hazardous substances. There may be an impact on the sale and use of the hazardous substance that has been suspended or restricted.
120. There was another option (Option 3) that would allow the EPA to immediately revoke an approval using a trusted regulator's decision. Similarly to Option 3 of Policy problem 1 this option would compromise the EPA's independence in making decisions and may risk adopting inappropriate decisions influenced by political or commercial biases. This option was not included in the discussion document but mentioned in the preliminary RIA.

#### Feedback from the public

121. Some submitters agreed with the proposal, but industry and end-users strongly opposed it because of potentially significant economic impacts on their businesses, especially where there are no suitable alternatives or the information used for suspension is biased or irrelevant to the New Zealand context. End-users requested compensation if a reassessment later showed that the suspension was unnecessary.

#### Referred option after consultation

122. Considering the feedback, we recommend no changes to the suspension of approvals during reassessment, but instead recommend introducing a new provision into the HSNO Act to enable the EPA to temporarily restrict certain uses of a hazardous substance while it is being reassessed subject to the following specific requirements:

- there is evidence of potential actual or imminent danger to human health, safety, or the environment
  - a restriction of certain uses<sup>18</sup> of a hazardous substance could only be implemented after the formal justification for reassessment of that hazardous substance has been established
  - the restriction will remain in place while the restricted hazardous substance is being reassessed, ie until a decision is made on the reassessment, or a decision is taken to not proceed with the reassessment, or the reassessment application is withdrawn
  - the restriction will expire if the EPA did not submit a reassessment application within one year of the restriction decision taking effect
  - the EPA must consider a hazardous substance that has been restricted as the highest priority when developing its work plan for reassessments.
123. Before taking the decision to restrict a hazardous substance temporarily, the EPA will be required to engage with persons who, in its opinion, would be likely to be directly affected by the decision.
124. Potential actual or imminent danger could be understood as the capacity to cause adverse impacts on human health, safety, or the environment if no immediate protections were put in place. Adverse impacts should be envisaged in an immediate future.
125. Evidence of potential danger to human health, safety, or the environment could come from domestic sources, such as an EPA assessment of related hazardous substances, or the results of peer-reviewed tests. It could also come from international channels, such as a trusted regulator's assessment and decision to prohibit or restrict certain uses of related chemicals or hazardous substances, which the EPA considers relevant to the New Zealand context. The actual scale of the adverse impacts on human health, safety, or the environment could be unclear when the action is taken.

### 3.2. Other improvements to the reassessment process

#### *Policy problem 4: Enabling more targeted consultation during modified reassessments*

##### *Proposed options in the discussion document*

126. In addition to the status quo, we proposed an option to provide more flexibility in ways the EPA can consult during modified reassessments. We sought public views on whether the HSNO Act should allow the EPA to undertake a targeted consultation process instead of carrying out public notification for most modified reassessments.
127. We indicated if the public supports the change, we would further work on new wording of Section 63A to reduce the risk of the EPA being legally challenged because of missing consultation.
128. The change is expected to benefit the EPA, industry and end-users. It would save time and resources as the EPA could use the targeted consultation more frequently and effectively, and raise the reassessment rate.

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<sup>18</sup> The uses that may cause the concern of potential actual or imminent danger

### Feedback from the public

129. Submitters generally supported a targeted consultation but noted that it may be difficult for the EPA to identify targeted stakeholders.

### Preferred option after consultation

130. Since the EPA considers that it can identify persons who would likely be directly affected by a reassessment, we propose minor changes to the wording of section 63A of the HSNO Act to lower the threshold for consultation. The EPA should only be required to consult with all persons who, in its opinion, may be directly affected by the modified reassessment. Section 63C, which provides a modified reassessment process to change controls following a change in the hazard classification system, or in controls in regulations, EPA controls, or controls under the Health and Safety at Work Act 2015, should also be changed accordingly for consistency.

### *Policy problem 5: Requiring the EPA to develop a publicly available work plan for reassessments, with items on this work plan deemed to meet the reassessment criteria*

### Proposed options in the discussion document

131. Option 1 was the status quo, which has been discussed in Section 2. We proposed two other two options.
132. Option 2 would amend the HSNO Act to give the EPA's Priority Chemical List (PCL) a statutory status and indicate that the chemicals in the PCL would meet the grounds criteria and the EPA would not be required to prepare a formal justification for reassessment of hazardous substances containing these chemicals.
133. We indicated that this option would require the EPA to make some minor changes to its prioritisation process for identifying the PCL.
134. This option could reduce the time and resources needed to reassess prioritised hazardous substances. It may create some uncertainty for industry and the public, as the 'grounds' step serves as a signal about upcoming reassessments. A solution was to indicate the order of PCL reassessments, and to promote communication between the EPA and industry about the work programme.
135. Option 3 would amend the HSNO Act to indicate that being included in the PCL is one of grounds criteria for reassessment of hazardous substances containing these priority chemicals. This means the EPA still has to prepare a formal justification for reassessments of these hazardous substances but the work would be more straightforward than it currently is.

### Feedback from the public

136. Feedback from the public showed that the EPA's prioritisation process needs some improvements, including more engagement with industry.

### Preferred option after consultation

137. We propose changes to the HSNO Act requiring the EPA to develop a publicly available work plan for reassessments and indicate that the hazardous substances or chemicals included in this work plan meet the grounds criteria for reassessment.
138. We also propose changes to the Methodology Order to further specify the work plan and the criteria of hazardous substances or chemicals that should be included. The work plan may indicate the priority order and timeframes of upcoming reassessments and updates of controls.



139. The EPA will need to formally justify the reassessment of any hazardous substances that it decides to temporarily restrict certain uses of those hazardous substances.
140. We also recommend that the EPA considers the question of engagement when it improves its prioritisation process.

*Policy problem 6: Enabling the EPA to align the timeframes of the assessments and reassessments of related hazardous substances*

**Proposed options in the discussion document**

141. Option 1 was the status quo, which has been discussed in Section 2. We proposed two other options.
142. Option 2 would allow the alignment of the two processes so that they are processed and decided at the same time with consistent controls.
143. This option might extend the time for assessing a new hazardous substance because it coincides with a related reassessment. However, the saving on resources and the benefits of consistency could outweigh the cost.
144. Option 3 would amend the HSNO Act to allow the EPA to decline or postpone the application of the new hazardous substance while waiting for a reassessment decision on related hazardous substances. The application of the new hazardous substance would proceed after a reassessment decision of the related hazardous substances is made.
145. This option means potentially late access to the market for the new hazardous substance. However, the approval for that new hazardous substance would not need to be reassessed.

**Feedback from the public**

146. Generally, submitters agreed there could be duplication of work but felt this would not happen often. Some submitters were concerned about the late access to the market of the new hazardous substance while waiting for a reassessment decision. They suggested adding a condition in the new approval to enable the automatic update of controls based on the reassessment decision.

**Preferred option after consultation**

147. Because of the differences in formulation and use scenarios of related substances, any automatic update of controls would not be appropriate and could circumvent a statutory process.
148. For efficiency and consistency, we propose changes to the HSNO Act to enable the EPA to align the timeframes for processing and decision-making of hazardous substances with related chemicals or substances when a new application of a hazardous substance is received while a reassessment of related substances is already happening. 'Related chemicals or substances' are those with the same or very similar active ingredient.
149. The alignment of timeframes of the processes means the EPA will have the ability to extend the timeframe of one or more of the related applications so that the related applications would be heard at the same time and place, and be decided on the same date. This will bring benefits of consistency and efficiency that are likely to outweigh any potential costs to the applicants who have to wait for another related application's decision.

*Policy problem 7: Providing a simplified process for updating controls on existing hazardous substances in a situation where the EPA has undertaken a recent assessment of a related hazardous substance*

**Proposed options in the discussion document**

150. Option 1 was the status quo, which has been discussed in Section 2. We proposed two other options.
151. Option 2 would allow the EPA to align the timeframes of assessing a new hazardous substance and reassessing related hazardous substances, including hazardous substances with the same active ingredient. This would require the EPA to initiate a reassessment process which is not always possible. The applicant for the new hazardous substance could have a long wait.
152. The benefit of this option is the consistency in controls of the new and existing substances.
153. Option 3 would allow the EPA to use a simplified process for updating hazardous substances controls to make changes to existing approvals to align with the new approval.
154. This process would not require a formal justification for reassessment (grounds step) and the EPA would have discretion over consultation.
155. 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.

**Feedback from the public**

156. This proposal was generally supported, although some submitters requested there should be a targeted consultation during this process. Industry was concerned that this proposal may enable the EPA's new assessment approaches or new controls to be constantly applied to existing hazardous substances. This would create instability to the market.

**Preferred option after consultation**

157. We propose amendments to the HSNO Act to:
  - i. allow the EPA to follow a simplified process ('a process of updating hazardous substances controls') to update controls on existing hazardous substances in a situation where the EPA has undertaken a recent assessment of a related hazardous substance
  - ii. specify that the process of updating hazardous substances controls will not require formal justification for reassessment
  - iii. allow the EPA to have discretion over consultation when making these changes
  - iv. specify that when the EPA decides not to undertake a consultation, the decision-making power will be delegated to the EPA's Chief Executive.
158. To implement the above amendments to the HSNO Act, we also propose amendments to the Methodology Order to:
  - i. set the criteria for the EPA's discretion over consultation and the extent of consultation
  - ii. require the EPA to be more transparent about its work plan for these updates and resultant decisions with underpinning evidence and rationale.

159. The proposed amendments to the HSNO Act will only take effect after the proposed amendments to the Methodology Order have taken effect.
160. The EPA's Chief Executive will make decisions on the appropriate process for these controls updates in accordance with amendments to the Methodology Order.
161. The EPA will be able to update controls on one or many hazardous substances at a time but controls of any approval will not be updated more than once a year, following this simplified process. Decision makers will have discretion over setting an appropriate transitional time for compliance with updated controls.

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#### Section 4: Impact Analysis

162. 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 hazardous 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
- potential impacts on stakeholders.

#### 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

#### 4.1. Making better use of information from trusted regulators

*Policy problem 1: Enabling the EPA to apply data, information, assessments, and decisions from trusted regulators*

**Table 1: Assessment of options**

	Appropriate management of hazardous 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
<b>Option 1: Status quo</b> 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 Slow and costly processes discourage the applicants of assessments and reassessments
<b>Option 2A</b> 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 could be available faster than currently possible.  Minor changes to existing proposals could happen in a timely manner.	+ If there are guidelines or regulations on trusted regulators and the EPA still undertakes its assessment.  Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.	+ Likely to have positive impacts on most stakeholders.  Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.
<b>Option 2B: Apply full assessments + consider NZ context</b>	++ 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 could be available faster than currently possible. Minor changes to existing proposals could happen in a timely manner.	+ If there are guidelines or regulations on trusted regulators.  Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.	+ Likely to have positive impacts on most stakeholders.  Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.
<b>Option 2C: Apply full assessments or</b>	++ Trusted regulator's decision may contain biases thus require a	++ Better use of international information → save	++ Better use of international information	++ Beneficial substances could be available faster than currently possible.	+ If there are guidelines or regulations on trusted regulators and	+ Likely to have positive impacts on most stakeholders.

decisions + consider the NZ context	thorough consideration of the NZ context to allow an appropriate management decision.	more time for the processes.	→ save more costs for the processes.	Minor changes to existing proposals could happen in a timely manner.	the EPA undertakes a thorough consideration of the NZ context and understands embedded biases in any trusted regulator's decisions. Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.	Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.
<b>Option 3: Immediate adoption of a trusted regulator's decision</b>	-- Without a consideration of the NZ context, the appropriate management of hazardous 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 any decisions. Not clear how the EPA would deal with complex applications, conflicting overseas assessments and decisions, and gaps in information, etc.
<b>Preferred option: Apply data, information, assessment, decisions with a consideration of the New Zealand context and discretion over consultation (except in particular circumstances) + more transparency about the EPA's work plan and decisions</b>	++ Information from trusted regulators could support the EPA processes + 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, low risk substances could be available faster than currently possible. Minor changes to existing approvals could be undertaken in a timely manner.	++ Proposed changes to the Methodology Order would clarify the criteria and process of identifying trusted regulators; and the process of applying information from them.  The EPA will continue to undertake a thorough consideration of the NZ context and understands embedded biases in any trusted regulator's decisions.	++ Likely to have positive impacts on most stakeholders.  Proposed changes to the Methodology Order would clarify the trusted regulators and the process of applying information from them.

Policy problem 2: Providing a simplified process for updating hazard classifications of hazardous substances and corresponding controls based on information from trusted regulators

Table 2: Assessment of options

	Appropriate management of hazardous substances to protect human health and the environment	Time saving	Cost effectiveness	Promote innovation and encourage competition	Integrity, certainty, and transparency of the processes	Stakeholders' satisfaction
Option 1: Status quo-Modified reassessment process	0 Inappropriate management of hazardous 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 Discouragement for applications of minor changes
Option 2: Adopting a trusted regulator's decision + internal process (discretion over consultation)	++ Appropriate management of hazardous substances.	++ A fast process for changes to classification and controls.	++ 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 + a simplified process of updating controls (no formal justification for reassessment and discretion over consultation)	+ Appropriate management of hazardous 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 an update process due to priority.	++ Reassessment could happen faster than the status quo because the formal justification for reassessment (grounds step) would not be needed and the EPA would have more discretion in consultation.	++ Some savings from a new simplified process.	+ Appropriate management encourages innovation and competition, depending on how the new simplified process is implemented.	+ Depending on how the new simplified process is implemented.	+ Depending on how the new simplified process is implemented.
Preferred option: a simplified process of updating hazardous substances controls (no	+ Appropriate management of hazardous substances can be achieved faster than the status quo but not as fast as in Option 2	++ Changes could happen faster than the status quo because the formal justification for reassessment (grounds step) would not be needed	++ Savings from a new simplified process.	++ Appropriate management encourages innovation and competition.  Criteria for discretion over consultation would be set in	++ Criteria for discretion over consultation would be set to ensure consultation would be undertaken for complicated situations.	++ Likely to have positive impacts on human health, safety and the environment.

<p>formal justification for reassessment and discretion over consultation) + changes to the Methodology Order to stipulate the discretion</p>	<p>Appropriate management might not be achievable if the EPA or industry does not initiate/apply for an update process due to priority.</p>	<p>and the EPA would have more discretion in consultation</p>		<p>the Methodology Order to ensure consultation would be undertaken for complex situations.</p>	<p>Straightforward changes of hazard classifications and controls could be undertaken quickly.</p>	<p>Likely to have positive impacts on the chemical industry and end-users.</p>
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Proactively released



Policy problem 3: Enabling the EPA to temporarily restrict certain uses of a hazardous substance

Table 3: Assessment of options

	Appropriate management of hazardous 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
<b>Option 1: Status quo- High threshold for suspension</b>	0 Unable to immediately react to risks to human health, safety, and the environment.	0	0 Potentially cause cost to human health, safety, and the environment.	0 No incentives for innovation and competition.	0 Lengthy process and inefficient use of information.	0 A lack of timely protection for human health, safety and the environment may negatively affect public confidence in the regulator
<b>Option 2: Feasible suspension or restriction.</b>	++ The suspension power protects human health, safety, and the environment.	++ Industry and end-users would be incentivised to provide information for reassessment of suspended or restricted hazardous substances.	+ Benefits from better management of hazardous substances.  Potentially saves cost for human health, safety, and the environment.	+ The suspension of restriction may encourage the introduction of safer alternatives.	+ More applicable power of suspension.	+ Likely to have positive impacts on human health, safety and the environment.  Potentially negative impacts on the chemical industry and end-users if there are no alternatives or the evidence is insufficient.
<b>Option 3: Immediate adoption of a trusted regulator's decision to revoke an approval</b>	- Without a reassessment, the appropriate management of hazardous 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.	- Hazardous 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.
<b>Preferred options: New temporary restriction power with the highest priority for the reassessment of restricted hazardous substances and other requirements</b>	++ An ability to restrict certain uses but maintain critical uses in some circumstances. Better protection of human health, safety, and the environment.	++ Industry and end-users would be incentivised to provide information for reassessment of restricted hazardous substances	++ Benefits from better management of hazardous substances.  Potentially saves cost for human health, safety, and the environment.	++ The temporary restriction may encourage the introduction of safer alternatives.	++ More applicable power of restriction.  Conditions are set to manage or reduce the negative impacts on the chemical industry and end-users	+ Likely to have positive impacts on human health, safety, and the environment.  Potentially negative impacts on the chemical industry and end-users of the temporarily restricted hazardous substances.  Conditions would be set to manage or reduce the negative impacts.

## 4.2. Other improvements to the reassessment process

*Policy problem 4: Enabling more targeted consultation during modified reassessments*

**Table 4: Assessment of options**

	Appropriate management of hazardous 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
<b>Option 1: current targeted consultation – deems to be a public notification</b>	0 Time-consuming modified reassessment process. → 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 Unnecessary lengthy modified reassessments may discourage applications for minor changes
<b>Option 2 – preferred option: New threshold to enable more targeted consultation</b>	++ A more applicable modified reassessment process to achieve appropriate management.	++ A faster modified reassessment process → increase reassessment rates.	++ Potentially saves costs for the regulators and costs for human health, safety, and the environment.	++ Potentially encourages innovation and competition.	++ A more applicable modified reassessment process.	+ Encourage more applications for minor changes.

Policy problem 5: Requiring the EPA to develop a publicly available work plan for reassessments, with items on this work plan deemed to meet the reassessment criteria

Table 5: Assessment of options for streamlining reassessments of priority chemicals

	Appropriate management of hazardous 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: formal justification (grounds step) for the reassessment of chemicals on the PCL	0 Lengthier reassessment than it could be.	0 Slower reassessments.	0 More costs for the regulator.	0 Do not promote innovation and encourage competition.	0 There could be some duplication of work between the prioritisation process and the formal justification for reassessment.	0 The formal justification (grounds step) is currently working as an indication of up-coming reassessment. However, some reassessment are not proceeded after the formal justification.
Option 2: Statutory recognition of PCL + no formal justification for the reassessments of chemicals on the PCL	+	++	++	+	+	+
	Shorter time for reassessments of chemicals on the PCL.	Save the time for the formal justification → increase reassessment rate.	Save the costs for the formal justification.	Encourage innovation.	If there are minor changes to the prioritisation process and the PCL to address the issue of some chemicals on the PCL are not in need of urgent review because existing approvals have set appropriate controls.	If there are ways to signal industry about the upcoming reassessment.
Option 3: Include the PCL in the list of grounds criteria	+	+	+	+	+	++
	Shorter time for the reassessments of chemicals on the PCL.	There is a small saving of the time for the formal justification.	Small saving of the costs for the formal justification.	Encourage innovation.	The formal justification maintained but would be more straightforward.	Industry would be signalled about the upcoming reassessment.
Preferred option: statutory EPA's work plan for reassessments + no formal justification for reassessment of items in this plan	+	++	++	+	+	+
	Shorter time for reassessments of chemicals or hazardous substances included in the EPA's work plan.	Save the time for the formal justification → increase reassessment rate.	Save the costs for the formal justification of reassessment of priority chemicals.	Encourage innovation.	The work plan will be specified by changes to the Methodology Order to ensure items meet the grounds criteria for reassessment	The publication of the EPA's work plan for reassessments would inform the public about the up-coming reassessments.

Policy problem 6: Enabling the EPA to align the timeframes of the assessments and reassessments of related hazardous substances

Table 6: Assessment of options

	Appropriate management of hazardous 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 where possible.	0 Heavily ineffective as more reassessments are needed.  Cannot save costs where possible.	0 Does not encourage innovation as applicants can still apply for an approval of a hazardous substance with an active ingredient being reassessed.	0 Uncertainty as the EPA has options to progress with more costs on the regulator.	0 Benefits for some applicants but not for the consistency in hazardous substances management and for human health, safety, and the environment.
Option 2 – Preferred option: Enabling the EPA to align the processes of the new assessment and concurrent reassessment	++ More consistencies in management decisions.	++ Save time for unnecessary reassessments.  Potentially save time from aligned processes.	++ Save costs for unnecessary reassessments.  Potentially save costs from aligned processes.	++ Potentially promote innovation and competition.	++ More clarity about the alignment of processing and decision-making processes.	++ Benefits from the consistencies for all stakeholders.  The applicant of the new hazardous substance may have to wait longer to be aligned with the ongoing reassessment process but the benefits outweigh the costs.
Option 3: Decline/Postpone an application, pending a reassessment decision	+ More consistencies in management decisions.	+ Save time for unnecessary reassessments.	+ Save 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 the market for the new hazardous substance.

Policy problem 7: Providing a simplified process for updating controls on existing hazardous substances in a situation where the EPA has undertaken a recent assessment of a related hazardous substance

Table 7: Assessment of options

	Appropriate management of hazardous 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 - following a modified reassessment process	0 Inconsistency in management decisions.	0 Long, inefficient reassessment process for minor changes.	0 Inefficient reassessment process for minor changes.	0 Does not encourage innovation and competition.	0 Not an appropriate process.	0 Difficult for stakeholders to apply for minor changes. Inconsistent management of hazardous substances created uneven playing field for the chemical industry.
Option 2: Aligned processes	+ More consistencies in management decisions.	+ Can save time of gathering information for reassessment.	+ Can save cost of gathering information for reassessment.	+	0 Create uncertainty for the new application especially where the EPA is not certain about initiating a reassessment. Alignment is not always possible.	- Applicant of the new hazardous substance may be negatively affected by the alignment.
Option 3 - Preferred option: A simplified process of updating hazardous substances controls + no formal justification for reassessment + discretion over consultation	++ More consistencies in management decisions.	++ Save time for a formal justification for reassessment.  Save time for a consultation process where there are minor or uncomplicated changes.	++ Save cost for a formal justification for reassessment.  Save cost for a consultation process where there are minor or uncomplicated changes.	+ Promote innovation and competition.	+ Criteria for the discretion over consultation would be set in the Methodology Order to ensure that the EPA would undertake consultation where needed.	++ Likely to have positive impacts on most stakeholders.  We set a condition that no existing approval would be updated more than once a year following this simplified process. We also indicate that decision-makers would set appropriate transition time for compliance with new controls to ensure market stability

## Section 5: Conclusion

163. Based on the impact analysis in Section 4, we have identified our preferred options for each proposal (see below). We also refer to a cost benefit analysis in choosing the preferred options.
164. The preferred options are aimed to reduce costs, speed up processes and reduce regulatory burden on the regulator and industry. They are also designed to minimise the potential impacts on industry and end-users to the extent possible.
165. A cost benefit analysis estimates small cost and small benefit of under \$10 million to the economy over 10 years from these proposals, provided effective engagement would be in place to ensure appropriate management of hazardous substances.
166. This benefit does not include non-monetised benefits from improvements to human health, safety, and the environment.
167. Changes to the Methodology Order would set criteria for the EPA's discretion over consultation to ensure that consultation would be in place where needed, such as where there would be important gaps in information, or an application would be complex. Increased transparency would also be in place to communicate the EPA's work plan, its implementation of discretion and the resultant decisions.

### 5.1. Making better use of information from trusted regulators

*Policy problem 1: Enabling the EPA to apply data, information, assessments, and decisions from trusted regulators*

Table 8 - preferred option: Applying trusted regulators' scientific information, data, assessments, and decisions with a consideration of the New Zealand context with discretion over consultation.

Affected parties (identify)	Comment: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	Impact <i>\$m present value, for monetised impacts; high, medium or low for non-monetised impacts</i>
Additional costs of proposed approach, compared to taking no action		
Regulators	Cost of amending the Methodology Order on the trusted regulator approach (one-off cost). Cost of establishing relationships with trusted regulators (one-off cost).	Low
Wider government	Cost to WorkSafe for collecting further information in some processes. Cost to WorkSafe for involvement in more assessments.	Not identifiable
Regulated parties	Perceived risks of mistakes or misuse of power where the EPA exercises discretion over consultation. Proposed changes to the Methodology Order will set parameters for this discretion.	Low
Other parties	Risks of losing an opportunity to submit and be heard in some assessments or reassessments + risks of the EPA applying inappropriate assessments or decisions These risks would be managed by proposed changes to the Methodology Order to implement the policy.	Low
<b>Total non-monetised costs</b>		<b>Low</b>

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Benefits of not re-producing data/information for applications (on-going benefits). On-going benefits of beneficial, low risk hazardous substances being available for use and minor changes to existing approvals could be achieved through a faster pathway, which could encourage innovation and competition.	Low
Regulators	Benefits of not re-producing data/information and not verifying and reviewing some data/information (on-going benefits). Benefits of not undertaking a public consultation in situations specified by the Methodology Order. Average costs of an assessments range from \$19,500 to \$111,000, depending on the categories of the applications. 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.	Low
Wider government	Depending on how WorkSafe and MBIE respond to the change, there may be benefits from sharing information.	Not identifiable
Other parties	On-going benefits of a more dynamic system which would allow for more appropriate hazardous substances management. On-going benefits of beneficial, low risk hazardous substances being available for use and harmful hazardous substances being replaced in a quicker way.	Low
<b>Total non-monetised benefits</b>		<b>Medium</b>

*Policy problem 2: Providing a simplified process for updating hazard classifications of hazardous substances and corresponding controls based on information from trusted regulators*

Table 9: preferred option 2: Applying a trusted regulator's assessments and decisions to change the hazard classifications of a hazardous substance and corresponding controls following a simplified process with consultation in the EPA's discretion

Affected parties	Comment	Impact
Additional costs of proposed approach, compared to taking no action		
Regulators	Costs of amending the Methodology Order to stipulate the trusted regulator approach (one-off cost).	Low
Wider government	WorkSafe may need to collect further information to set or update workplace controls in some circumstances.	Not identifiable
Regulated parties	Perceived risks of mistakes or misuse of power where the EPA exercises discretion over consultation. Changes to the Methodology Order would set parameters to ensure the discretion would be used properly.	Low

Total non-monetised costs		Low
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Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Benefits of faster changes of hazard classifications and corresponding controls.	Medium
Regulators	On-going benefits of an efficient pathway to make changes to hazard classifications and corresponding controls.	Medium
Other parties	On-going benefits of an efficient pathway to make changes to hazard classifications and corresponding controls, which would allow for more appropriate hazardous substances management.	Medium
<b>Total non-monetised benefits</b>		<b>Medium</b>

*Policy problem 3: Enabling the EPA to temporarily restrict certain uses of a hazardous substance*

Table 10: preferred option: Amending the HSNO Act to enable the EPA to temporarily restrict certain uses of a hazardous substance with specific requirements

Affected parties	Comment	Impact
Additional costs of proposed approach, compared to taking no action		
Regulated parties	On rare occasions, a temporary restriction could be a too cautious decision, and thus have significant impacts on their businesses, especially where there would be no suitable alternatives.  This risk will be managed by requirements of the restriction power.	Low
Regulators	Costs of restriction decision-making (on-going costs).	Low
<b>Total non-monetised costs</b>		<b>Low</b>

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	On-going benefits of not using substances which pose potential danger to human health, safety, or the environment.	Low
Regulators	On-going benefits of being more responsive in hazardous substances management.	High
Other parties	On-going benefits of appropriate hazardous substances management.  On-going benefits of high risk hazardous substances, which pose potential danger to human health, safety, and the environment, could be temporarily restricted for a period of time to reduce adverse effect before being reassessed.	High
<b>Total non-monetised benefits</b>		<b>High</b>



## 5.2. Other improvements to the reassessment process

### *Policy problem 4: Enabling more targeted consultation during modified reassessments*

Table 11: Option 2: Amending the HSNO Act to provide more targeted consultation during the modified reassessment process.

Affected parties	Comment	Impact
<b>Additional costs of proposed approach, compared to taking no action</b>		
Other parties	No more opportunities to submit because there would be no public notification for modified reassessments. However, directly affected parties would still be consulted.	Low
<b>Total non-monetised costs</b>		<b>Low</b>
<b>Expected benefits of proposed approach, compared to taking no action</b>		
Regulators	On-going benefits of avoiding the risk of missing consultation and effective targeted consultation and faster reassessment.	Medium
<b>Total non-monetised benefits</b>		<b>Medium</b>

### *Policy problem 5: Requiring the EPA to develop a publicly available work plan for reassessments, with items on this work plan deemed to meet the reassessment criteria*

Table 12: Option 2 – Preferred option: Amendments to the HSNO Act to require the EPA to develop a work plan for reassessments and indicating items in the work plan meeting the round criteria

Affected parties	Comment	Impact
<b>Additional costs of proposed approach, compared to taking no action</b>		
Regulators	On-going, baseline costs for developing a work plan for reassessments.	Low
<b>Total non-monetised cost</b>		<b>Low</b>
<b>Expected benefits of proposed approach, compared to taking no action</b>		
Regulators	On-going benefits of faster reassessment of priority hazardous substances. Saved cost of an average formal justification for reassessment is about \$16,000.	Low
Other parties	On-going benefits of faster reassessments of priority hazardous substances	Low
<b>Total non-monetised benefits</b>		<b>Low</b>

*Policy problem 6: Enabling the EPA to align the timeframes of the assessments and reassessments of related hazardous substances*

Table 13: Option 2 – preferred option: Enabling the EPA to align the timeframes of the two processes so that they are processed and decided at the same time

Affected parties	Comment	Impact
<b>Additional costs of proposed approach, compared to taking no action</b>		
Regulated parties	Applicants of new hazardous substances might have to wait longer for an approval until a reassessment decision of related hazardous substances is made.	Low
<b>Total non-monetised cost</b>		<b>Low</b>
<b>Expected benefits of proposed approach, compared to taking no action</b>		
Regulators	Avoiding a second reassessment process.	Low
Regulated parties	Consistency in hazardous substances management.	Low
Regulators	Consistency in hazardous substances management.	Low
Other parties	Consistency in hazardous substances management.	Low
<b>Total non-monetised benefits</b>		<b>Low</b>

*Policy problem 7: Providing a simplified process for updating controls on existing hazardous substances in a situation where the EPA has undertaken a recent assessment of a related hazardous substance*

Table 14: Option 3 – preferred option: Using a simplified process of updating hazardous substances controls to change existing approvals to align with the new approval.

Affected parties	Comment	Impact
<b>Additional costs of proposed approach, compared to taking no action</b>		
Regulated parties	May not be consulted on in circumstances specified by the Methodology Order	Low
<b>Total non-monetised costs</b>		<b>Low</b>
<b>Expected benefits of proposed approach, compared to taking no action</b>		
Regulated parties	Consistency in hazardous substances management.	Medium
	A simplified process for updating controls in specific circumstances, easier to apply for minor changes.	Medium
Regulators	Consistency in hazardous management, easier to undertake a review for minor changes in controls.	Medium
Other parties	Consistency in hazardous substances management	Medium
<b>Total non-monetised benefits</b>		<b>Medium</b>

## Section 6: Implementation and operation

168. We propose these changes to the HSNO Act:

(i) enabling the EPA to apply data, information, assessments, and decisions from trusted regulators with a consideration of the New Zealand context (with consultation at its discretion, except in particular circumstances)

(ii) enabling the EPA to make changes to hazard classifications and corresponding controls, based on a trusted regulator's assessment and decision to change the hazard classifications, following a simplified process of updating hazardous substances controls without the need to formally justify the reassessment (no grounds step) and with discretion over consultation (subject to specific requirements)

(iii) enabling the EPA to temporarily restrict certain uses of a hazardous substance after the formal justification for reassessment of that hazardous substance (grounds) has been established, where there is evidence of potential actual or imminent danger to human health, safety, or the environment (subject to specific requirements)

(iv) enabling more targeted consultation during modified reassessments by amending the consultation requirements in section 63A and section 63C

(v) requiring the EPA to develop a publicly available work plan for reassessments, with items on this work plan deemed to meet the reassessment criteria (grounds)

(vi) enabling the EPA to align the timeframes of the assessment and reassessment of related hazardous substances if an application of a new hazardous substance is made while a reassessment of related hazardous substances is already happening

(vii) enabling the EPA to update controls on existing hazardous substances following a process of updating hazardous substances controls without the need to formally justify the reassessment (no grounds step) and with discretion over consultation (subject to specific requirements), in a situation where the EPA has undertaken a recent assessment of a related hazardous substance

(viii) delegating decision-making power to the EPA's Chief Executive where the EPA decides not to consult, or is not required to consult when applying information from trusted regulators or from a recent EPA assessment in proposals 168 (i), (ii), and (vii).

169. To implement the changes to the HSNO Act, changes to the Methodology Order are needed to:

- set the criteria and process for identifying trusted regulators
- specify the assessment and reassessment processes when the EPA applies information from trusted regulators
- specify other requirements on the way the EPA applies information from trusted regulators
- set the criteria for the EPA's discretion over consultation
- require the EPA to be more transparent about its work plan and decisions.

170. Subject to Cabinet approval and prioritisation, drafting of a Bill will be undertaken in 2020. During the drafting period, drafting of proposed changes to the Methodology Order will be initiated. The Bill is expected to be introduced in 2020/2021.

171. As the Methodology Order is made by regulations, the proposed changes require public consultation (led by the EPA). This will provide additional opportunity for stakeholders to be involved in developing the criteria and process.

172. Following changes to the HSNO Act being made, the Minister for the Environment will invite the EPA to start the regulatory process to amend the Methodology Order. The proposed changes to the Methodology Order will be brought to Cabinet for approval following the EPA's consultation.
173. The proposed amendments to the HSNO Act will only take effect after the proposed amendments to the Methodology Order have taken effect.
174. Decision-makers would also need to consider a transitional period for compliance with new controls.
175. The EPA and the chemical industry will implement the changes. Some proposed changes will provide the EPA with more flexibility and discretion in its decision-making. Criteria would be set in the Methodology Order to ensure they are balanced with the EPA's accountability and function as an independent regulator of hazardous substances.
176. There may be operational and resource implications on WorkSafe from the trusted regulator approach.
177. We expect the changes to be adopted and implemented in 2021.

## Section 7: Monitoring, evaluation and review

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

178. The impacts of the proposed changes could be measured by the saving from using information from trusted regulators when assessing and reassessing hazardous substances, and from other improvements, especially from the simplified process of updating hazardous substances controls. Another important impact would be how the EPA implement the new temporary restriction power to better manage hazardous substances and to protect human health, safety, and the environment.
179. The number and timing of new assessments and reassessments would be one indication of the impacts.
180. Feedback from the EPA, the chemical industry, end-users, and the public would be important for evaluating the impacts of changes.

### 7.2 When and how will the new arrangements be reviewed?

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