

Decision on application for approval to import or manufacture EDN for release

APP202804

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Environmental
Protection Authority
Te Mana Rauhi Taiao



Te Kāwanatanga
o Aotearoa
New Zealand Government

Chair's introduction

New Zealand's forestry industry relies on the use of chemical fumigants to ensure continued access to its major offshore markets. Methyl bromide, an ozone-depleting gas, has been the primary fumigant used by the industry to meet this need. A 2010 decision by the EPA to require recapture of residual methyl bromide used in log fumigations within a decade has proved unattainable at a scale commensurate with the growth in New Zealand's log exports. A decision on the reassessment of methyl bromide was made in 2021 and provided a pathway for reducing methyl bromide use. A search for alternative fumigants resulted in STIMBR identifying ethanedinitrile (EDN) as the leading candidate. An application to import or manufacture EDN as a fumigant for logs and timber was lodged with the EPA by manufacturer Lučební Závody Draslovka a.s. Kolín in July 2017 for consideration under section 28 of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The application was publicly notified in February 2018.

Assessment of a new fumigant within the hazard classification applicable to EDN was a significant undertaking. This was particularly so given the absence of approvals (and associated documentation) for the use of EDN sought by the applicant in international regulatory jurisdictions which New Zealand often aligns with. The applicant and STIMBR provided extensive data in support of the application and 43 parties made submissions on the application.

After the first part of the hearing in 2018, the Decision-making Committee (the Committee) concluded that further consideration of the application under the HSNO Act could not proceed until WorkSafe, the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW), completed a parallel process of assessment of the risks of EDN to workers. WorkSafe completed the draft safe work instruments (SWIs) in December 2020, enabling resumption of the assessment under the HSNO Act. EDN is the first such application considered by the EPA at the intersection of these two separate statutory regulatory processes, and this has undoubtedly contributed to the extended timeline of the application process. At the same time, the Committee considered the processes to be complementary; WorkSafe's draft SWIs formed a baseline from which to assess residual risks to the public and the environment.

We have approved the application to import or manufacture EDN for release as a phytosanitary treatment for logs or timber for export, though the HSNO approval will only take effect at the same time as the SWIs. EDN fumigation performed under a sheet or in a shipping container is permitted but, as the Committee did not have sufficient information to assess risk in ship's holds this use is not permitted.

The Committee recognised the concerns of members of the public, including Māori, and the regional council in respect to the risk to human health posed by EDN. Assessment of this risk (to bystanders and the public) has formed a major part of the Committee's consideration of

this application. The Committee concluded that the tolerable exposure limit (TEL) set out in the EPA Staff Reports and Science Memos was based on a cautious and conservative interpretation of toxicological data available and accounted for inherent uncertainties, and was therefore appropriate. We also considered that, through application of the controls specified in the draft SWIs (once given legal effect) and HSNO approval, the residual risk to members of the public would be negligible.

The Committee recognises the length of time taken to reach a decision on the application. The process has undoubtedly been impacted by the unprecedented constraints and demands imposed on all parties due to COVID-19. It has also been tested by the incremental provision of important technical information and time needed for parties to the proceedings to consider and provide comment on this information. Lastly, the Committee wishes to acknowledge the enormous amount of work invested throughout this process by the applicant, submitters, and staff of the EPA and WorkSafe and wish to thank each and all for the quality of information provided, participation in, and commitment to the process.

Nāku noa

Nā Dr John Taylor

Chair EDN Decision-making Committee, EPA

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Executive summary

The Decision-making Committee (the Committee) has approved EDN as a new fumigant for logs and timber for export. The actual approval will take effect at the same time as the WorkSafe safe work instruments (SWIs).

The application

On 17 July 2017, the Environmental Protection Authority (EPA) formally received an application to import or manufacture EDN for release under section 28 of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). In their application, Lučební Závody Draslovka a.s. Kolín (the applicant) proposed that EDN be used as a phytosanitary treatment on logs and timber in shipping containers, fumigation chambers, under sheets and in ship's holds. The applicant also stated that EDN would be a suitable alternative to the ozone-depleting fumigant methyl bromide.

The active ingredient of EDN, ethanedinitrile, has not been previously assessed under the HSNO Act, so the application was considered to be of significant public interest. Therefore, the application was publicly notified on 27 February 2018 and open for submissions until 19 April 2018. Forty-three submissions were received, and a public hearing was held over four days in Wellington (21 August 2018) and Rotorua (28 and 29 August), and adjourned on 29 August. The hearing was reconvened on 25 November 2021 and adjourned again on 25 November 2021. The hearing was formally closed on 1 March 2022.

In making its decision, the Committee received and reviewed a significant amount of information. This included the application, written submissions, presentations at the hearing, advice from the EPA, expert witness statements, field trial data, results from ambient air monitoring, outputs from air dispersion modelling, and WorkSafe's draft SWIs.

Summary of decision

The Committee accepted the evidence that EDN is the most viable replacement for methyl bromide as a fumigant of logs and timber, and that this would confer significant benefits to New Zealand's economy, society, and environment. The Committee noted that the likely decrease in methyl bromide use as a consequence of approval of EDN would help New Zealand address its obligations under the Montreal Protocol. The Committee also acknowledged the concerns of Māori and the wider public regarding the health and environmental effects of EDN and so considered the benefits against the risks and costs of the substance.

The Committee decided to approve with controls the import or manufacture of EDN for release, on the basis that the associated benefits are significant and that the adverse effects

are negligible with appropriate control measures applied. These measures include HSNO controls and the requirements of the draft “Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021” and draft “Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for Ethanedinitrile) Safe Work Instrument 2021” (once given legal effect).

The Committee set a range of controls, including:

Maximum application rate and fumigation duration

The Committee set the maximum application rate of 120 g of EDN/m³. However, the Committee concluded that the proposed 24-hour time constraint on fumigation was not required.

Use restriction

The Committee decided to restrict EDN use to fumigation of logs or timber for export under a sheet or in a shipping container. Other uses, such as fumigation on imported forest products or in ship’s holds, were not included as the Committee concluded that it did not have sufficient information to assess the risks of these uses. The Committee also noted that the draft Requirements for Specified Fumigants Amendment SWI restricts fumigation with EDN to logs and processed wood and does not allow use in ship’s holds. Alterations to the SWIs are a matter for WorkSafe.

Wind speed

The Committee decided that ventilation of EDN should occur only when there is wind to aid gas dispersion and manage risks to the public. Therefore, the Committee determined that EDN ventilation can only be undertaken when the wind speed is at least 2 m/s in the 10 minutes prior to ventilation.

Notification of fumigation and tolerable exposure limit (TEL) exceedance

The Committee set the TEL for ethanedinitrile to 0.034 ppm as a 24-hour average. The Committee acknowledged the draft Requirements for Specified Fumigants Amendment SWI requirements to notify specified parties of intended fumigations, and to notify WorkSafe and the relevant medical officer of health of any TEL exceedances within five working days. The Committee considered that both notifications should be supplemented by notification to the relevant local authority, and that any TEL exceedance should be notified within 24 hours. This will allow the local authority to respond in a timely manner and manage any health or environmental risks that may arise.

1. Background

- 1.1 Lučební Závody Draslovka a.s. Kolín (the applicant) has applied to import into or manufacture EDN in New Zealand. EDN contains the active ingredient ethanedinitrile (also known as oxalonitrile or cyanogen; CAS number 460-19-5) as a compressed gas at a concentration of 1000 g/kg, and a minimum purity of 95%.
- 1.2 The applicant has requested approval for use of EDN as a phytosanitary treatment of wood products (including logs) to control a wide range of insects, nematodes, and fungi. The applicant proposed that fumigation be carried out in shipping containers, fumigation chambers, under sheets, and in ship's holds. The maximum application rate of 150 g/m³ in the application was later reduced by the applicant to 120 g/m³. EDN was proposed as an alternative to methyl bromide.
- 1.3 This active ingredient is new to New Zealand but has previously been granted containment approvals (HSC100070, HSC100135, and HSC100191). HSC100191 was approved in 2019 and expired in February 2022. There is no approval of ethanedinitrile under the Agricultural Compounds and Veterinary Medicines Act 1997.
- 1.4 EDN is currently approved in Australia, South Korea, Malaysia, and Russia as a fumigant. Ethanedinitrile fumigation is an officially recognised treatment option for logs and timber imported into Malaysia and Australia. However, India and China – who are New Zealand's major log export trading partners – do not yet accept EDN fumigation as a treatment option.

2. Process, consultation, and notification

Lodgement and formal receipt

- 2.1 The Environmental Protection Authority (EPA) formally received the application to import or manufacture EDN for release on 17 July 2017.

Notification of application

- 2.2 The application was considered of significant public interest, as EDN is a new active ingredient not previously assessed under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). The application was therefore publicly notified in accordance with section 53 of the HSNO Act.
- 2.3 However, as further information was requested from the applicant under section 52 of the HSNO Act, the timeframe before public notification of this application was waived under section 59 of the HSNO Act.
- 2.4 The application was publicly notified on 27 February 2018 and was open for submissions until 19 April 2018. This included an extension of one week, made under section 59 of the HSNO Act, to allow interested parties additional time to submit.

Submissions

- 2.5 Forty-three submissions were received during the public submissions period. Thirty-eight submissions supported the application, three opposed the application and two neither supported nor opposed it.
- 2.6 A Science Memo and a Staff Report were prepared by the EPA for this application in July 2018. The Science Memo focused on determining the classification, hazards, and risks to people and the environment. The Staff Report summarised the content of the submissions and integrated the findings of the Science Memo with cost and benefit considerations.

Decision-making Committee

- 2.7 A Decision-making Committee (the Committee) was confirmed on 9 July 2018 and comprised three members.
- 2.8 Prior to the hearing, as well as throughout the hearing process, the Committee provided directions by way of published Direction and Minutes. These, together with other documents the Committee received, are summarised in Appendix A.

First part of the hearing

- 2.9 Due to the volume of supporting information in the submissions received requiring evaluation and analysis, the timeframe between the close of submissions and the hearing was waived under section 59 of the HSNO Act.
- 2.10 The public hearing was held in Wellington (21 August 2018) and Rotorua (28–29 August 2018) and was adjourned on 29 August 2018.
- 2.11 Presentations from 12 submitters (and their witnesses), as well as EPA staff, WorkSafe, and the applicant, were heard over the three days. A full list of presentations and presenters is included in Appendix B, and specific points raised by the presenters are discussed in Section 3.

New information received, further information requested, and opportunities for feedback

- 2.12 Parties to the proceedings have had further opportunities to provide additional information or submit written feedback on new information that has been received.
- 2.13 Immediately prior to the first part of the hearing, the applicant provided further air dispersion modelling data. On 21 August 2018, Stakeholders in Methyl Bromide Reduction (STIMBR) (a submitter on this application) also provided new information on wood odour during fumigation.
- 2.14 Considering the late provision of evidence and to assist in reaching a robust decision, the Committee directed two sets of expert conferencing be held to resolve areas of disagreement highlighted during the hearing.
- 2.15 The expert conferencing sessions were held on 4 October 2018 and 11–12 October 2018 and covered the Tolerable Exposure Limit (TEL) and air concentration dispersion modelling, respectively. Joint statements on TEL and air concentration dispersion modelling were issued on 12 and 15 October 2018 respectively.
- 2.16 The Committee requested written comment from interested parties on the new information provided and the joint witness statements.
- 2.17 Further rounds of information requests and responses from parties on information received included analysis of worker exposure data, data from trials in Tokoroa, and collated data from international trials.
- 2.18 On 7 October 2019, the EPA published an Addendum to the Staff report, which outlined what impact the new information had on the views outlined in the EPA Staff Report and EPA Science Memo.

Safe work instruments

- 2.19 As the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW Act) and associated regulations, WorkSafe has responsibility for determining that the HSW Act requirements are adequate to manage the risks from a substance in the workplace. The EPA therefore sought WorkSafe's views under section 58 of the

HSNO Act. WorkSafe provided advice to the Committee in August 2018, proposing it develop a safe work instrument (SWI) for EDN and amend the Requirements for Specified Fumigants SWI, thereby giving effect to provisions of the General Risk and Workplace Management Regulations (GRWM Regulations).

- 2.20 The Committee considered that SWIs relating to the management of the risk of EDN in workplaces were directly relevant to its consideration, and therefore determined that this separate statutory process needed to be undertaken before further steps were taken.
- 2.21 WorkSafe conducted a public consultation on two draft SWIs:
- Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021
 - Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for Ethanedinitrile) Safe Work Instrument 2021
- between 28 February 2020 and 5 April 2020. Some changes to the original proposals were made, and a further targeted consultation on the changes was held between 23 July 2020 and 7 August 2020.
- 2.22 On 8 December 2020, WorkSafe notified the EPA that the draft Requirements for EDN SWI and draft Requirements for Specified Fumigants Amendment SWI had been approved in principle.
- 2.23 The EPA published the Updated Science Memo and Updated Staff Report on the 23 August 2021 to provide the Committee with an overview of the changes in respect of hazard classification and risk assessment. The reports focused on residual risk on the basis that the draft SWIs would take legal effect (details of how the SWIs take legal effect are detailed in paragraph 3.57).
- 2.24 Parties to the proceedings had an opportunity to comment on the Updated Science Memo and Updated EPA Staff Report before the hearing was reconvened.

Reconvened hearing

- 2.25 The Committee determined that the hearing would be reconvened, with the scope confined to information before the Committee that had been substantially updated or revised since the adjournment of the first part of the hearing.
- 2.26 On 25 November 2021, the hearing was reconvened via video conference.
- 2.27 Presentations from seven submitters (and their witnesses) as well as EPA staff, WorkSafe, and the applicant were heard. A full list of presentations and presenters is included in Appendix B, and specific points raised by the presenters are discussed in Section 3.
- 2.28 During the reconvened hearing, STIMBR spoke to legal submissions, which raised legal issues that had not yet been addressed by parties to the application.
- 2.29 The hearing was adjourned at the close of business on 25 November 2021.

- 2.30 Following the reconvened hearing, the Committee directed STIMBR to provide a written copy of their legal submissions and the EPA to provide a written response. The EPA was also directed to publish legal advice regarding ship's holds that had been previously provided to the Committee.
- 2.31 Four parties provided comment or responses to the legal submissions and advice.

Information available for consideration

- 2.32 In reaching its decision, the Committee considered information from a variety of sources:¹
- application form and associated appendices
 - further information requested and provided
 - submissions
 - expert input (including joint witness statements)
 - EPA Science Memo and Updated Science Memo
 - EPA Staff Report, Addendum to the Staff Report, and Updated EPA Staff Report
 - hearing: witness statements, oral submissions, legal submissions, questions, responses, and presentations by applicant, EPA staff, and submitters.
- 2.33 After considering all relevant information, the Committee decided it had sufficient information to determine the outcome of this application. The Committee formally closed the hearing on 1 March 2022.

¹ All documents associated with this application can be found at: <https://www.epa.govt.nz/database-search/hsno-application-register/view/APP202804>

3. Key matters

- 3.1 The Committee identified several key matters pertinent to their consideration of the application. These matters are set out in the subsequent paragraphs, highlighting the key aspects. The Committee's consideration of these and other matters is presented in Section 4.

Hazardous properties

- 3.2 The applicant proposed the following hazard classifications for EDN, using the HSNO classification system: 2.1.1A, 6.1B (inhalation), and 9.1A.
- 3.3 The applicant stated that EDN diffuses rapidly in air, degrades rapidly in the environment to carbon dioxide and ammonia products, does not move into the aqueous environment, is not ozone depleting, is not a greenhouse gas, and does not bioaccumulate in any aquatic or terrestrial organisms.
- 3.4 The proposed hazard classifications for EDN in the 2018 EPA Science Memo were the same as the applicant's, however, the Science Memo noted that as EDN has been approved in other jurisdictions as a soil fumigant, it is expected to be toxic to the soil environment. However, as no reliable study data on soil toxicity was provided, the ecotoxicity of EDN to the soil environment could not be determined.
- 3.5 The EPA noted that EDN reacts to form hydrogen cyanide upon contact with water in the atmosphere or in the body, which is considered the cause of its toxicity. This and other reaction products then break down to form ammonia and carbon dioxide. The EPA agreed that EDN is not expected to bioaccumulate or persist in the environment.
- 3.6 The EPA updated the hazard classifications proposed for EDN when New Zealand adopted the seventh revised edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS 7) in 2021. The updated hazard classifications are:
- flammable gas Category 1A
 - liquified gas
 - acute inhalation toxicity Category 2
 - hazardous to the aquatic environment acute Category 1
 - hazardous to the aquatic environment chronic Category 1.
- 3.7 The EPA noted that these hazard classifications trigger prescribed controls under the HSNO Act and the HSW Act.

Effects of the substance during its life cycle

- 3.8 In the application, the applicant described the life cycle of EDN. In its risk assessment, the EPA recognised exposure was unlikely to occur during the importation, manufacture, transportation, storage, and disposal of EDN. The EPA stated that

proposed controls and other legislative requirements would be sufficient to mitigate the risks associated with these stages of the substance lifecycle to a negligible level.

Field trials and ambient air monitoring

- 3.9 The applicant provided information obtained from field trials conducted in the Czech Republic, Russia, South Korea, Australia, USA, and New Zealand. The applicant noted that these were undertaken using various dose rates and fumigation periods and under differing regulatory regimes. The trials showed the expected decrease in EDN concentration over the fumigation period and in the ambient air following ventilation.
- 3.10 The overseas trials were of stack sizes, dose rates, and fumigation periods that did not provide information relative to stack sizes treated in New Zealand nor at the proposed dose rate. The New Zealand trials, undertaken in 2016 and 2019, were more applicable, however, there was a significant difference in recorded stack volumes, leading to uncertainty. The trials also involved a staged removal of the sheet, whereas Bay of Plenty Regional Council (BOPRC) had provided evidence that sheet removal is usually in the order of 8 minutes. The slower sheet removal in the trials would have resulted in a slower release of residual EDN and lower ambient concentrations than would be found in normal operations.
- 3.11 The applicant acknowledged that, as the 2019 New Zealand trials were to confirm efficacy of EDN, the ambient air monitoring was less comprehensive than if monitoring were the focus of the trial.

Air dispersion modelling

- 3.12 The applicant provided air dispersion modelling reports from Sullivan Environmental Consulting in 2018 and 2020. In the development of the SWI, WorkSafe commissioned a report from Todoroski Air Sciences in 2019, which assessed a wide variety of discharge scenarios and meteorological conditions.
- 3.13 The Todoroski modelling was criticised by the applicant as being too conservative. At the reconvened hearing, BOPRC was critical of the modelling and said that it underestimated concentrations by a factor of four.
- 3.14 WorkSafe noted that the two sets of modelling could be viewed as complementary and, when considered jointly, provided useful predictions about the likely behaviour of EDN in a fumigation setting. Both sets of modelling as well as other sources of information were used to inform the draft SWI requirements.

Use of EDN for the treatment of logs and timber

Use of EDN on imported logs and timber

- 3.15 The applicant requested approval to import or manufacture EDN in New Zealand as a phytosanitary treatment of wood products (including logs).
- 3.16 In the 2018 EPA Staff Report, the EPA introduced a restriction limiting the use of EDN to fumigation of logs and timber for export only. No information on EDN use on imported timber was provided by the applicant, and therefore this use was not considered in the risk assessment carried out by the EPA. This use restriction was retained in the Updated EPA Staff Report.
- 3.17 In response to the Updated EPA Staff Report, both STIMBR and the Ministry for Primary Industries (MPI) requested that EDN also be available to treat incoming logs and timber at the border. Additionally, MPI stated that it is responsible for managing risks from pests and diseases moving between countries and therefore requested that EDN not be restricted to use on timber only but also be available for fumigation of imported goods, machinery, and equipment. The New Zealand Forest Owners Association (NZFOA) also discussed the interest of forest owners in protecting New Zealand's forests from imported pests and said an effective fumigant for imported products is essential.
- 3.18 In its closing statement, the applicant reiterated its request that the Committee not limit EDN use to the fumigation of logs and timber for export only but include imported logs and timber to cater for domestic biosecurity needs. However, the applicant noted that should any important commodities not be covered by the approval, it would work with MPI and STIMBR on a potential reassessment.
- 3.19 This request was supported by both STIMBR and MPI as it would make EDN more useful for industry and for biosecurity.
- 3.20 At the reconvened hearing, the EPA stated that fumigation of imported logs and timber would not change its risk assessment, and it no longer proposed to restrict EDN fumigation on logs and timber for export only.
- 3.21 Following the reconvened hearing, in its legal submission MPI stated that any approval of EDN should not be limited solely for use on logs and timber for export. MPI noted that the application did not limit itself to seeking approval to use EDN for export purposes only and that the draft Requirements for Specified Fumigants Amendment SWI does not differentiate between import and export.

Use of EDN in shipping containers

- 3.22 In its application to import or manufacture EDN in New Zealand, the applicant requested that fumigation with EDN be permitted within shipping containers. However, the applicant did not provide any information on such use at that time.
- 3.23 In its 2018 report, WorkSafe noted EDN's flammability and stated that, due to the likely presence of non-intrinsically safe ignition sources, default controls for flammable

atmospheres could not be met in containers. Therefore, WorkSafe did not consider EDN fumigation in shipping containers to be appropriate, unless evidence were provided showing that the risks of flammable atmosphere zones could be managed. The EPA acknowledged WorkSafe's position in its 2018 Staff Report, adding that only information and air dispersion modelling relating to log fumigation under sheets had been provided, which could not be extrapolated to use in shipping containers. As the EPA did not assess the risks of use in containers, it proposed a control limiting EDN fumigation to under sheets.

- 3.24 Subsequently, the applicant provided field trial data on log fumigation with EDN in shipping containers.
- 3.25 In the consultation document for the draft SWIs, WorkSafe stated that if the EPA approves the use of EDN for fumigations in shipping containers, the proposed requirements of the draft SWIs (that ventilation may not proceed until a residual concentration of 700 ppm EDN is reached) would also be appropriate for that use, due to the enclosed nature of shipping containers and the smaller volume of logs that they contain.
- 3.26 In the Updated EPA Staff Report, the EPA stated that the risk of fire during log fumigation in a shipping container is negligible if prescribed and additional HSNO controls and requirements of the draft SWIs (once given legal effect) are followed.
- 3.27 At the reconvened hearing, the applicant stated that shipping containers used to fumigate and transport logs do not contain electrical equipment as they do not need to be refrigerated and therefore are unlikely to generate sparks. Additionally, the applicant pointed out that the requirements of the draft SWI require elimination or isolation of ignition sources in or near the treated volume. The applicant reiterated the request to allow EDN to also be used in shipping containers.

Use of EDN in ship's holds

- 3.28 The application for import and manufacture of EDN in New Zealand included its use as a fumigant in ship's holds. This was supported by several submitters.
- 3.29 Rayonier Matariki Forests and NZFOA both stated that approval of EDN for ship's hold cargo is critical. TPT Forests Ltd agreed, saying that due to the large buffer zone requirements set for methyl bromide, it essentially cannot be used in ship's holds from January 2022. Therefore, the industry would be unable to meet India's fumigation requirements, which could reduce market diversity. TPT Forests Ltd said an additional in-hold fumigant is needed. NZFOA also agreed, saying ship's hold treatment is important for the Indian market, which helps reduce reliance on China.
- 3.30 However, BOPRC did not consider that EDN can be used safely for fumigation in ship's holds, largely due to its flammability risk and concerns about volumes of residual gas that would be discharged. BOPRC supported a limit on its use to only under a sheet or in a shipping container.
- 3.31 WorkSafe stated that it considered ship's hold fumigation during the drafting and consultation of the draft SWIs but had insufficient information available on this use.

Additionally, the modelling suggested that, as the volume of logs in these fumigations is significantly larger than in stacks, buffer zones required for ship's hold fumigation would be too large to be practicable. As a result, the draft SWIs exclude ship's hold fumigation.

- 3.32 Consequently, at the reconvened hearing, the applicant requested that the Committee grant a conditional approval for ship's hold fumigation, contingent on the development of a new SWI by WorkSafe.
- 3.33 WorkSafe indicated at the reconvened hearing in 2021 that, if more information became available, it would consider the use of EDN for ship's hold fumigations through an SWI process. However, this process would be subject to the usual regulatory steps under the HSW Act, including consultation.
- 3.34 At the reconvened hearing, STIMBR's counsel stated that no jurisdictional bar exists to prevent the Committee granting such a conditional approval.
- 3.35 In response to STIMBR's legal submissions (provided after the reconvened hearing at the Committee's request), the EPA Legal Team provided advice to the Committee. The EPA Legal Team said while it did not consider there to be any jurisdictional bar to granting an approval that would permit use of EDN in ship's holds, the Committee had insufficient information before it regarding the risks and mitigations/controls of using EDN in a ship's hold.
- 3.36 That advice also stated the following points.
- The HSW Act already requires an SWI to be in force for EDN to be used in a workplace (such as a ship's hold), so the proposed 'condition' simply reflects the law as it stands. A conditional HSNO approval would in essence circumvent the EPA conducting a proper assessment of risks arising from this use of EDN to the environment and bystanders, thereby undermining the regulatory regime.
 - The Committee cannot rely on the outcome of a separate statutory process that WorkSafe may run in the future (to assess and mitigate the risks of EDN in a workplace) in order to determine risks and appropriate mitigations for that use under the HSNO Act.
 - As a result, the Committee cannot approve the import or manufacture of EDN without controls that prohibit use in ship's holds.
- 3.37 Four parties to the proceedings responded to the EPA's legal advice in response to an invitation from the Committee.
- 3.38 In its legal submission, the BOPRC largely agreed with the EPA's legal advice and was particularly concerned that proceeding with the approach proposed by STIMBR would result in it not being able to be heard about matters of protection of people and the environment under the HSNO jurisdiction.
- 3.39 In its legal submission, MPI's position was that the Committee can approve EDN without a control prohibiting use in ship's holds if the Committee determines that the positive effects of EDN being available for this use outweigh the negative effects.

- 3.40 Similarly, in its legal submission, STIMBR's position was that it is open to the Committee to approve EDN without a control prohibiting use in ship's holds. STIMBR noted that the Committee must make its own assessment of the evidence and risks and considered the draft SWIs and a TEL control to be relevant to this risk assessment. STIMBR reiterated that it considered the Committee could make a conditional approval under the HSNO Act.
- 3.41 The applicant made no additions or comments regarding these legal opinions. The applicant stated that should the approval not allow use of EDN in ship's holds, it would apply for a reassessment of any HSNO approval as soon as it has sufficient data to inform a risk assessment.

Application rate and duration of use in the fumigation of logs and timber

- 3.42 EDN is intended to be used as a fumigant to control insect pests and pathogens on logs and timber.
- 3.43 In the application, the applicant proposed an EDN application rate per treatment of 150 g/m³ based on laboratory trials that were yet to be completed. Consequently, the EPA proposed a maximum application rate control of 150 g/m³.
- 3.44 Subsequently, the applicant provided new information from field trials that showed EDN was efficacious against all forest pests commonly associated with logs and timber in New Zealand at a concentration of 120 g/m³. Therefore, the applicant requested a reduction in the maximum application rate from 150 g/m³ to 120 g/m³.
- 3.45 Consequently, the proposed maximum application rate control was updated to 120 g/m³ in the Updated EPA Staff Report.
- 3.46 The Updated EPA Staff Report specified that an individual fumigation would be conducted over a period of 24 hours, referring to standard international practice. Subsequently, the applicant requested a revision to the application rate control from "over" 24 hours to "up to" 24 hours, which would allow for future flexibility. Field trials provided by the applicant have shown that both the efficacy and meeting the end-point concentration of EDN in the enclosed space before ventilation may be achieved in as little as 16 hours.
- 3.47 The EPA clarified at the reconvened hearing that the wording "over 24 hours" was always meant to be an upper limit of what is potentially intended.

Impacts specific to Māori and Māori culture

- 3.48 Te Runanga o Ngāi Tahu spoke of Ngāi Tahu's interest in the application, both due to the fumigation that occurs within their takiwā and their major interest in the forestry sector. Ngāi Tahu supported the phase-out of methyl bromide and recognised that an alternative fumigant, such as EDN, would be needed to maintain the log export industry. Ngāi Tahu considered that the risks to the aquatic environment and birds were negligible and that the risks to port workers can be managed. Ngāi Tahu

acknowledged the tangata whenua of Tauranga, Whangarei, and Napier and expressed concern that these iwi were not participating in the hearing process. However, Ngāi Tahu believes that EDN is unlikely to raise serious concerns regarding potential risks and impacts on Māori values and that discussions with the Tauranga iwi suggested that they consider EDN to be the best for the job.

- 3.49 Conversely, the Tauranga Moana Fumigation Action Group (TMFAG) stated that it has Māori members who are particularly concerned about EDN's interaction with water and what happens if residual amounts in bark and dust from the port are washed into storm water.
- 3.50 The EPA acknowledged that EDN's high aquatic ecotoxicity could pose a risk to culturally significant species in harbour waters but that minimal amounts of EDN are expected to be absorbed into water. Culturally significant insects, soil organisms, and birds are considered unlikely to be present at ports locations and so have a low risk of exposure to EDN. Therefore, the EPA considered the risk to culturally significant species to be negligible if prescribed and additional HSNO controls and requirements of the draft SWIs (once given legal effect) were implemented.
- 3.51 The EPA noted that Māori have a higher incidence of respiratory disease than non-Māori and are represented in occupations where they may be exposed to EDN as workers. This means that Māori are considered a high-risk or potentially vulnerable group. However, the EPA considered that the health risks can be managed with the appropriate controls (including SWIs) in place.
- 3.52 The EPA also recognised that EDN would have benefits for Māori. The forestry industry employs many Māori, so the availability of EDN to this industry would support social and economic opportunities for Māori in rural areas and the productive use of Māori land for growing pine trees.

International obligations

- 3.53 The EPA and three submitters (Don Hammond of Hammond Resource Management, MPI, and Te Runanga o Ngāi Tahu) pointed out that New Zealand has obligations under the Montreal Protocol to reduce the use of ozone depleting substances and therefore requires an alternative to methyl bromide for log fumigation.

Risks to workers – the draft SWIs

- 3.54 WorkSafe discussed how it works with the EPA on hazardous substance applications to assess whether existing regulations will adequately manage the risks to workers. If not, WorkSafe may set additional or modified requirements in safe work instruments (SWIs), which must be consistent with the purpose of the HSW Act.
- 3.55 Following its review of relevant documents in 2018 and participation in the first part of the hearing, WorkSafe confirmed its opinion that the current regulations were not sufficient to manage the risks of EDN to workers and that it would therefore develop two draft SWIs.

- 3.56 At the reconvened hearing, WorkSafe described the main requirements of the draft SWIs:
- minimising risk to the public and workers
 - making sure people know what is happening
 - minimising risk during fumigation
 - minimising risk through adaptive controls
 - minimising risk during ventilation
 - administrative controls
 - prescribed workplace exposure standards
 - health monitoring.
- 3.57 WorkSafe stated that any site could fumigate with EDN using the draft SWIs (once they take legal effect) without the application of location-specific requirements. The Minister for Workplace Relations and Safety (the Minister) has approved these draft SWIs in principle, pending the Committee's decision. If EDN is approved by the Committee with controls described in the Updated EPA Staff Report, WorkSafe stated it will return to the Minister and seek final approval of the draft SWIs. If the Committee approves EDN with controls that differ from those proposed in the Updated EPA Staff Report, WorkSafe may need to review the draft SWIs, which may require additional work including redrafting and further consultation before Ministerial approval is sought. Once approved by the Minister, the SWIs will be notified in the New Zealand Gazette and come into force 28 days later.
- 3.58 The applicant and several submitters endorsed the WorkSafe draft SWIs and agreed that they would manage the risks to workers.
- 3.59 The EPA acknowledged that WorkSafe is responsible for workplace health and safety and evaluated the residual risks to public health and the environment assuming the controls in the draft SWIs were in place. The EPA noted that the draft SWIs provide clarity around considerations such as buffer zones and that though the requirements set are primarily to reduce worker exposure, they also reduce public and environmental exposure to EDN.

Risks to members of the public and the environment

- 3.60 Several submitters commented on the impact the approval of EDN may have on communities.
- 3.61 The BOPRC said that there was significant public concern around the use of EDN because of the proximity of the Port of Tauranga to the community: Whareroa Marae, sports fields, a Playcentre, residential housing, industry, and the marina are within a few hundred metres of fumigation at the port.
- 3.62 The Soil & Health Association of New Zealand said that EDN would pose a risk beyond the fumigation area, as modelling and trials had shown extensive spread of EDN, endangering fumigation workers, bystanders, and the community. The Soil &

Health Association added that boundary monitoring at head height would be ineffective if the EDN plume were to pass above the monitors and then descend into other areas.

- 3.63 WorkSafe's draft SWIs manage the risks to workers, and therefore, the Updated Science Memo and Updated EPA Staff Report focused on the remaining risks to bystanders or residents near areas where fumigation may occur and use is permitted under the draft SWIs. The Updated EPA Staff Report proposed controls that complemented the draft SWIs rather than duplicated them and removed previously proposed controls associated with uncertainties that were now addressed by the draft SWIs.

Sensitive areas exclusion zone

- 3.64 The 2018 EPA Science Memo noted that, while EDN is acutely toxic by inhalation, the risk to bystanders from acute short-term exposure would be negligible, as modelled exposures were less than the Acute Exposure Guidelines² (AEGL) values.
- 3.65 The EPA also undertook an assessment of the long-term risk posed by fumigation operations to the public based on air dispersion modelling data provided by the applicant, and an assumed TEL and proposed a buffer zone of 120 m. In this assessment, the EPA applied a scenario based on ventilation of 30 log stacks. This buffer zone was proposed in recognition of the risk of a chronic and continuous type of exposure to individuals who may be residing near a fumigation operation.
- 3.66 The draft Requirements for Specified Fumigants Amendment SWI set a minimum buffer zone of 50 m based on WorkSafe's interpretation of air dispersion modelling data to ensure the concentration of EDN during venting of log stacks does not exceed the TEL at or beyond this distance from the perimeter of the fumigation area. In its Updated Science Memo, the EPA noted that provided the requirements described in the draft Requirements for Specified Fumigants Amendment SWI are adhered to, it considered that the risks to members of the public would be negligible as EDN concentrations outside the buffer zone would always be maintained below the TEL.
- 3.67 In order to further protect sensitive populations, the Updated EPA Staff Report proposed that a 120 m distance be maintained as an additional exclusion zone between the fumigation area and "sensitive sites". The Updated EPA Staff Report defined sensitive sites to include schools, playgrounds, early childhood centres, prisons or places of detention, hospitals, or long-term care facilities where members of the public may be unable to evacuate themselves in case of breaches of the TEL.
- 3.68 At the reconvened hearing, BOPRC said that buffer zones or exclusion distances are one of the most important controls for protecting people's health, as they are easy to set up and verify and are very effective. BOPRC also stated that the 50 m buffer zone

² Established by the United States National Research Council and the United States Environmental Protection Agency.

for the public in the draft SWI was insufficient based on modelling prepared for the EPA, which indicated a buffer zone of 120 m would be necessary.

Tolerable Exposure Limit (TEL)

- 3.69 In the 2018 Staff Report, the EPA proposed a TEL of 0.034 ppm as a 24-hour average.
- 3.70 However, at the first part of the hearing, the applicant considered this to be too conservative and asked for the TEL to be reconsidered, proposing an increase to 0.56 ppm. The applicant pointed out that the EPA used a very conservative uncertainty factor of 100 in its calculation, when other references use an uncertainty factor of six.
- 3.71 Subsequently, a joint expert conference that included a representative of the applicant's team and a representative of the EPA was held on the topic of TEL. The TEL was agreed upon at the conference, and all parties had the opportunity to comment on the TEL value. The EPA considered this a robust process that has resulted in the setting of a relatively conservative but good-quality TEL value.
- 3.72 At the reconvened hearing, the applicant supported the use of a TEL value of 0.034 ppm as determined following the joint expert conference process.
- 3.73 STIMBR agreed that, as the proposed TEL incorporates significant conservatism, it would provide appropriate protection to members of the public.
- 3.74 The BOPRC stated that a 1-hour TEL as well as the 24-hour TEL was essential. However, the applicant stated that EDN does not produce any measurable short-term effects upon which a 1-hour TEL could be established. To set a 1-hour TEL would require extrapolation of repeated chronic exposure down to the order of minutes that would make the value so imprecise as to be meaningless.

Wind speed

- 3.75 The 2018 EPA Staff Report initially proposed a wind speed control whereby EDN must not be vented under very low wind speed conditions (less than 5 km/h [1.8 m/s]) or under inversion³ conditions. This was to protect marine life as EDN could be absorbed into harbour waters under still weather conditions.
- 3.76 In its response to Direction and Minute 10, the applicant stated that this was overly precautionary and that such a control would unduly limit fumigation at the port without significantly reducing any risk that may be present. The applicant argued that very low wind speeds or inversion conditions would not typically occur in port locations where sea breezes are expected and requested that this control be removed.
- 3.77 STIMBR also stated that the wind speed control should be lower or even removed.

³ Normally air temperature decreases with height, but an inversion is a layer in the atmosphere in which temperature increases with altitude. An inversion can act as a cap to suppress convection.

- 3.78 In the response to Direction and Minute 10, the applicant stated that information from field trials showed EDN does not “pool” or linger in the fumigation area during the venting process but diffuses rapidly.
- 3.79 At the reconvened hearing, WorkSafe discussed one of the requirements of the draft Requirements for Specified Fumigants Amendment SWI: that ventilation of EDN can only occur between sunrise and sunset. Modelling showed this to be a means of reducing risk, as a lack of sea breezes limited fumigant dispersion during night hours.
- 3.80 The Updated EPA Staff Report, published after the draft SWIs were prepared, stated that the draft SWI requirements for ventilation and monitoring address the risk by reducing potential exposure, making a wind speed control unnecessary.
- 3.81 BOPRC stated it did not believe the sunrise to sunset control would be a sufficient replacement for a wind speed control. BOPRC said that requiring a minimum wind speed during venting ensures that mixing and dispersion occurs. Additionally, the wind helps in predicting the direction of the gas plume, which assists with placement of monitors. BOPRC also pointed out that the recent decision on the reassessment of methyl bromide set a minimum wind speed control of 2 m/s (or 7.2 km/h) before venting can occur. BOPRC suggested that having consistent controls across all fumigants would be useful.

Recapture

- 3.82 At the 2018 hearing, the Soil & Health Association said that EDN is known to be lethal at high concentrations but that its carcinogenicity, mutagenicity, and reproductive or developmental toxicity have not been studied. Because of this, the Soil & Health Association considered that a precautionary approach should be taken and EDN not be approved without recapture until these studies are completed. TMFAG also wanted the recapture of EDN to be a requirement.
- 3.83 Nordiko Quarantine Systems stated that EDN recapture should be used to reduce risk and improve environmental and health and safety outcomes as accurate monitoring of EDN emissions is a challenge, and modelling has many uncertainties. Nordiko Quarantine Systems presented its activated carbon recapture system, stating it is technically and economically feasible to use even on very large-scale fumigations.
- 3.84 However, Mr Hammond disagreed, stating that scrubbing or recapture is not necessary as EDN is broken down during fumigation, leaving negligible levels at the end of the process.
- 3.85 On 25 March 2020, the applicant provided further justification in the form of a written report as to why recapture or scrubbing may not be required. WorkSafe considered the applicant’s justification in light of this possible requirement, concluding that recapture was not necessary and therefore did not include it in the draft SWIs.

Notification

- 3.86 At the reconvened hearing, BOPRC and WorkSafe discussed notification requirements.
- 3.87 BOPRC explained that it monitors activity at the Port of Tauranga for compliance purposes and so needed advance notice of fumigations in order to appropriately place its monitors. BOPRC noted that neither the draft SWIs nor the EPA's proposed controls required the PCBU to notify local authorities about fumigation events or report any information to local authorities. BOPRC therefore requested that a control be introduced requiring that local authorities be kept fully informed.
- 3.88 WorkSafe stated that while it did receive some submissions requesting such a control, it was not its role to be setting requirements on behalf of councils. WorkSafe felt that councils had tools to collect this information as they required it.

Benefits

- 3.89 The applicant and several submitters commented on the importance of the forestry industry to the New Zealand economy and specifically the importance of log exports. MPI submitted that forestry makes up a significant part of New Zealand's primary production in the export sector, and revenue is expected to reach \$6.7 billion by 2025. Four submitters (NZFOA, Rayonier Matariki Forests, Port Blakely Ltd, and MPI) highlighted the forestry industry's role in the New Zealand Government's post-COVID-19 economic recovery strategy Fit for a Better World.
- 3.90 International markets, such as China and India, require fumigation of timber before arrival, with India accepting only methyl bromide as a fumigant. Rayonier Matariki Forests said that the reassessment of methyl bromide has left the forestry industry with no fumigation options for log exports to India and in some cases to China. Additionally, Rayonier Matariki Forests commented that this has also made diversifying their export markets (so becoming less dependent on China) more difficult. MPI said that overseas markets may change their fumigation requirements, so New Zealand requires fumigation options to maintain market access.
- 3.91 The applicant and several submitters supported the use of EDN as an alternative to methyl bromide for log fumigation. The Updated EPA Staff Report recognised the potential benefits of EDN as an alternative to methyl bromide, including continued viability and expansion of the forestry industry in New Zealand.
- 3.92 The applicant considered EDN to currently be the only possible replacement for methyl bromide that is safe and environmentally sustainable. Many other parties agreed with this.
- 3.93 Dr John Armstrong of Quarantine Scientific Limited said that he undertook a review in 2014 of all known literature on alternatives to methyl bromide, both chemical and non-chemical. This review found that EDN was the only potential alternative treatment that could be safely and economically adapted and applied under commercial conditions by 2020 (the deadline for methyl bromide recapture at the time). NZFOA also said that

several alternatives to methyl bromide, such as debarking, had been explored but that, in its opinion, EDN was the only viable option.

- 3.94 Mr Hammond agreed that EDN is the single best replacement for methyl bromide, especially since it uses the same logistical structures and therefore does not require large upfront costs or new port space to be taken up. NZFOA said that exporters need a range of phytosanitary options and that EDN would be a significant addition.
- 3.95 TPT Forests Ltd stated that the company must fumigate a significant proportion of the logs they export. TPT Forests needs an alternative to methyl bromide and the ability to adapt in case export markets such as Japan and South Korea (which currently fumigate shipments upon arrival) change their protocols to require fumigation before departure. EDN is a phytosanitary tool that could be used to meet those needs.
- 3.96 TPT Forests also commented that the scale at which the industry operates means the immediate employment and contribution to local community is significant. Mr Hammond agreed, saying that the impact of disruption to the export log trade on local communities would be considerable.
- 3.97 Several submitters also discussed the potential benefit of EDN as a biosecurity tool. MPI stated that EDN could be a valuable phytosanitary tool in preventing biosecurity incursions that threaten New Zealand flora and fauna. The applicant, STIMBR, and Mr Hammond agreed that this was critically important.
- 3.98 The EPA recognised the importance of the forestry industry to New Zealand's economy and that another fumigant option for operators would support the industry's continued viability. The 2018 EPA Staff Report stated that the level of benefits of EDN range from low to high, though noting that, should EDN be approved, trading partners such as China and India would still need to accept it as a treatment.
- 3.99 The Updated EPA Staff Report stated that, with the prescribed controls, draft SWI requirements (once given legal effect) and proposed additional HSNO controls, the benefits of EDN outweigh the risks to people and the environment (which are negligible).

Alternatives to EDN

- 3.100 The applicant and submitters discussed alternative phytosanitary measures, including debarking, joule heating, and other chemical fumigants.
- 3.101 TPT Forests explained that though debarking is sometimes an option for log exports to China, it only removes the habitat rather than killing the insects. This increases the risk of live insects being found on arrival and a possible ban on New Zealand logs. TPT Forests stated that such a ban (as has happened in Australia) would be devastating to the forestry industry.
- 3.102 Several forestry industry representatives noted that, for smaller growers and exporters, their location and scale limits opportunities to use alternative tools, such as debarking. They also noted that debarking is not accepted by all markets, and some

low grades of logs are physically not able to be effectively and economically debarked.

- 3.103 MPI and STIMBR discussed the higher costs of using debarking, which limits its use. Nevertheless, MPI did acknowledge an increase in debarking use over time. STIMBR also noted improvements and developments that were being progressed with respect to debarking.
- 3.104 STIMBR discussed the use of joule heating, which involves passing an electric current through the log to kill any insect pests by heat. However, this method has a high capital or upfront cost and is still not commercially viable. Mr Hammond agreed, stating that while joule heating may potentially be a long-term solution to address issues with chemical fumigations, this is still a way off.
- 3.105 Phosphine was referred to by several submitters as another alternative chemical fumigant, with submitters noting that it is used on around 75% of log exports to China. However, submitters also pointed out that it does have limitations. MPI stated phosphine fumigation takes 10 days and is done in transit in ship's holds.⁴ NZFOA stated that phosphine is not accepted by India and cannot be used for logs on deck. The applicant pointed out that phosphine is more flammable and does not break down as quickly as EDN.
- 3.106 The applicant mentioned another alternative fumigant, sulfuryl fluoride, but pointed out it is a known greenhouse gas and does not control insect eggs without unacceptably high concentrations or long fumigation times.
- 3.107 The applicant, submitters from the forestry industry, MPI, and STIMBR all agreed that EDN would be a significant and useful addition to the phytosanitary toolbox.

⁴ Under maritime law, phosphine is the only chemical allowed for fumigation in a ship's hold during transit.

4. Consideration

Matters in Part 2 of the HSNO Act

- 4.1 The Committee considered Part 2 of the HSNO Act and is confident that the controls align with the purpose and the principles of the HSNO Act.

Impacts on Māori

- 4.2 The Committee took into account the principles of the Treaty of Waitangi as required by section 8 of the HSNO Act. The Committee considered the submissions by Te Runanga o Ngāi Tahu and TMFAG in relation to impacts on Māori and Māori culture, as well as the EPA Staff Report and Updated EPA Staff Report. The Committee also noted the requirement to notify neighbouring marae, as specified under clause 4 of the draft SWI. The Committee was satisfied that the impacts of EDN on Māori culture or traditional relationships with ancestral lands, water, wāhi tapu, valued flora and fauna, or other taonga will be negligible with the HSNO controls and the requirements of the draft SWIs (once given legal effect) in place.

International obligations

- 4.3 The Committee agreed that EDN is a viable alternative to methyl bromide and that its approval would likely result in a reduction in the use of methyl bromide. Such reduction would help New Zealand to address its obligations under the Montreal Protocol.

Uncertainties

- 4.4 The Committee considered all the evidence available to it through the application process in making its decision. In considering this evidence, the Committee has taken into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects (section 7 of the HSNO Act). The Committee noted that there were areas of the application where such technical and scientific evidence and its interpretation by parties varied and considered these areas to be indicative of uncertainty. Accordingly, the Committee has taken a precautionary approach, as provided for in section 7 of the HSNO Act, in setting controls to manage the adverse effects.

Hazardous properties

- 4.5 The Committee considered the applicant's information, the EPA Staff Report and Updated EPA Staff Report, and the EPA Science Memo and Updated Science Memo. Having considered the evidence, the Committee agreed that the human health and environmental classifications in the Updated EPA Staff Report (updated to GHS

classifications) were appropriate. The Committee noted that these hazard classifications trigger prescribed controls under the HSNO Act and the HSW Act.

Effects of the substance during its life cycle

- 4.6 The Committee considered that adherence to the HSNO controls, draft SWI requirements (once given legal effect), and other legislative requirements would ensure that the level of risk to human health and the environment of EDN throughout its life cycle (which includes importation, transportation, storage, and disposal) would be negligible.

Field trials and ambient air monitoring

- 4.7 The Committee noted that the field trial information indicated that relatively low concentrations will be found following ventilation. However, the Committee considered that this was not a robust, reliable indication of EDN concentrations at distances not in close proximity to the stack, and air dispersion modelling had to be considered as well.

Air dispersion modelling

- 4.8 The Committee noted that there is significant uncertainty in the results of air dispersion modelling as discussed in the Expert Conferencing Joint Witness Statement.
- 4.9 Nevertheless, the Committee considered that the latest air dispersion modelling results are consistent with the general picture provided by the ambient air monitoring in field trials.

Use of EDN for the treatment of logs and timber

Use of EDN on imported logs and timber

- 4.10 The Committee considered the documentation supplied by the applicant, including results from overseas field trials. The Committee noted that the applicant's documentation referred only to the use of EDN on logs and timber for export. As such, potential risks associated with fumigation of imported timber were not considered in the risk assessment undertaken by the EPA.
- 4.11 While the Committee accepted that the use of EDN on imported timber would be a benefit, limited information regarding this use was provided. The Committee determined it was unable to assess the risks associated with fumigation of imported timber.
- 4.12 Similarly, the Committee noted that while MPI requested EDN use for fumigation of imported goods beyond logs and timber, no evidence to determine the risks associated with this use was presented. Therefore, the Committee was unable to

assess the risks associated with fumigation of other goods. Additionally, the Committee noted that the draft Requirements for Specified Fumigants Amendment SWI restricts fumigation with EDN to logs and processed wood, and alterations to this are a matter for WorkSafe..

Use of EDN in shipping containers

- 4.13 The Committee considered the information available regarding fumigation in shipping containers and agreed with the assessment in the Updated EPA Staff Report that the risks associated with this use were low, as a consequence of the small volumes being fumigated. The Committee acknowledged the requirement of the draft Requirements for Specified Fumigants Amendment SWI that the end concentration of EDN within the container be 700 ppm or less before ventilation. Therefore, the Committee considered that there was no requirement for any additional controls for shipping containers under HSNO.

Use of EDN in ship's holds

- 4.14 The Committee acknowledged the request by the applicant (and STIMBR) for a conditional approval permitting use of EDN for fumigation in ship's holds, subject to WorkSafe drafting of an SWI for this use.
- 4.15 The Committee noted also that while the draft Requirements for Specified Fumigants Amendment SWI prohibits the use of EDN in ship's holds, WorkSafe indicated at the reconvened hearing that (subject to receipt of appropriate information) it would consider developing an SWI for this use.
- 4.16 The Committee noted that no information was provided by the applicant in the application to evaluate the risk associated with the use of EDN in ship's holds. Air dispersion modelling information on ship's holds was provided prior to the reconvened hearing, but with no data on volumes, ship capacities, operational procedures, and ventilation. The Committee did not consider that it had sufficient information to assess the risks to the public or the environment of fumigation using EDN in ship's holds. The Committee also noted that an applicable SWI would be key to such an assessment.
- 4.17 The Committee therefore concluded that use of EDN should be restricted to under a sheet or in a shipping container.

Application rate and duration of use in the fumigation of logs and timber

- 4.18 The Committee considered the evidence presented by the applicant, including data from field trials and assessments presented in the EPA Science Memo and Updated Science Memo. The Committee agreed that the maximum application rate should be set as 120 g of substance/m³.
- 4.19 The Committee considered the proposed 24-hour fumigation duration and the requested change to "up to 24 hours" by the applicant. The Committee considered

that any time constraint would potentially result in ambiguity, with the controls requiring a maximum end concentration and minimum wind speed before ventilation. The Committee also noted that evidence showed that the end concentration may not always be met by the end of 24 hours. The Committee concluded that a specified time constraint was not required, as actual fumigation time would be determined by other factors.

Risks to workers – the draft SWIs

- 4.20 The Committee acknowledged that the applicant and several submitters endorsed the draft SWIs as a means of managing risks to workers. The Committee accepted the assessment of relevant information undertaken by WorkSafe in developing the draft SWIs and considered that the proposed controls were reasonable.
- 4.21 The implications for when the HSNO approval will take effect, that flow from the draft status of the SWIs, will be detailed in section 5.

Risks to members of the public and the environment

- 4.22 The Committee noted that the EPA used the draft SWIs as a baseline from which to assess residual risks. The Committee also noted the requirement of the draft SWI that ventilation can only commence once the residual EDN concentration in an enclosed space drops to 700 ppm. The Committee considered the risks to the public and the environment on the basis that the draft SWIs would take legal effect and considered whether additional controls were required to mitigate such risks as might be identified from the available evidence.

Tolerable Exposure Limit (TEL)

- 4.23 The Committee considered the evidence for a TEL of 0.034 ppm presented in the EPA Staff Reports and Science Memos and noted acceptance of this value as a measure of cumulative exposure over a 24-hour period by all parties following the expert conference process. The Committee noted that the TEL was based on a cautious and conservative interpretation of toxicological data available and accounted for inherent uncertainties. Therefore, the Committee concluded that a TEL of 0.034 ppm set out in the EPA Staff Reports and Science Memo was appropriate.
- 4.24 The Committee noted that the average EDN concentration at a monitoring location may be affected by discharges from ventilation of other stacks in the vicinity (earlier or later in the day), which may pass through the monitoring location but not be recorded. However, the Committee considered that this would not change the conclusion that the TEL would not be exceeded beyond the buffer zone boundary.

Sensitive areas exclusion zone

- 4.25 The Committee noted that the 2018 Staff Report had a proposal for a buffer zone of 120 m from the site of fumigation in order to reach 24-hour average EDN

concentrations below the TEL value of 0.034 ppm. The Committee also noted that the EPA subsequently revised its assessment to conclude that (provided the requirements described in the draft SWI are adhered to) residual risks to members of the public would be negligible as EDN concentrations outside the buffer zone would be maintained below the TEL at all times.

- 4.26 The Committee considered that a minimum buffer zone of 50 m and management of the fumigation area in accordance with the SWI is sufficient, with additional HSNO controls, to manage the acute and chronic risks to the public of exposure to EDN.
- 4.27 The Committee considered that the application of an additional exclusion zone based on the ability of the public to evacuate was not supported by any evidence for a likely exposure scenario occurring, provided the conditions of the SWI are met, nor was evidence presented supporting 120 m as being an appropriate distance for such an exclusion zone.

Wind speed

- 4.28 The Committee noted that while the EPA Staff Report initially proposed a control to prohibit venting under very low wind speed conditions or under inversion conditions, the Updated EPA Staff Report no longer proposed this control, stating that the SWI requirements mitigated the risk.
- 4.29 The Committee noted concerns expressed by BOPRC regarding the absence of a wind speed control and its use in establishing effective buffer zone monitoring locations. The Committee also noted the evidence presented by BOPRC regarding measured wind speeds at the Port of Tauranga, which could be below 2 m/s during daylight hours, and that inversion conditions may also occur.
- 4.30 The Committee reviewed the arguments presented by the applicant that the control was not necessary due to a number of factors that would result in air movement and thus higher wind speeds. The Committee accepted that there will often be sea breezes and the presence of warm asphalt will induce air movement. The Committee also accepted the applicant's evidence that EDN does not pool or pond. However, the Committee considered that, at low wind speeds, the released plume of EDN will not disperse as readily as under higher wind speeds. Thus, under low wind speed conditions, higher concentrations of EDN could persist for longer and travel further and potentially pose a greater risk to the public. This would be especially so with ventilations from stack sizes greater than that used for the modelling (up to 3000 m³ compared with the modelled 1500 m³). The Committee noted that a minimum wind speed control, along with wind speed and direction monitoring requirements specified in clause 10 of the draft Requirements for Specified Fumigants Amendment SWI would assist the PCBU in determining an appropriate buffer zone and monitoring location(s).
- 4.31 The Committee considered that the replacement of a wind speed control with a constraint on fumigation operations to sunrise-to-sunset (as set out in clause 11 (b) (i) of the draft SWI) may not be sufficient to protect members of the public at all times

and in all locations because still or inversion conditions can occur during the day at the Port of Tauranga and may occur at other locations.

- 4.32 Therefore, the Committee considered a minimum wind speed of 2 m/s (rounded up from the original 1.8 m/s for consistency with the methyl bromide control) is necessary before ventilation takes place. Further, the Committee considered that the most important time at which this minimum wind speed needed to be met was immediately prior to ventilation occurring. The Committee therefore considered that a requirement for a minimum wind speed of 2 m/s should be met in the 10 minutes before ventilation.
- 4.33 The applicant argued that having a wind speed control would unduly interfere with port operations. The Committee noted that the meteorological data provided indicated that wind speeds of less than 2 m/s are infrequent and occur predominantly during the hours of darkness and concluded that there would be minimal interference in fumigation operations. The Committee noted that wind speed is not a guaranteed constant during the fumigation operation but considered nevertheless that the application of a minimum wind speed control before ventilation is appropriate to manage the risks to the public.

Recapture

- 4.34 The Committee acknowledged the concerns expressed by some submitters regarding the need for recapture of EDN before ventilation. However, the Committee noted that WorkSafe's assessment of risks to workers undertaken in preparation of the draft SWIs concluded that recapture of EDN was not necessary given the requirement to ensure the concentration of EDN is below 700 ppm before venting. The Committee accepted WorkSafe's assessment and concluded that recapture of EDN is not required for the protection of members of the public provided all other controls are implemented.

Notification

- 4.35 The Committee acknowledged the notification of intended fumigation requirements in clause 4 of the draft Requirements for Specified Fumigants Amendment SWI.
- 4.36 The Committee also acknowledged that the draft Requirements for Specified Fumigants Amendment SWI under clause 13 requires the PCBU to notify WorkSafe and the relevant medical officer of health of any TEL exceedances as practicable but within five working days.
- 4.37 The Committee considered that both notifications should be supplemented by notification to the relevant local authority.
- 4.38 The Committee also considered that the local authority should be notified, as a matter of urgency, of any TEL exceedances – within 24 hours. This is so that the health and environmental risks that arise from such events can be responded to in a timely manner and managed by the relevant local authority.

Annual reporting

- 4.39 The Committee acknowledged the annual reporting requirements under clause 17 of the draft Requirements for Specified Fumigants Amendment SWI and considered that the same annual report should also be provided to the EPA to support compliance, monitoring, and enforcement under HSNO.

Benefits

- 4.40 The Committee considered the evidence presented by the applicant and industry regarding the economic and societal benefits resulting from an approval of EDN, specifically related to its use as a replacement for methyl bromide. These benefits include:

- immediate “drop-in” replacement for methyl bromide, using essentially the same logistical structures
- reduced risks to human health and the environment
- continued viability of the forestry industry
- diversification of markets and applications (for example, biosecurity)
- resilience in the face of changes in market acceptance.

- 4.41 The Committee accepted the evidence that EDN is the most viable replacement for methyl bromide for log and timber fumigations.

- 4.42 However, the Committee considered that those benefits must be considered against the costs and risks.

Alternatives to EDN

- 4.43 The Committee has considered the evidence and submissions presented on alternative fumigation methods or insect pest treatments. The Committee concluded that the alternatives have limitations and EDN would be a valuable addition to the phytosanitary toolbox.

Risks, costs, and benefits summary

- 4.44 After taking into account the assessment of the potential risks and benefits associated with EDN, the Committee considered that, with all of the HSNO controls in place and the draft SWIs taking legal effect:

- the overall risks to human health and the environment arising from the hazardous properties and the use of EDN are negligible
- significant adverse impacts on the social or economic environment from the use of EDN are not anticipated
- significant impacts on Māori culture or traditional relationships with ancestral lands, water, wāhi tapu, valued flora and fauna, or other taonga have not been identified
- EDN will be of significant benefit to New Zealand.

4.45 Therefore, the Committee considered that benefits of EDN, based on the assessment of the information available, outweigh its adverse effects.

5. Decision

- 5.1 Pursuant to section 29 of the HSNO Act, the Committee has considered this application for approval under section 28 of the HSNO Act. The Committee has considered all the effects of this substance throughout its life cycle, the controls that may be imposed on this substance, and the likely effects of this substance being unavailable. The Committee has also taken into account the considerations set out in Part 2 of the HSNO Act, and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 as detailed in Appendix C.
- 5.2 In making its decision, the Committee took into account best international practices and standards for the safe management of hazardous substances.
- 5.3 The Committee considered that, with controls under the HSNO Act and the HSW Act in place, the risks to human health and to the environment will be negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, the Committee has made the decision to **approve with controls** (presented in Appendix D) the import or manufacture of EDN for release in accordance with section 29 of the HSNO Act and clause 26 of the Methodology.
- 5.4 **It is important to note that the HSNO approval will take effect at a future date.** That is because the draft Requirements for EDN SWI and draft Requirements for Specified Fumigants Amendment SWI were a fundamental part of the Committee's assessment of risks to the public and the environment. The draft SWIs have been approved in principle, but a number of steps are required in order for the SWIs to take legal effect. Therefore, in order for the HSNO approval to take effect, the Committee must confirm that the final SWIs do not materially differ from the draft SWIs considered and that their assessment of risk therefore remains valid. When the SWIs are gazetted, the Committee will confirm this and sign an addendum to this decision and the HSNO approval. The HSNO approval will come into effect on the same date as the SWIs (28 days after the SWIs are gazetted).



Signed by: **Dr John Taylor**

Date: **05 April 2022**

**Chair, Decision-making Committee of the
Environmental Protection Authority**

Appendix A. Correspondence to and from the Committee

Table 1. Chronological summary of correspondence to and from the Committee

Date	Document	Subject summary
10 August 2018	Staff Report Science Memo Consultant report WorkSafe report	The EPA published the Staff Report and Science Memorandum, as well as a report by EPA's consultant and a WorkSafe report.
20 August 2018	New information Air dispersion modelling report	The applicant supplied new information in support of their application, including air dispersion modelling from Sullivan Environmental Consulting Incorporated.
21 August 2018	New information	STIMBR provided information on wood odour.
23 August 2018	WGT001	The Committee requested a site visit to observe a commercial fumigation operation.
24 August 2018	WGT002	The Committee directed that expert conferencing take place. The Committee also directed the EPA to evaluate the additional information received and update the EPA advice as appropriate. Submitters then had time to comment on the documents.
4 September 2018	WGT003	This direction and minute documented the site visit.
14 September 2018	WGT004	The Committee confirmed the nominated experts for the expert conferencing.
12 October 2018	Joint statement (TELs) Appendix 1, 2, 3, 4	A joint witness statement was issued as a result of the expert conferencing on tolerable exposure limits.
15 October 2018	Joint statement (modelling) Appendix	The joint witness statement was issued as a result of the expert conferencing on air concentration dispersion modelling.

Date	Document	Subject summary
2 November 2018	Consultant advice	The EPA consultant provided advice following expert conferencing.
22 November 2018	BOPRC response STIMBR response TMFAG response	Interested parties commented on new information provided by the applicant and expert conferencing.
18 December 2018	WGT005 Appendix	The Committee issued the minutes of the 18 December teleconference with the Committee and the EPA consultant for matters related to air dispersion modelling.
12 February 2019	WGT006	The Committee requested more information from the applicant, WorkSafe, and other interested parties.
22 February 2019	Applicant response Aubade Global Resources response BOPRC response Matariki Forests response Nordiko Quarantine Systems response Port Blakely response Quarantine Scientific response STIMBR response WorkSafe response	Interested parties responded to WGT006.
5 April 2019	WGT007	The Committee acknowledged responses to WGT006 received, extended the period of adjournment of the public hearing, and set down timeframes for the applicant to provide new information.
10 May 2019	New information 1, 2, 3, 4, 5, 6, 7, 8	The applicant provided some of the information requested in WGT007.

Date	Document	Subject summary
15 May 2019–14 June 2019	Further information 1, 2, 3	The applicant provided further new information.
18 June 2019	WGT008	The Committee acknowledged receipt of new information from the applicant, invited parties to the process to provide comment on this, and further extended the adjournment.
29 June 2019	TMFAG response	TMFAG responded to WGT008.
9 October 2019	Addendum to Staff Report	The EPA prepared an update on what impact, if any, new information provided by the applicant, WorkSafe, and various public submitters since 20 August 2018 had on the views outlined in the EPA Staff Report (dated 27 February 2018) and the EPA Science Memorandum (dated July 2018).
23 October 2019	Applicant request	The applicant sought agreement to submit new information in response to the Addendum to the Staff Report to inform the decision-making process.
11 December 2019	WGT009	The Committee addressed the request by the applicant to provide new information and asked the applicant to provide a timeframe for the provision of this information.
23 January 2020	WorkSafe response Applicant response	WorkSafe and the applicant responded to WGT009.
18 February 2020	WGT010	The Committee agreed to the date proposed by the applicant for the provision of new information. The Committee also directed the applicant to provide a summary of how information submitted since the first hearing had impacted on the original application.
25 March 2020	Applicant response New information 1, 2, 3, 4, 5	In response to WGT010, the applicant provided a document summarising the key elements of information provided to the EPA since August 2018 and provided new information.
1 April 2020	WGT011	The Committee granted the applicant an extension to the time granted for provision of new information and invited all parties to the process to comment on the new information received.

Date	Document	Subject summary
4 May 2020	BOPRC response Matariki Forests response Red Stag Timber response STIMBR response TPT Forests response	Parties to the proceedings provided responses to WGT011.
23 August 2021	Updated EPA Staff Report Updated EPA Science Memo	The EPA published the updated EPA Staff Report and updated Science Memo.
23 August 2021	Consultation documents Consultation on revised proposals Draft SWI 1 Draft SWI 2	WorkSafe provided draft safe work instruments and consultation documents.
31 August 2021	WGT012	The Committee addressed key developments since WGT011 and invited all parties to the process to comment on the updated EPA Staff Report and the updated Science Memo.
30 September 2021	BOPRC response MPI response NZ Forest Owners Association response STIMBR response	Interested parties provided responses to WGT012.
1 November 2021	WGT013	The Committee named a date for the reconvened public hearing and addressed its scope.
9 November 2021	WGT014	The Committee directed all parties speaking at the reconvened hearing to provide their discussion points.

Date	Document	Subject summary
10 November 2021	WGT015	The Committee notified all parties of the scope, timing, and expectations of the reconvened hearing procedures.
2 December 2021	WGT016	The Committee requested that legal submissions spoken to at the reconvened hearing be provided by the submitter, and that the EPA provide legal advice in response to these legal submissions. The Committee also directed the EPA to make available to all parties the legal advice previously provided on EDN's use in ship's holds. All parties were invited to provide legal submissions in response.
6 December 2021	Legal submission from STIMBR Talking notes for STIMBR presentation	STIMBR provided legal submissions in response to WGT016.
7 December 2021	EPA legal advice	EPA legal advice in respect to ship's holds that was provided to the Committee on 18 November 2021 was published.
20 December 2021	EPA response	EPA Legal Team responded to legal points raised by STIMBR during the reconvened hearing.
18 January 2022	WGT017	The Committee granted an extension to the deadline for providing responses to legal submissions by STIMBR and EPA.
19 January 2022	Applicant response STIMBR response BOPRC response MPI response	Parties to the proceedings commented on the legal submissions.
1 March 2022	WGT018	The Committee directed that the hearing be closed as of 1 March 2022.

Appendix B. List of hearing presentations

Transcripts of the hearing can be found on the EPA website.⁵

Table 2. List of hearing presentations

Presentation	Submitter	Presenters
21 August 2018 (Wellington)		
Applicant's presentation	Lučební Závody Draslovka a.s. Kolín	Helen Gear Pavel Bruzek Jr Adam Jonas Matt Hall Swaminathan Thalavai Sundaram Kade McConville
EPA presentation	EPA	Teresa Vaughan
WorkSafe presentation	WorkSafe	Susan Collier Philippa Gibson
Submission 126969	Te Rūnanga o Ngāi Tahu	Oliver Sutherland
Submission 126940	Port Blakely Ltd	Philip Taylor
Submission 126967	Nordiko Quarantine Systems Ltd	Wil Grullemans
Submission 126977	MPI	Shane Olsen
Submission 126982	STIMBR	Ian Gear
Submission 126978	The Soil & Health Association of New Zealand Inc	Mischa Davis
Applicant's right of reply	Lučební Závody Draslovka a.s. Kolín	Kade McConville
28 August 2018 (Rotorua)		
Applicant's presentation	Lučební Závody Draslovka a.s. Kolín	Kade McConville David Sullivan Pavel Bruzek Jr Matt Hall

⁵ www.epa.govt.nz/public-consultations/decided/decision-to-approve-edn/background

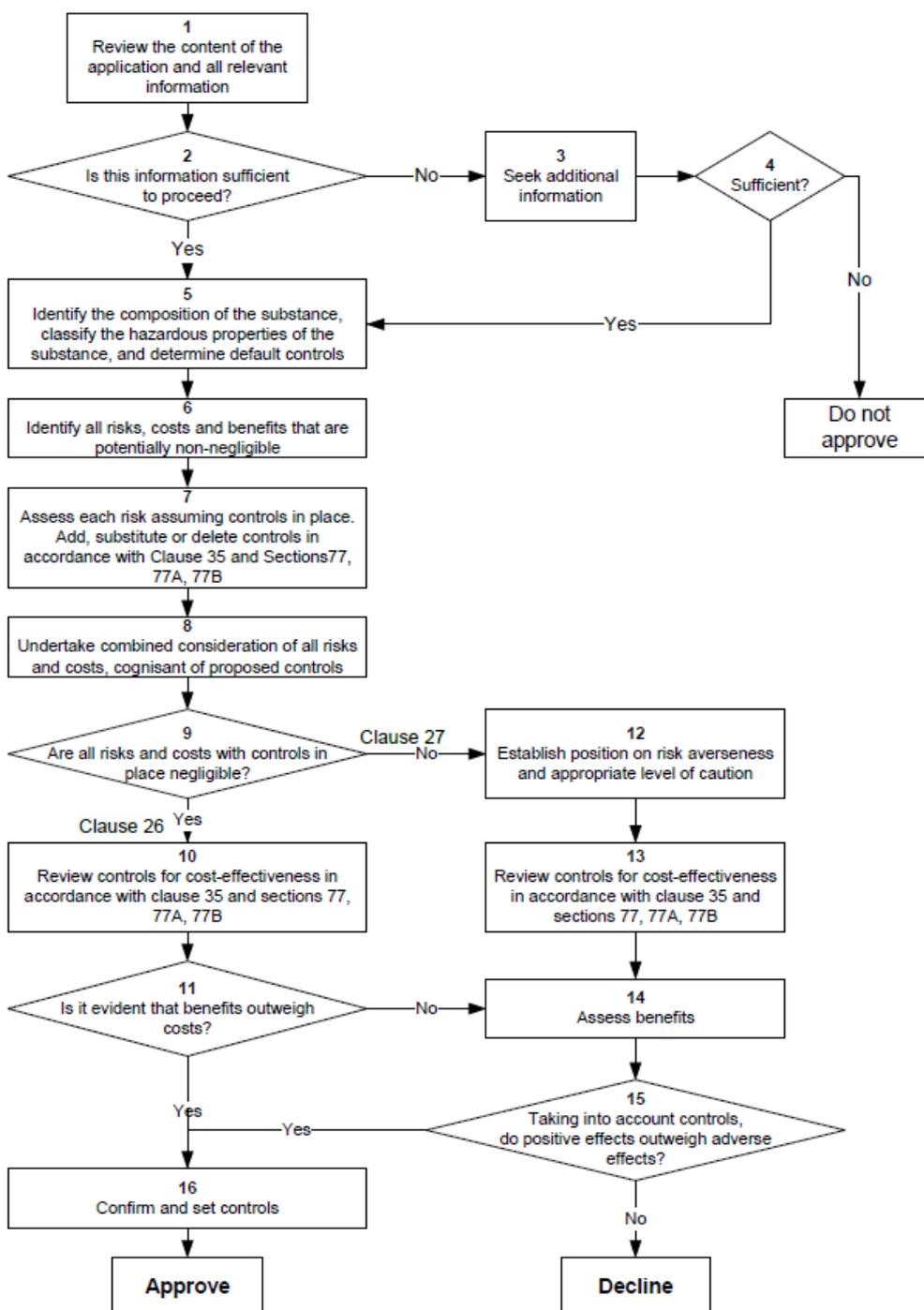
Presentation	Submitter	Presenters
		Swaminathan Thalavai Sundaram Helen Gear
EPA presentation	EPA	Teresa Vaughan
WorkSafe presentation	WorkSafe	Susan Collier Philippa Gibson
Submission 126960	Tauranga Moana Fumigant Action Group	Steffan Browning
Submission 126970	Quarantine Scientific Ltd	John Armstrong
Submission 126980	Bay of Plenty Regional Council	Sam Weiss
29 August 2018 (Rotorua)		
Submission 126963	TPT Forests Ltd	Mark Proctor
Submission 126964	Hammond Resource Management	Don Hammond
Submission 126950	New Zealand Forest Owners Association	Russell Dale
25 November 2021 (virtual)		
Applicant's presentation	Lučební Závody Draslovka a.s. Kolín	Kade McConville
WorkSafe presentation	WorkSafe	Susan Collier Paul Moenboyd
EPA presentation	EPA	Michael Berardozzi
Submission 126980	Bay of Plenty Regional Council	Sam Weiss Jenny Barclay
Submission 126950	New Zealand Forest Owners Association	Glen Mackie
Submission 126946	Rayonier Matariki Forests	Chris Rayes
Submission 126940	Port Blakely Ltd	Philip Taylor
Submission 126982	STIMBR	Morgan Slyfield
Submission 126963	TPT Forests Ltd	Mark Procter
Submission 126977	MPI	Shane Olsen Ken Glassey

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Presentation	Submitter	Presenters
Applicant's right of response	Lučební Závody Draslovka a.s. Kolín	Kade McConville

Appendix C. Decision path

This decision path describes the decision-making process for applications to import or manufacture a hazardous substance. These applications are made under section 28 of the HSNO Act and determined under section 29. For proper interpretation of the decision path, it is important to work through the flowchart in conjunction with the explanatory notes.



Explanatory notes

Item 1:	<p>Review the content of the application and all relevant information</p> <p>Review the application, the E&R Report, and information received from experts and provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16, and 20 of the Methodology.</p>
Item 2:	<p>Is this information sufficient to proceed?</p> <p>Review the information and determine whether or not there is sufficient information available to make a decision.</p> <p>The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information that is significant to the proper consideration of the application; ie, information that is “necessary and sufficient” for decision-making.</p>
Item 3:	<p>(if ‘no’ from item 2) Seek additional information</p> <p>If there is not sufficient information, then additional information may need to be sought from the applicant, EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).</p>
Item 4:	<p>Sufficient?</p> <p>When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision?</p> <p>If the HSNO decision-maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).</p>
Item 5:	<p>(If ‘yes’ from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls</p> <p>Identify the composition of the substance and establish the hazard classifications for the identified substance.</p> <p>Determine the default controls for the specified hazardous properties using the regulations “toolbox”.</p>
Item 6:	<p>Identify all risks, costs, and benefits that are potentially non-negligible⁶</p> <p>Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these “values” are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as “sunk” costs (see footnote 1). Where such costs arise and they have a market economic effect, they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11).</p> <p>Identification is a two-step process that scopes the range of possible effects (risks, costs, and benefits).</p>

⁶ Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called “sunk” costs since they are incurred whether or not the application is successful.

<p>Step 1:</p>	<p>Identify all possible risks, costs (adverse effects), and benefits (positive effects) associated with the approval of the substance(s) and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act.⁷ Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)).</p> <p>Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14).</p> <p>Consider short-term and long-term effects.</p> <p>Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.</p>
<p>Step 2:</p>	<p>Document those risks, costs, and benefits that can be readily concluded to be negligible,⁸ and eliminate them from further consideration.</p> <p>Note that where there are costs that are not associated with risks, some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.</p>
<p>Item 7:</p>	<p>Assess each risk assuming controls in place. Add, substitute, or delete controls in accordance with clause 35 and sections 77, 77A, and 77B of the Act.</p> <p>The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29–32 of the Methodology. The assessment is carried out with the default controls in place.</p> <p>Assess each potentially non-negligible risk and cost, estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks, then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account.</p> <p>The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.</p> <p>This assessment includes consideration of how cautious the HSNO decision-maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)).</p> <p>Consider the HSNO decision maker’s approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.</p> <p>See EPA report ‘Approach to Risk’ for further guidance.⁹</p>

⁷ Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.

⁸ Negligible effects are defined in the Annotated Methodology as “Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits.”

⁹ <http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf>

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Where it is clear that residual risks are non-negligible and where appropriate controls are available, add, substitute, or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13.

If changes are made to the controls at this stage, then the approach to uncertainty and the approach to risk must be revisited.

Item 8: Undertake combined consideration of all risks and costs, cognisant of proposed controls

Once the risks and costs have been assessed individually, if appropriate, consider all risks and costs together as a “basket” of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.

Item 9: Are all risks with controls in place negligible?

Looking at individual risks in the context of the “basket” of risks, consider whether all of the residual risks are negligible.

Item 10:

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graph TD
    A[9] --> B{Are all risks with controls in place negligible?}
    B --> C[Clause 26 Yes]
    
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(from item 9 - if ‘yes’) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B

Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.

Item 11: Is it evident that benefits outweigh costs?

Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7.

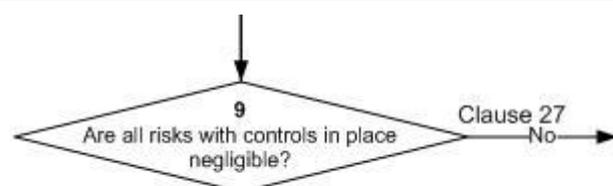
Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community.

Consider whether there are any non-negligible external costs that are not associated with risks.

If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of

internal or private net benefit, and therefore total benefits outweigh total costs¹⁰. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs.

However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).



Item 12:

(if 'no' from item 9) Establish position on risk averseness and appropriate level of caution

Although "risk averseness" (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).

Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B

This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12).

Item 13:

Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)).

Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result.

As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.

Item 14:

(if 'no' from item 11 or in sequence from item 13) Assess benefits

Assess benefits or positive effects in terms of clause 13 of the Methodology.

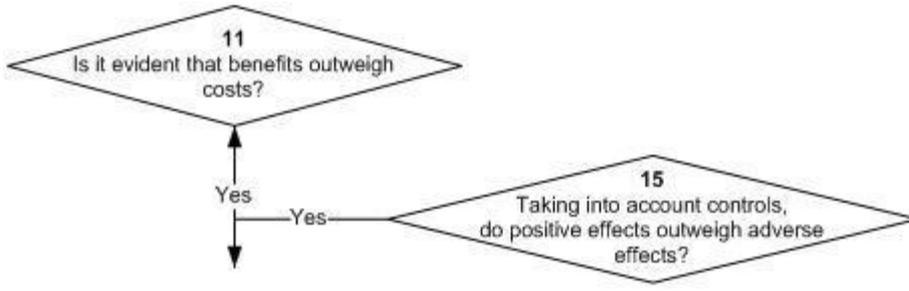
Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the

¹⁰ Technical Guide "Decision making" section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 "General requirements for the Identification and Assessment of Risks, Costs, and Benefits".

same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs¹¹. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs.

As for risks and costs, the assessment is carried out with the default controls in place.

<p>Item 15:</p>	<p>Taking into account controls, do positive effects outweigh adverse effects?</p> <p>In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13.</p> <p>Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology.</p> <p>Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.</p>
<p>Item 16:</p>	 <pre> graph TD A{11 Is it evident that benefits outweigh costs?} -- Yes --> B{15 Taking into account controls, do positive effects outweigh adverse effects?} B -- Yes --> A </pre> <p>(if 'yes' from items 11 or 15) Confirm and set controls</p> <p>Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.</p>

¹¹ This principle derives from Protocol Series 1, and is restated in the Technical Guide "Decision making".

Appendix D. Controls

EPA controls

Control code	Regulation	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-2	EPA Hazardous Property Controls Notice 2017 Part 2	Certain substances restricted to workplaces only
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for substances that are hazardous to the environment
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of substances that are hazardous to the environment
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of substances that are hazardous to the environment

HSNO additional controls and modifications to controls

Definitions

For the purpose of this approval—

Enclosed space means:

- (a) the space under a sheet;
- (b) a shipping container.

Exposure level means the concentration of EDN in the air recorded at the monitoring location.

PCBU has the meaning defined in section 17 of the Health and Safety at Work Act 2015.

Sheet means a heavy-duty cover that—

- (a) has a low mass transfer coefficient for EDN; and
- (b) is waterproof and impenetrable.

Ventilate means the intentional release of EDN into the atmosphere following fumigation, and **ventilation** has a corresponding meaning

Code	HSNO Act	Control
Application rate	Section 77A	The maximum application rate of this substance is 120 g of substance/m ³ .
Use restriction	Section 77A	This substance must only be used as a fumigant for logs or timber for export under a sheet or in a shipping container.
Label	Section 77 Variation to Labelling Notice	The substance label must include the following statements, or words to the same effect: <ul style="list-style-type: none"> • This substance must only be used as a fumigant for logs or timber for export under a sheet or in a shipping container. The application rate must be included on the label.
Max impurity	Section 77A	The following limit is set for the toxicologically relevant impurity in the active ingredient, ethanedinitrile, used to manufacture this substance: Hydrogen cyanide: 1% v/v maximum
Tolerable exposure limit (TEL)	Section 77B	The Tolerable Exposure Limit (TEL) set for ethanedinitrile is 0.034 ppm as a 24-hour average.

Code	HSNO Act	Control
Wind speed	Section 77A	A PCBU with management or control of fumigation of logs or timber using EDN must ensure that ventilation of any fumigation only occurs when a minimum wind speed of 2 m/s is measured at the site of fumigation in the 10 minutes prior to ventilation.
Notification of fumigation	Section 77A	<ol style="list-style-type: none"> 1. A PCBU with management or control of fumigation of logs or timber using EDN must notify the PCBU's intention to carry out a fumigation to the relevant local authority. 2. The PCBU must ensure that the notification referred to in subclause (1) is made not less than 24 hours before the start of the fumigation event.
Notification of TEL exceedance	Section 77A	<p>A PCBU with management or control of fumigation of logs or timber using EDN must—</p> <ol style="list-style-type: none"> a. notify the relevant local authority as soon as practicable and within 24 hours if the exposure level exceeds the TEL value for EDN; and b. include in the notification— <ol style="list-style-type: none"> i. the source of that exceedance; and ii. the exposure value(s) that exceed the appropriate TEL value; and iii. the individual monitoring values that were used to generate each relevant 24-hour exposure level.
Annual reporting	Section 77A	A PCBU with management or control of fumigation of logs or timber using EDN in the preceding calendar year must provide a copy of the annual report provided to WorkSafe under the Requirements for Specified Fumigants Amendment SWI to the Environmental Protection Authority by 31 March each year.

Health and safety at work (HSW) requirements

Advisory Note: These requirements are not set for the substance but apply in their own right under the HSW (Hazardous Substances) Regulations 2017 according to the classification of the substance. They are listed here for information purposes only.

Control code	Regulation	Control description
HSW1	Part 1	Application
HSW2	Part 2	Labelling, signage, safety data sheets, and packaging
HSW3	Part 3	General duties relating to risk management
HSW4	Part 4	Certified handlers and supervision and training of workers
HSW5	Part 5	Emergency management
HSW8	Part 8	Controls applying to all class 1 to 5 substances
HSW10	Part 10	Class 2, 3, and 4 substances
HSW11	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances
HSW13	Part 13	Class 6 and 8 substances
HSW14	Part 14	Fumigants
HSW15	Part 15	Gases under pressure
HSW16	Part 16	Tank wagons and transportable containers
HSW17	Part 17	Stationary container systems
HSW19	Part 19	Tracking hazardous substances

Additional requirements for the substance will be set through safe work instrument(s) (SWIs), a form of legislation that supports or complements health and safety regulations. Draft SWIs specific to EDN are listed below. The draft SWIs and the steps required to give them legal effect are discussed in the body of the decision.

- Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Safe Work Instrument 2017 as amended by the Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument (draft as at date of decision).
- Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for Ethanedinitrile) Safe Work Instrument (draft as at date of decision).

Appendix E. List of abbreviations

Abbreviation	Meaning
AEGL	Acute exposure guideline levels
BOPRC	Bay of Plenty Regional Council
CAS	Chemical Abstracts Service
EPA	Environmental Protection Authority
GHS 7	Seventh revised edition of the Globally Harmonised System
GRWM	General Risk and Workplace Management
HSNO	Hazardous Substances and New Organisms Act 1996
HSW	Health and Safety at Work Act 2015
MPI	Ministry for Primary Industries
NZFOA	New Zealand Forest Owners Association
PCBU	Person conducting a business or undertaking
ppm	Parts per million
STIMBR	Stakeholders in Methyl Bromide Reduction Incorporated
SWI	Safe work instrument
TEL	Tolerable exposure limit
TMFAG	Tauranga Moana Fumigation Action Group