In Confidence

Office of the Minister for the Environment

Chair, Cabinet Legislation Committee

Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill: Approval for Introduction

Proposal

- I propose to introduce the attached Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill (the Bill) into the House of Representatives.
- The purpose of the Bill is to amend the Hazardous Substances and New Organisms Act 1996 (HSNO Act) to improve the assessment and reassessment of hazardous substances.

Policy

Background

- The HSNO 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.
- Under the Act, the Environmental Protection Authority (EPA) is the regulator responsible for making decisions on whether to approve new hazardous substances and setting controls (conditions on how the substance can be used) to manage risk and safeguard people and the environment. The EPA also reassesses hazardous substances already in use, and makes new decisions about whether the controls need to be updated, or whether the substance needs to be banned.
- Currently, the assessment and reassessment of hazardous substances in New Zealand can be time-consuming and resource intensive. These lengthy and costly processes can mean that beneficial chemicals, including safer alternatives to existing ones, take longer to be in use. Delayed reassessments may also mean chemicals continue to be used when their safety and environmental controls may not be fit for purpose.
- The EPA and the Ministry for the Environment (MfE) have been working on proposals to improve the efficiency of assessment and reassessment of hazardous substances. Public consultation took place in 2019.
- Amendments to the HSNO Act are needed to improve the processes for assessing and reassessing hazardous substances, for example to enable the EPA to make better use of relevant information from international regulators.

Cabinet agreement

- The proposals were agreed by Cabinet in June 2020 [ENV-20-MIN-0020; CAB-20-MIN-0312].
- The changes which Cabinet agreed to last year were a package of eight main changes to the HSNO Act, with associated changes to the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology Order) to implement those changes to the Act.
- The agreed changes to the HSNO Act include both changes to enable making better use of information from comparable international regulators and other improvements to the reassessment process.

Further policy development since Cabinet decisions

- Last year, Cabinet authorised me to "make minor or technical changes to the proposals ... during the drafting process that are consistent with the agreed policy" [Point 9, ENV-20-MIN-0020].
- 12 The following changes fall into this category:
 - A new global provision (section 20B) requiring the EPA to give public notice of its decisions on assessment applications of hazardous substances and new organisms and group standards.
 - Including a pre-requisite for the new rapid assessment process (added to existing section 28A) for when the EPA could grant an approval under the new assessment process based on information from international regulators.
 - The terminology for the new empowering provision of the Act under which the EPA can temporarily restrict a substance has changed from "...where there is evidence of potential, actual or imminent danger to human health, safety or the environment" to "...evidence of actual or likely danger ...". This change was made as the latter wording gives better effect to the policy intent.
 - An offence and consequent penalty has been added for breach of the above temporary restriction. This is a strict liability offence, with a maximum penalty of a fine not exceeding \$50,000 for individuals and not exceeding \$100,000 for bodies corporate.
 - Detailing that the EPA workplan for reassessments must include:
 - a list of substances or groups of related chemicals or substances to be reassessed;
 - indicative timeframes to begin work for a reassessment.
 - Clarifying as to when the EPA should notify the Minister for the Environment and other government agencies in relation to applications under Part 5 of the HSNO Act.
 - Aligning the processes for the two new modified reassessment processes as there is no policy reason for these to be different.
 - Transitional provisions.

• Other minor drafting matters, such as referring to "international regulators" rather than "trusted regulators."

Providing for all changes in the HSNO Act (rather than amending the Methodology Order)

- Cabinet had last year agreed to the proposal that the following changes be made to the Methodology Order, in order to implement the changes to the HSNO Act:
 - Setting the criteria and process for identifying the appropriate international regulators.
 - Specifying the assessment and reassessment processes when the EPA applies information from international regulators.
 - Specifying other requirements as to how the EPA applies information from international regulators.
 - Setting the criteria for the EPA's discretion over consultation in certain processes.
 - Requiring the EPA to be more transparent about its workplan and decisions.
- Cabinet also noted that after changes to the HSNO Act were made, the EPA would be invited to undertake a consultation on these proposed changes to the Methodology Order. After that consultation, the changes proposed would have been brought back to Cabinet for approval.
- When the Parliamentary Counsel Office (PCO) drafted the Bill, they advised to put more of the substantive detail of the amendments into the HSNO Act rather than into secondary legislation. MfE and EPA Policy and Legal teams considered the practicalities of this approach and recommended that all the changes originally proposed for the Methodology Order be put into the HSNO Act instead. The advantage of doing this is that the full detail of the proposed changes will be in the Act, rather than in secondary legislation. Furthermore, the changes to the Act will be able to come into force the day after Royal assent is given, rather than at a later date after making the changes to the Methodology Order.
- As noted above, it had originally been planned that the EPA undertake a subsequent consultation as part of the process of amending the Methodology Order, and as a result some of the details of these changes were not consulted on in the 2019 public consultation. However, there will still be opportunity for public submissions during the select committee process.
- I have therefore included these changes to the Methodology Order agreed by Cabinet last year into the amendments to the HSNO Act itself.

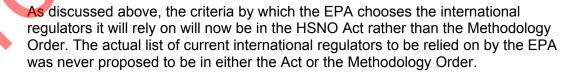
Cabinet approval on further policy details

- The following details were going to be approved by Cabinet as part of the amendment to the Methodology Order. I am seeking Cabinet approval on these matters which are now included in the draft Bill.
- The specifics of what I am seeking Cabinet agreement on are slightly different to the list in paragraph 13 above, this is due to the work process of developing the draft Bill.

Through the drafting process it became clear that on some of the points in paragraph 13 there were no further details that would have gone into the Methodology Order.

How the points in paragraph 13 above are being dealt with is broadly as set out in this table:

Changes to the Methodology Order which Cabinet agreed to in 2020	What is being put into the HSNO Act instead	Recommendation in this Cabinet paper
Setting the criteria and process for identifying the appropriate international regulators	Criteria and process for choosing international regulators are to be in the HSNO Act	Recommendation 9
	A notice will list the particular regulators	
Specifying the assessment and reassessment processes when the EPA applies information from international regulators.	The specific additional rapid pathways that will be triggered by the availability of information from international regulators will be included in the HSNO Act.	Recommendation 7
Specifying other requirements on the way the EPA applies information from international regulators.	 The drafting of the Bill specifies how the EPA will use the information, such as triggering a rapid pathway and enabling the short cut assessment as well as requiring consideration of the NZ context. The Bill also includes obligations around the use of proprietary data and that applicants will need to either own the safety studies they are submitting or have a letter of access in order to benefit from the new rapid pathways. 	This is not in a specific Recommendation as it covers a number of different aspects of the draft Bill.
Setting the criteria for the EPA's discretion over consultation in certain processes	The Bill amends the HSNO Act to set the criteria for consultation in these various processes	Recommendations 6 and 7
Requiring the EPA to be more transparent about its workplan and decisions.	The Bill amends the HSNO Act to specify that the EPA workplan for reassessments must include: • a list of substances or groups of related chemicals or substances to be reassessed; • indicative timeframes to begin work for a reassessment.	No specific Recommendation on transparency, but several of the Recommendations are around issues of transparency.



I propose that this list of regulators be in an administrative notice. The notice will not be secondary legislation. The draft Bill inserts a new section into the HSNO Act, which will enable the EPA to prescribe international regulators by way of notice in the Gazette.

- I propose that the EPA will only be able to prescribe international regulators once it has publicly notified its intention to issue the above notice and given interested parties a reasonable time to make submissions on the proposal, and consulted with appropriate stakeholders and government agencies. The EPA must also, prior to issuing such a notice, consider whether:
 - the international regulator operates in a manner comparable to the EPA in regulating hazardous substances; and
 - the legislative regime regulating hazardous substances that the international regulator operates in is comparable to the HSNO Act; and
 - the information from the international regulator is readily accessible by the EPA.
- The 2020 Cabinet paper provided for changes to the HSNO Act to allow for a more targeted consultation by the EPA during its modified reassessment process under section 63A of the Act. Details of consultation criteria were anticipated to be provided for in the amended Methodology Order.
- The consultation pathway I propose to be included in the HSNO Act for the new modified reassessment processes is:
 - The EPA may decide to publicly notify the application under section 53;
 - If the EPA does not publicly notify the application, the EPA must consult if it considers that the application will have—
 - (a) significant cultural, economic, environmental, ethical, health or international effects; or
 - (b) significant effects in an area in which the EPA lacks sufficient knowledge or expertise.
 - If the EPA consults it must—
 - (a) do everything reasonably practicable on its part to consult with all persons who, in its opinion, are likely to be directly affected by the reassessment; and
 - b) give those persons a reasonable opportunity to make submissions and comments to the EPA on the reassessment; and
 - (c) consider all submissions and comments received before approving or declining the application.
 - If the EPA is not required to consult, the EPA may consult with any person before approving or declining the application.
- In addition, I propose that the consultation requirements for the existing modified rapid assessment processes (sections 63A and 63C) are slightly modified to match the new consultation pathways for the new reassessment processes (new section 63D). This is in addition to the amendments agreed to by Cabinet last year to allow for a more targeted consultation in these existing processes.

Additional 'technical' amendments to the HSNO Act

- In addition to the policy proposals agreed by Cabinet last year, I propose three technical amendments to the HSNO Act to correct omissions or ambiguous language. These are not policy changes to the application of the HSNO Act. I consider that it is appropriate to use the Bill as an opportunity to make these amendments, and seek Cabinet approval to include these amendments in this Bill.
- Currently, there is an offence prescribed by section 109(1)(da) of the HSNO Act, but no corresponding penalty. I propose that section 114, the penalties section of the Act, be amended to add "or paragraph (da)" to section 114(1). This is to correct the omission of not having included a penalty when creating the new offence section 109(da) in the 2015 amendments to the HSNO Act. The offence prescribed by section 109(1)(da) is not a strict liability offence.
- Another omission occurred in the 2015 amendments to the HSNO Act. In those amendments, section 103A was created (*Powers of entry for inspection related to hazardous substances*). As part of the amendments, references to section 103 in other parts of the Act should have been amended to include section 103A. However, in sections 11(1)(b)(ii), *Powers, functions, and duties of Authority*, and 137(1)(a) and (b), *Emergency powers*, this amendment was not made. I propose that the current Bill be used to correct this omission.
- I also propose an amendment to section 68 of the HSNO Act, which is the Ministerial call-in section. An application that relates to a hazardous substance can only be called-in (which means the application would be determined by the Minister rather than the EPA) if it is an application "referred to in section 53". Currently there is some ambiguity as to whether the section 68 call-in provisions apply to reassessments, although on a purposive reading of the HSNO Act, publicly-notified reassessments would be subject to section 68. I propose an amendment to clarify that section 68 applies to applications to which section 53 applies.
- While the above three technical amendments were not part of the 2019 public consultation undertaken by MfE, there will be the opportunity for public submission during the select committee process.

Impact analysis

A regulatory impact assessment was prepared, reviewed by MfE's Regulatory Impact Analysis Panel (which considered that it partially met the quality assurance criteria), and submitted at the time that Cabinet committee approval of the policy relating to the Bill was sought last year [ENV-20-MIN-0020; CAB-20-MIN-0312].

Compliance

- The Bill complies with:
 - the principles of the Treaty of Waitangi.
 - the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.
 - the disclosure statement requirements a disclosure statement has been prepared and is attached to the paper.

- the principles and guidelines set out in the Privacy Act 2020.
- relevant international standards and obligations.
- the Legislation Guidelines (2018 edition, maintained by the Legislation Design and Advisory Committee).

Consultation

- In July 2019, Cabinet agreed that MfE consult on proposed improvements to the HSNO Act for assessments and reassessments of hazardous substances [CAB-19-MIN-0362]. Public consultation took place in August and September 2019 on MfE's discussion document, *Hazardous substances assessments: Improving decision-making*. MfE received 44 submissions from a range of individuals and groups.
- The following agencies and Government departments were consulted on the draft Cabinet papers, both at the policy stage and at the draft Bill stage: Department of Internal Affairs, Department of Conservation, Ministry of Business, Innovation and Employment, WorkSafe New Zealand, Ministry of Health, Ministry for Primary Industries, Ministry of Justice, Ministry of Foreign Affairs and Trade, Te Puni Kōkiri and Treasury.
- The Department of the Prime Minister and Cabinet has been informed of the contents of this paper.
- 37 The Government caucus has been consulted.
- Officials consulted with the Ministry of Justice in relation to the offences and penalties included in the Bill.

Binding on the Crown

- 39 The HSNO Act already binds the Crown, except as provided for in section 3 of that Act. I consider that there are no good reasons why the Crown should not be bound by the legislative change to be progressed through this bill to amend the HSNO Act.
- I note that the paper Hazardous Substances and New Organisms (Assessments)

 Amendment Bill: Request for Priority in the 2021 Legislative Programme, which
 Cabinet recently considered [CAB-21-MIN-0144] stated that "It is likely to be
 recommended that the changes included in the Bill will be partially binding on the
 Crown in the same way as the HSNO Act currently is. That is, being binding on the
 Crown except for an exclusion for the Minister of Defence. The implications for
 government departments of these potential amendments will be minimal as the
 HSNO Act already binds the Crown in this way. Additional costs to the Crown are
 unlikely to be significant."



Not applicable.

Allocation of decision-making powers

Not applicable.

Associated regulations

There are no regulations needed to bring the Bill into operation.

Other instruments

The Bill does not include any provision empowering the making of other instruments that are deemed to be legislative instruments and/ or disallowable instruments.

Definition of Minister/department

Not applicable.

Commencement of legislation

The Bill will come into force on the day after the date of Royal assent.

Parliamentary stages

- I propose that the Bill should be introduced in August 2021 and passed by the end of the year.
- I propose that the Bill be referred to the Environment Select Committee.

Proactive Release

I propose to proactively release this Cabinet paper on MfE's website, within 30 business days following final Cabinet decisions. Proactive release is subject to redaction as appropriate under the Official Information Act 1982.

Recommendations

- The Minister for the Environment recommends that the Committee:
- note that the Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill holds a category 3 priority on the 2021 Legislation Programme (to be passed if possible within the year);
- 2 **note** that the Bill seeks to improve the assessment and reassessment of hazardous substances:
- note the decisions taken within the scope of my delegation [ENV-20-MIN-0020], as set out in paragraph 12 above;
- note that I propose to not progress the amendment to the Methodology Order but have provided for all matters in primary legislation, as set out in paragraphs 13 to 17 above;
- note that the consultation criteria for the new processes to improve the assessment and reassessment of hazardous substances will now be set in primary legislation rather than in the Methodology Order;
- **agree** that the consultation pathway for the new modified reassessment processes will be that:

- the EPA may decide to publicly notify the application under section 53;
- if the EPA does not publicly notify the application, the EPA must consult if it considers that the application will have—
 - significant cultural, economic, environmental, ethical, health or international effects; or
 - significant effects in an area in which the EPA lacks sufficient knowledge or expertise.
- if the EPA consults it must—
 - do everything reasonably practicable on its part to consult with all persons who, in its opinion, are likely to be directly affected by the reassessment; and
 - give those persons a reasonable opportunity to make submissions and comments to the EPA on the reassessment; and
 - consider all submissions and comments received before approving or declining the application. If the EPA is not required to consult, the EPA may consult with any person before approving or declining the application.
- agree that the consultation requirements for the existing modified rapid assessment processes (sections 63A and 63C) are slightly modified to align with the new consultation pathways for the new section 63D reassessment processes. This in addition to the amendments agreed to by Cabinet last year to allow for a more targeted consultation in these existing processes;
- 8 **note** that the criteria for identifying comparable international regulators will now be set in primary legislation rather than in the Methodology Order;
- 9 **agree** that the criteria for choosing international regulators are that:
 - 9.1 the international regulator operates in a manner comparable to the EPA in regulating hazardous substances; and
 - 9.2 the legislative regime regulating hazardous substances that the international regulator operates in is comparable to the HSNO Act; and
 - 9.3 the information from the international regulator is readily accessible by the EPA;
- agree that the EPA may prescribe, by notice in the Gazette, one or more international regulators on whose information it may rely. The EPA must follow the above criteria when choosing the international regulators;
- agree that a new penalty be added to section 114 of the HSNO Act for breach of the offence prescribed by section 109(1)(da) of the HSNO Act, as described in paragraph 28 above (this is to correct an omission made in 2015 when the offence was created without a corresponding penalty);
- agree that the Act be amended to refer in the relevant places to section 103A, as described in paragraph 29 above (this is to correct another omission made in 2015);

- agree that the HSNO Act be amended to clarify that the Ministerial call-in powers in section 68 apply to reassessments, as described in paragraph 30 above (this is to clarify an ambiguity);
- 14 **approve** the Hazardous Substances and New Organisms (Assessments)
 Amendment Bill for introduction, subject to the final approval of the Government caucus and sufficient support in the House of Representatives;
- agree that the Bill be introduced in August 2021;
- agree that the Government propose that the Bill be:
 - 16.1 referred to the Environment Select Committee for consideration;
 - 16.2 enacted by the end of 2021.

Authorised for lodgement

Hon David Parker Minister for the Environment