

In Confidence

Office of the Minister for the Environment

Chair, Cabinet Economic Development Committee

Approval to release a discussion document on proposed improvements to assessments and reassessments of hazardous substances

Proposal

1. I am seeking Cabinet approval to release a discussion document for public consultation on proposed improvements to assessments and reassessments of hazardous substances.

Background

2. The Hazardous Substances and New Organisms Act 1996 (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.
3. Under the Act, new hazardous substances that have not been legally present in New Zealand must be assessed and approved with appropriate controls before being introduced.
4. Hazardous substances legally present in New Zealand prior to 2001 were transferred to the new HSNO Act. Many substances are managed by Group Standards¹ while other higher risk substances, such as explosives, pesticides, wood preservatives and chemicals toxic to vertebrates, require individual approvals² for use with specific controls.
5. Reassessments are a mechanism for the Environmental Protection Authority (EPA) to change or revoke existing approvals. Any person, including the Chief Executive of the EPA can apply for a reassessment if there is new information on the effect or use of a substance.
6. Currently, the assessments of new substances and reassessments of existing substances tend to be slow and resource-intensive. Slow assessments are likely to defer the introduction of beneficial substances, including 'safer' alternatives to existing chemicals or substances for urgent use. Delayed reassessments can have safety and environmental implications.
7. Since 2001, the EPA has completed 31 Chief-Executive-initiated reassessments and 20 external reassessments. Low rates of assessment and reassessment of existing chemicals are a common issue in many of the Organisation for Economic

¹ Group Standards are approvals for a group of hazardous substances of similar nature, type, or use. Group Standards were introduced in 2005 and re-issued in 2017 to set controls for substances of relatively low risk. There are currently 208 Group Standards.

² There are about 9,350 individual approvals.

Co-operation and Development countries.

8. There are a significant number of priority substances that need to be reassessed. In 2018, the EPA identified 39 chemicals that it considers are most in need of review in New Zealand. Timely reviews of these chemicals would ensure appropriate management of chemicals to protect human health and the environment.
9. The EPA has recently undertaken an operational review to improve the reassessment process. This review identified that there are opportunities for further improvements of the process. The Ministry for the Environment (MfE) and the EPA has identified options for improvements to protect human health and the environment.
10. The proposals, which are explained in detail in the discussion document, are aimed to:
 - making better use of international information available for assessments and reassessments
 - other improvements to reassessments, including streamlining consultation and avoiding duplication of work.
11. Integral to some of the proposals is the use of information provided by 'trusted regulators', which will be explained below.

'Trusted regulator' approach

12. 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 reliability³ of the regulator, and the quality and applicability of information.
13. The information referred to here includes scientific information, data, hazard assessments, risk assessments and decisions. Note however that data is not always available for sharing between regulators because of confidentiality requirements. Some risk assessments and decisions can be influenced by local context, risk appetites and political or commercial biases.
14. Internationally, no jurisdictions automatically apply the decisions of another regulator. However, some regulators are seeking to use international data and assessments from others. Domestically, other agencies are also making good use of international information by using special pathways for evaluation and registration of agricultural compounds and medicines.
15. The discussion document proposes an introduction of regulations or guidelines on 'trusted regulator' which will identify who are trusted regulators, what information to be trusted and how.
16. The document also suggests applying 'trusted regulators' data, assessments and decisions to improve efficiencies of domestic processes, and contribute to international alignment in chemical management. It is expected that the 'trusted regulator' approach would facilitate the introduction of beneficial substances and incentivise the replacement of harmful substances. The proposal is also likely to

³ A reliable regulator can be one that follows a quality, transparent and robust chemical assessment process, and has assessment reports accessible to the EPA.

save time and resources for the regulator and industry.

17. Options for applying information provided by ‘trusted regulators’ to assist the domestic processes have taken into consideration the purpose and principles of the HSNO Act, international and domestic best practices, and matters such as risk appetites, biases, local context, and differences in chemical management systems.
18. Using information provided by ‘trusted regulators’ is included in different proposals as summarised below.

Making better use of information

Proposal 1: Making better use of international information for assessments and reassessments

19. Currently, the HSNO Act only allows the EPA to consider, but not apply, international information. The EPA is required to verify and review all types of information during assessments and reassessments. In many cases, this means the EPA is repeating the technical work done by international regulators to reproduce evidence for reassessments.
20. The discussion document proposes options for making better use of international information by allowing the EPA to apply data, assessments or decisions from identified ‘trusted regulators’ during the EPA’s processes.

Proposal 2: immediately reacting to high-risk substances based on trusted information

21. Section 64 of the HSNO Act allows the EPA to suspend an approval to protect human health and the environment. However, the threshold to immediately suspend or revoke a chemical from sale is very high and difficult to exercise. The provision requires the EPA to prove that there is a “significant actual or imminent danger to human health or safety of the environment”.
22. The discussion document proposes options to allow the EPA to take temporary suspensions or restrictions in reacting to risks posed by high-risk substances by considering options to lower the threshold and applying trusted information to the decision-making process.

Proposal 3: Applying a ‘trusted regulator’s decision to change a hazard classification of a substance

23. A hazard classification describes the hazardous properties of a substance. The EPA is planning to update the current classification system to align with a recent revision of Globally Harmonized System of Classification and Labelling (GHS): an internationally agreed system for classifying chemicals based on their physical, health, and environmental hazards. It is envisioned that once this alignment is complete, the EPA should be able to apply trusted regulators’ decisions to assist the process to change a hazard classification.
24. The discussion document proposes options which would allow the EPA to avoid repeating technical work done by trusted regulators in changing the hazard classification of a substance. This would lead to the changes of controls on the substance faster than is currently possible.

Streamlining consultation

Proposal 4: Improving the current consultation process to collect quality information for reassessments

25. A significant barrier to making more robust reassessment decisions is the lack of timely quality information required to progress an application. The current HSNO Act provides the EPA with various mechanisms for obtaining information from interested parties.
26. Currently the EPA uses a non-statutory voluntary 'call for information' process to collect information for preparing reassessment applications. This means that the EPA is not able to make use of the mechanisms available in the HSNO Act to require submitters to provide further information before an application is formally received.
27. The discussion document proposes options to consider ways to incentivise the sharing of quality information for reassessments.

Proposal 5: Improving the targeted consultation process during the modified reassessment process

28. Currently, the HSNO Act provides for a modified reassessment process intended to allow for a more efficient review of controls.
29. The targeted consultation process for a modified reassessment is disproportionate and effectively requires a full consultation process which is as time-consuming and resource-heavy as a public notification. The discussion document proposes options to allow for a more efficient targeted consultation process.

Avoiding duplication of work during reassessments

Proposal 6: Avoiding duplication of work during the early stage of the reassessment process of substances on the EPA's Priority Chemicals List

30. In 2018, the EPA used the Flexible Reassessment Categorisation Screening Tool (FRCaST) to determine the Priority Chemical List. This internationally peer-reviewed screening tool allows the EPA to make a robust identification of the chemicals which require further scrutiny and review. In cases where grounds for reassessment have already been established, it is inefficient for the EPA to undertake the same process of determining grounds for reassessment of these chemical.
31. The discussion document proposes options to avoid duplication of work in determining grounds for reassessments of chemicals on the EPA's Priority Chemical List.

Proposal 7: Avoiding duplication of work in the assessment and reassessment processes of substances that contain the same active ingredient

32. There is currently duplication of work in the assessment and reassessment of substances which contain the same active ingredient and have similar risk profile. The discussion document proposes options to better align the processes to save time and resources for reassessments of relevant substances to achieve greater consistency in chemical management.

Proposal 8: updating controls on existing substances based on a recent assessment of a substance that contains the same active ingredient

33. Assessment of new substances may require updating controls on existing substances that have the same active ingredient. The discussion document proposes options to allow a more efficient process to update these controls.

Other considerations

34. The discussion document also consults on whether a new controls updating process should be introduced to allow for technical changes to be made efficiently. These changes include the change of a hazard classification of a substance and its controls based on a trusted regulator's decision, and updating controls on existing substances based on a recent EPA's assessment of a related substance.

35. The controls updating process would be similar to the modified reassessment process provided under section 63C of the HSNO Act where there is no requirement to determine there is information to trigger a reassessment process (ie, 'grounds' step) and the EPA would have discretion in undertaking a targeted consultation.

36. It is also worth noting that the process of setting and updating workplace controls on hazardous substances will continue separately under the Health and Safety at Work Act 2015. However, WorkSafe New Zealand will be involved during the EPA's processes to ensure appropriate workplace controls are in place.

Consultation

37. These proposals have been developed by a joint MfE and EPA project team.

38. The following agencies have been consulted: Department of Internal Affairs, Department of Conservation, Ministry of Business, Innovation and Employment, Ministry of Health, Ministry of Primary Industries, Ministry of Justice, Te Puni Kōkiri, and Treasury.

39. The Department of Prime Minister and Cabinet has been informed of the contents of the Discussion document and this paper.

40. No significant issues were noted from agency consultation.

41. A public consultation process is required to obtain public input into the options. Feedback from the public will provide the information needed to notify a final set of policy proposals by the end of the year.

42. The main stakeholders targeted by the public consultation are the chemical industry, the agricultural communities and the general public.

Financial implications

43. There are no direct financial implications associated with this paper.

44. Depending upon the outcome of this consultation, there may consequently be financial implications of implementing the proposed changes. These may include the costs of introducing regulations or guidelines on 'trusted regulator' approach and the costs of establishing relationships with 'trusted regulators'.

Legislative implications

45. There are no immediate legislative implications from this paper.
46. Depending upon the outcome of this consultation, legislation may be required to implement the proposals. A bid was submitted for the 2019 Legislation Programme for this purpose, with a priority of category 5 – instructions to be provided to Parliamentary Counsel Office in 2019.

Regulatory impact analysis

47. The Ministry for the Environment's Regulatory Impact Analysis Panel has reviewed the attached Regulatory Impact Assessment (RIA) (Appendix 2) prepared by the Ministry for the Environment. The Panel considers that the RIA partially meets the quality assessment criteria.
48. The Panel considers that the regulatory impact analysis is adequate to support the level of Ministerial decisions being sought in this Cabinet paper, given that consultation has yet to occur. For the post-consultation RIA, more detailed information will be required on the impact of any recommended option to allow the development of a formal cost-benefit analysis, as well as more detail on how the proposals will be monitored and implemented. The RIA provides sufficient evidence of policy problems, and assesses a range of options which have been assessed against several criteria. The Panel considers that any final policy decisions should be informed by consultation responses received from stakeholders in terms of likely costs, impacts and benefits.
49. The Panel also informally reviewed the attached discussion document. The Panel considers that the document will facilitate effective consultation and elicit information to further inform Government decisions on the issues, including further detail on potential costs and benefits of the options.
50. While many proposals provide the EPA with more flexibility and discretion in its decision-making, these considerations have been carefully balanced with the EPA's accountability and function as an independent regulator of hazardous substances. The proposals are expected to allow the regulator to make decisions in a timely manner and to save time and resources for both the regulator and industry.
51. Some proposals intend to bring benefits to the chemical industry and the public as they enable more appropriate chemical management. Other proposals might have impacts on the chemical industry and end-users as they will be required to provide quality information for reassessments. Some proposals allow the EPA to temporarily remove high risk substances from shelves in some circumstances. The consultation would seek stakeholders' opinion on these proposals.
52. While the proposals could bring benefits to the EPA's process, they may have operational and resource implications on WorkSafe's process in setting and updating workplace controls on hazardous substances. This is because WorkSafe is largely relying on information from HSNO applications during its own process. The implementation of the 'trusted regulator' approach may suggest ways to mitigate the impact.

Human rights

53. There are no inconsistencies between any of the proposals in this paper and the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Gender implications

54. There are no gender implications for this paper.

Disability perspective

55. There are no disability perspective implications for this paper.

Publicity

56. I propose to release the discussion document for public consultation for 6 weeks following Cabinet's approval. Māori consultation is an integral part of this consultation.

Proactive Release

57. I also propose to proactively release this Cabinet paper and the Regulatory Impact Assessment alongside the discussion document.

58. The release is subject to redactions as appropriate under the Official Information Act 1982.

Recommendations

The Minister for the Environment recommends that the Committee:

1. **note** the discussion paper, *Proposed improvements to assessments and reassessments of hazardous substances* sets out options for improvements to the hazardous substances management system. The proposals are aimed to make better use of international information during assessments and reassessments, and other improvements to the reassessment process
2. **agree** to release the discussion document for public consultation following Cabinet approval
3. **agree** to proactively release this Cabinet paper and the Regulatory Impact Assessment alongside this Cabinet paper on the Ministry for the Environment's website
4. **agree** to delegate authority to the Minister for the Environment to make minor technical and editorial changes to the discussion document and Regulatory Impact Assessment prior to its public release
5. **invite** the Minister for the Environment to report back to Cabinet by December 2019 with policy proposals.

Authorised for lodgement.

Hon David Parker

Minister for the Environment

Appendix 1.

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

Proactively released

Appendix 2.
Regulatory Impact Assessment

Proactively released