



Environmental
Protection Authority
Te Mana Rauhi Taiao

UPDATED EPA STAFF REPORT

Application for approval to import EDN for release

APP202804

August 2021



Overview

Substance	EDN
Application code	APP202804
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Lučební Závody Draslovka a.s. Kolín
Purpose of the application	To import EDN (ethanedinitrile), a fumigant for use on timber/logs under commercial conditions
Date application formally received	17 July 2017
Submission periods	<p>27 February 2018 – 12 April 2018 (prior to hearing)</p> <p>8 November 2018 – 22 November 2018 (during hearing adjournment, response to Direction and Minute 2)</p> <p>28 January 2019 – 22 February 2019 (during hearing adjournment, response to Direction and Minute 6)</p> <p>18 June 2019 – 2 July 2019 (during hearing adjournment, response to Direction and Minute 8)</p> <p>2 April 2020 – 4 May 2020 (during hearing adjournment, response to Direction and Minute 11)</p>
Submissions	<p>43 submissions were received (prior to hearing). 38 submissions supported the application, three opposed the application and two were neutral.</p> <p>During the hearing adjournment, three responses were received for Direction and Minute 2, seven responses were received for Direction and Minute 6, one response was received for Direction and Minute 8 and five responses were received for Direction and Minute 11</p>
Information requests and time waivers	The timeframe before public notification of this application was waived under section 59 of the Act and further information was requested under section 52 of the Act.

The timeframe for public notification of this application was waived under section 59 of the Act to allow interested parties additional time to submit.

The timeframe for consideration of this application was waived under section 59 of the Act.

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1. Executive summary

Background

- 1.1. Lučební Závody Draslovka a.s. Kolín (“the applicant”) has applied for approval to import or manufacture EDN for use as a fumigant for the phytosanitary treatment of timber and logs under commercial conditions prior to export. It was given application number APP202804 and was formally received on 17 July 2017 as a notified Category C application.
- 1.2. EDN is the product name for ethanedinitrile gas. Ethanedinitrile (CAS number 460-19-5), also known as cyanogen and oxalonitrile, is a new active ingredient to New Zealand.
- 1.3. A Science Memorandum (EPA 2018d) and a Staff Report (EPA 2018c) were generated for this application in July 2018. The Science Memorandum focussed on determining hazards, classification and associated human and environmental risks while the Staff Report integrated the findings of the Science Memorandum, with costs and benefits considerations along with submissions made during the public consultation period (open from February to April 2018).
- 1.4. As the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations, WorkSafe has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. The EPA has therefore sought WorkSafe’s views in line with Section 11(2A) of the Act. WorkSafe provided advice in August 2018 (WorkSafe 2018), proposing they develop two SWI (s) giving effect to provisions of the General Risk and Workplace Management Regulations (GRWM).
- 1.5. A Decision-Making Committee (DMC) was appointed and a public hearing for APP202804 was held on 21, 28 and 29 August 2018. Further information on air concentration dispersion modelling was received from the applicant prior to commencement of the hearing. The hearing was adjourned in order for the new information to be reviewed and to allow for the draft SWI (s) to be developed.
- 1.6. WorkSafe conducted a public consultation on the draft SWI (s) between 28 February 2020 and 5 April 2020 (WorkSafe 2020a). Some changes to the original proposals were made and a further targeted consultation on the changes was organised between 23 July 2020 and 7 August 2020 (WorkSafe 2020b).
- 1.7. On 8 December 2020, WorkSafe notified the EPA that two draft SWI (s), ‘*Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021*’ (WorkSafe 2021b) and ‘*Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for Ethanedinitrile) Safe Work Instrument 2021*’ (WorkSafe 2021a) had been approved in principle (referred to as “draft SWI (s)” for the purpose of this report), and these were provided to the EPA and shared with the DMC. The EPA has since reviewed the requirements of the draft SWI (s), paying

particular attention to the assessment of risks in the workplace, and focussing on residual risks for public health and the environment.

- 1.8. The assessment undertaken by the EPA has been done on the basis that the draft SWI (s) will take legal effect in their current form. .
- 1.9. In response to Direction and Minute 11 (EPA 2020b) and the draft SWI(s) being approved in principle, the EPA has prepared an updated Science Memorandum (EPA 2021) and this Staff Report that provide an overview of the changes in terms of hazard characterisation and risk assessment for the use of ethanedinitrile with a focus on the requirements of the draft SWI (s) for the DMC's consideration. An updated recommendation is also made as well as integrating further submissions received from 2018.
- 1.10. Full details on the process and the information considered is provided in Section 3 of this report.
- 1.11. This Staff Report is to be read in conjunction with the Science Memorandum (EPA 2018d), Staff Report (EPA 2018c) and the Addendum to the Staff Report (EPA 2019d), as well as the updated Science Memorandum (EPA 2021).

Hazardous properties

- 1.12. The following hazard classifications have been identified as applicable to EDN (Table 1). Please note: the proposed classifications from the 2018 Staff Report (EPA 2018c) and Science Memorandum (EPA 2018d) have been updated to the Global Harmonized System (GHS) following the adoption of GHS by the EPA in April 2021.

Table 1: Hazard classifications of EDN

Hazard Endpoint	EPA classification
Flammability	Flammable gas Category 1A
Gases under pressure	Liquefied gas
Acute toxicity	Acute inhalation toxicity Category 2
Aquatic ecotoxicity	Hazardous to the aquatic environment acute Category 1; M-factor 10
Aquatic ecotoxicity	Hazardous to the aquatic environment chronic Category 1; M-factor 10

- 1.13. A detailed overview of the hazardous properties of EDN is provided in section 4 and in the updated Science Memorandum (EPA 2021).

Submissions

- 1.14. The application was publicly notified on 27 February 2018 and 43 submissions were received during the submission period which closed on 19 April 2018. Of these 43 submissions, 38 supported the application, three opposed the application and two neither supported nor opposed.
- 1.15. Further information relating to the public submissions prior to the EDN hearing can be found in the initial Staff Report (EPA 2018c).
- 1.16. Since the adjournment of the hearing, there have been further opportunities for parties to comment on additional information relating to the application. These have included submissions relating to two rounds of expert conferencing on Tolerable Exposure Limits (TELs) air concentration dispersion modelling as outlined in [Direction and Minute 2](#) (EPA 2018f), and providing comments at the request of the DMC for further information (EPA 2019e, EPA 2019b, EPA 2020b). The timeline for the application is available on the EPA website under '[EDN application timeline](#)'.
- 1.17. These submissions were taken into account by the EPA and full details are provided in section 6 of this report.

Risk assessment

- 1.18. The EPA conducted an initial quantitative human health and environmental risk assessment to determine if the amount of exposure that people and organisms may experience during use of EDN would likely result in adverse effects [see July 2018 Science Memorandum (EPA 2018d)].
- 1.19. As noted in section 3, an updated Science Memorandum (EPA 2021) has been generated integrating the new information received since the 2018 hearing. This includes a revised human health and environmental risk assessment. Details can be found in section 7 of this Staff Report and in the updated Science Memorandum (EPA 2021). An interpretation of the requirements and controls proposed for EDN is provided in Figure 1, page 47 of this report. The main conclusions are reported below:

Physical risks

- 1.20. EDN is a flammable gas. It is noted that the prescribed controls and requirements for a flammable gas Category 1A apply to EDN.
- 1.21. WorkSafe has developed two draft SWI (s) that include signage requirements to prevent unintended ignition of the substance. The EPA notes that only the use of EDN under a sheet or in a shipping container is covered by the draft SWI (s). [The EPA notes that previous documents published by the EPA for EDN, including the Science Memorandum (EPA 2018d), Staff Report (EPA 2018c) and the Addendum to the Staff Report (EPA 2019d), have made

reference to tarpaulin¹ use in the fumigation process. For consistency with the draft SWI (s), the EPA will henceforth refer to these tarpaulins as sheets.]

- 1.22. The EPA considers that the risk of fire during log fumigation under a sheet or in a shipping container is negligible if prescribed and additional HSNO controls and requirements of the draft SWI(s) are followed (once they are given legal effect).

Human health effects

Risks to Workers

- 1.23. The draft SWI related to fumigation requirements (WorkSafe 2021b) includes the description of an affected area surrounding the enclosed space where fumigation occurs. There is no size or dimension prescribed for the affected area, and its setting needs to be ensured by the PCBU.
- 1.24. The EPA notes that the setting of fixed buffer zones for workers from the treatment area without wearing appropriate PPE (as proposed in the July 2018 Science Memorandum) has been replaced with the designation of this affected area by WorkSafe in their draft SWI (WorkSafe 2021b).
- 1.25. The EPA notes that the responsibility and jurisdiction for the setting of controls and requirements to manage adverse effects of a substance in the workplace rest with WorkSafe.
- 1.26. The EPA suggests the addition of controls that ensure that EDN is used in accordance with the requirements of the draft SWI (s) generated by WorkSafe. The proposed controls are provided in Appendix A.

Risks to members of the general public

- 1.27. The July 2018 Science Memorandum (EPA 2018d) proposed a 120 m buffer zone for members of the public based on the results of the modelling results available at the time. This buffer zone considers a chronic and continuous type of exposure reflective of individuals who may be residing near a fumigation operation.
- 1.28. In the draft SWI (WorkSafe 2021b), WorkSafe requires a buffer zone to be set at a minimum distance of 50 meters around the enclosed space where fumigation takes place. Requirements are also established in terms of setting and monitoring exposure levels and entry for the buffer zone.
- 1.29. Provided the requirements described in the draft SWI related to fumigation requirements (WorkSafe 2021b) are adhered to (once they are given legal effect), it is considered that the

¹ Tarpaulin is considered an equivalent term to sheet, being defined in draft SWI (WorkSafe 2021b) as a heavy-duty cover that has a low mass transfer coefficient for EDN and is waterproof and impenetrable.

risks to members of the public would be negligible, as concentrations outside of the buffer zone would be maintained below the TEL.

- 1.30. In order to account for sensitive populations or populations that might be unable to evacuate themselves in case of breaches of the TEL being reported, the EPA suggests the addition of a further exclusion zone around sensitive sites. More details are available in the updated Science Memorandum (EPA 2021) and in section 7 of this document.

Environmental effects

- 1.31. The July 2018 Science Memorandum (EPA 2018d) included an environmental risk assessment with proposed controls based on a number of assumptions and data. Since then, draft SWI (s) setting a number of requirements have been approved in principle for EDN (WorkSafe 2021b, WorkSafe 2021a). Although the draft SWI (s) (and the intended use patterns) are designed to address risks related to workers, they also contribute to reducing potential exposure levels outside of the fumigation area, and therefore address risks to the environment.
- 1.32. It is considered that the controls proposed in Appendix I of the July 2018 Science Memorandum (EPA 2018d) are no longer necessary as risks to the environment are better addressed by the requirements described in the draft SWI (WorkSafe 2021b). These will further reduce exposure levels for non-target organisms outside of the treatment areas.

Cultural Risk Assessment

- 1.33. It is considered that the conclusion in the Cultural Risk Assessment summarised in and appended to the Staff Report (2018c), that potential risks of EDN to Māori interests are likely to be negligible in terms of Māori cultural beliefs and environmental frameworks, remains valid.

Benefit assessment

- 1.34. EDN is proposed as a potential alternative to methyl bromide for the fumigation of timber and logs prior to export. Methyl bromide is an ozone depleting substance under the Montreal Protocol, while EDN is not. Therefore, the use of EDN in place of methyl bromide has the potential to help New Zealand meet our obligations under the Montreal Protocol.
- 1.35. It is considered that there are potentially significant benefits associated with the approval of EDN, including continued viability and expansion of the forestry industry in New Zealand. These have been assessed as having a high level of benefit.
- 1.36. It is considered that the potential benefits of the substance outweigh the risks of the substance, if used in accordance with the appropriate controls and requirements.

Recommendation

- 1.37. It is considered that there is sufficient information available to assess the application to import or manufacture EDN for release.
- 1.38. It is considered there is potential for significant exposure to people and the environment during the use phase of the lifecycle of EDN.
- 1.39. WorkSafe is responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations and has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. WorkSafe have produced draft SWI (s) to achieve this. The assessment undertaken by the EPA has been done on the basis that the draft SWI (s) will take legal effect in their current form. Should this application be approved, WorkSafe will need to take steps to finalise the draft SWI (s) so that they take legal effect.
- 1.40. It is considered that based on the requirements set out in the draft SWI (s), risks to workers would be adequately managed. The EPA also proposes controls to ensure that the substance would be used in line with the conditions of the draft SWI (s). The EPA also proposes that an additional control is set to protect members of the public in case the TEL, outside the buffer zone determined by the draft SWI related to fumigation requirements (WorkSafe 2021b), is exceeded.
- 1.41. It is considered that the conditions prescribed in the draft SWI related to fumigation requirements (WorkSafe 2021b), along with the proposed controls under the Act, would be sufficient to reduce risks to aquatic organisms, soil organisms, terrestrial vertebrates and invertebrates to a negligible level.
- 1.42. Therefore, the risks to people and the environment are considered negligible with proposed controls and requirements from the EPA and WorkSafe in place. The EPA recommends approving EDN for import or manufacture under section 29 of the Act with the prescribed and additional controls listed in Appendix A, in line with the requirements of the draft SWI (s).

2. Background

- 2.1. EDN contains ethanedinitrile in the gas phase at a concentration of 1000 g/kg, and a minimum purity of 95%. It is intended for use as a fumigant for timber and logs under commercial conditions prior to export. Ethanedinitrile, also known as cyanogen and oxalonitrile, is a new substance to New Zealand.
- 2.2. Ethanedinitrile has previously been granted containment approvals by the EPA (HSC100040, HSC100135 and HSC100191).
- 2.3. The background of EDN and information on the life cycle of the substance can be found in more detail in the EPA Staff Report (EPA 2018c).

Substance use

- 2.4. An application rate of 120 g/m³ of EDN for 24 hours is intended, which is a reduction from a rate of 150 g/m³ proposed by the applicant prior to the EDN hearing in August 2018.
- 2.5. The applicant has proposed the use of EDN under sheets, in shipping containers and in a ship's hold.

Regulatory status

- 2.6. As outlined in Table 2, ethanedinitrile has been approved for the fumigation of logs and soil in Australia under the trade names Sterigas 1000™ (for use on timber) and EDN Fumigas (for soil fumigation). Ethanedinitrile is also approved in South Korea for the fumigation of pine weevil and white ant species on timber and has been approved as a fumigant in Malaysia. Evaluation of ethanedinitrile is currently in progress in the United States of America. The applicant also indicates that evaluation of the substance is in progress in Russia and that they are preparing submissions for the substance in Canada, the Czech Republic, Israel and South Africa. Further information on the regulatory status can be found in the Updated Science Memorandum (EPA 2021).

Table 2: Regulatory status of EDN in New Zealand and overseas

Substance	Regulatory history in New Zealand	International regulatory history (Australia, Canada, Europe, Japan, USA)
EDN	New substance (not previously approved)	<p>Approved with controls in Australia for the fumigation of timber (Sterigas 1000™ fumigant) and strawberries (EDN Fumigas®); APVMA product number P60096.</p> <p>Approved in South Korea for fumigation of timber, under the tradename Sterigas (registration 96-Insecticide-45).</p> <p>Approved in Malaysia in December 2020 as a fumigant (registration number 10107).</p> <p>An application has been received in the United States of America in March 2021 for approval of EDN as a preventive wood preservative treatment (EPA-HQ-OPP-2021-0071).</p> <p>Currently being evaluated in Russia.</p> <p>In process of submission in Canada, the Czech Republic, Israel and South Africa.</p> <p>Not included as an approved active ingredient on the list published by Food and Agricultural Materials Inspection Centre (FAMIC) on their website.</p>

3. Process, consultation and notification

- 3.1. Information on the process, consultation and notification prior to the EDN hearing can be found in the Staff Report (EPA 2018c).
- 3.2. A Science Memorandum (EPA 2018d) and a Staff Report (EPA 2018c) were generated for this application in July 2018. The Science Memorandum focussed on determining hazards, classification and associated human and environmental risks while the Staff Report integrated the findings of the Science Memorandum, with costs and benefits considerations along with submissions made during the public consultation period (open from February to April 2018).
- 3.3. As the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations, WorkSafe has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. The EPA has therefore sought WorkSafe's views under section 58 of the Act. WorkSafe provided advice in August 2018 (WorkSafe 2018), proposing they develop two SWI (s) giving effect to provisions of the General Risk and Workplace Management (GRWM) Regulations.
- 3.4. A Decision-Making Committee (DMC) was appointed and hearings for EDN were held in Wellington, New Zealand on 21 August 2018 and in Rotorua, New Zealand on 28 and 29 August 2018. On 20 August 2018, further information on air concentration dispersion modelling was received from the applicant. On 21 August 2018, STIMBR, a submitter on APP202804 also provided new information.
- 3.5. In light of the late provision of evidence and in order to assist in reaching a robust decision, the hearing was adjourned and a Direction and Minute (EPA 2018f) was issued on 23 August 2018 by the DMC, directing two rounds of expert conferencing to be held to resolve areas of disagreement highlighted by the new information.
- 3.6. The expert conferencing sessions were held on 12 October 2018 and 15 October 2018 and covered the Tolerable Exposure Limits (TEL) and air concentration dispersion modelling, respectively. A joint expert witness statement was produced for both sessions (EPA 2018b, EPA 2018a).
- 3.7. Although an agreement was reached on the TEL value, points of disagreement remained on modelling parameters relative to air concentration dispersion modelling. The DMC asked for further clarifications and further advice from the EPA consultant (Graham 2018) and discussions with the EPA consultant occurred (EPA 2018i).
- 3.8. In the DMC Direction and Minute 6, dated 28 January 2019 (EPA 2019e), the DMC expressed the following views on modelling data:

“The DMC considers that an absence of sufficient data acquired through measurement of environmental EDN concentrations during appropriately scaled fumigation trials is a significant limitation in its consideration of the application.” And

“The DMC considers that reliance on air dispersion modelling to predict environmental concentrations of EDN during fumigation, with the inherent uncertainties therein, (including significant uncertainty in the concentration of EDN assumed to be present under the tarpaulin at the time of ventilation), is by itself insufficient to ensure worker and public safety of the fumigant use without recapture at the Port of Tauranga.”

- 3.9. In response to DMC Direction and Minute 6 (EPA 2019e), WorkSafe indicated they would develop the SWI (s) they identified in their previously given advice (WorkSafe 2018) and the applicant indicated that they could provide field data addressing some of the limitations identified by the DMC in Direction and Minute 6 (EPA 2019e).
- 3.10. In Direction and Minute 7, dated 5 April 2019 (EPA 2019a), the DMC considered the responses to Direction and Minute 6 (EPA 2019e) and laid out a schedule and conditions for receiving information from the applicant. This indicated *“that they regard any SWI relating to the management of the risks of EDN in workplaces as directly relevant to its consideration of this application under the HSNO Act”* and advised that *“while the separate statutory process to develop an SWI(s) is allowed to run it is likely there will be a prolonged adjournment of this application”*.
- 3.11. Following receipt of the information from the applicant as per the established schedule, the DMC issued Direction and Minute 8 (EPA 2019b), dated 14 June 2019, in which they noted limitations associated with the data received by the applicant, and further gave options for timing of consideration for the application as per below points:

“...the adjournment of the hearing of this application will continue until such time that:

- a) *WorkSafe*
- a. *Advises that an SWI (s) has been made or approved in principle, provides the DMC with any supporting information that has not already been made available to the DMC and provide copies of the relevant SWI (s); or*
 - b. *advises that all processes that could potentially lead to the making of an SWI(s) are concluded and that no SWI(s) has been made*

This would then be considered as information to enable the HSNO DMC to consider if adequate workplace requirements are in place and to enable assessment of any residual risk arising to public health in light of these workplace requirements being known, or

- b) The Applicant chooses to notify the DMC indicating they would prefer the certainty of a final decision under HSNO, and as such, wish the DMC to enter into final consideration of the application in advance of provision of a SWI(s) prepared by WorkSafe.*
- c) The DMC uses its discretion to conclude the hearing and to initiate consideration of the application.”*

- 3.12. On 9 October 2019, an Addendum to the Staff Report (EPA 2019d) was released by the EPA outlining the new information received from the applicant, WorkSafe and others from August 2018 to October 2019. This document gave an update on what impact, if any, the further information had on the views outlined in the EPA Staff Report (EPA 2018c) and Science Memorandum (EPA 2018d).
- 3.13. Following the release of the Addendum to the Staff Report (EPA 2019d), the applicant asked to submit new information in support of changes to some areas such as application rate, log stack sizes and ship's hold and container fumigation (requested on the 23 October 2019). The DMC issued Direction and Minute 9, dated 11 December 2019 (EPA 2019c), which allowed new information to be submitted but noted that introducing new information would further delay the decision-making process. The issuing of Direction and Minute 10, dated 18 February 2020 (EPA 2020a) outlined the timeframe for responses from the applicant and WorkSafe to Direction and Minute 9 (EPA 2019c).
- 3.14. The applicant provided a response to DMC Direction and Minute 10 on 25 March 2020 (Draslovka 2020).
- 3.15. The DMC issued Direction and Minute 11, dated 31 March 2020 (EPA 2020b), "*direct[ing] the EPA to prepare a Staff Report covering all information received for this application in its totality, to be made available to the parties, no later than ten working days prior to the date the hearing reconvenes*".
- 3.16. WorkSafe conducted a public consultation on the draft SWI (s) between 28 February 2020 and 5 April 2020 (WorkSafe 2020a). Some changes to the original proposals were made and a further targeted consultation on the changes was organised between 23 July 2020 and 7 August 2020 (WorkSafe 2020b).
- 3.17. On 8 December 2020, WorkSafe notified the EPA that the two draft SWI (s) had been approved in principle (WorkSafe 2021b, WorkSafe 2021a) and the draft documentation was provided to

the DMC. The EPA has undertaken a review of the requirements of the draft SWI (s), paying close attention to reconcile any residual risks for public health and the environment. An analysis of the further submissions received from 2018 was also conducted (see section 6).

- 3.18. In response to Direction and Minute 11 (EPA 2020b) and the draft SWI(s) being approved in principle, the EPA has prepared an updated Science Memorandum (EPA 2021) and this updated Staff Report for the DMC's consideration. These documents provide an overview of the changes in respect of hazard characterisation and risk assessment for the use of EDN and focuses on residual risks in light of the draft SWI (s). An updated recommendation is also made.
- 3.19. In preparing this report, the following documents and information were taken into account:
- The application form;
 - Confidential material submitted by the applicant with the application form, including:
 - toxicological and ecotoxicological studies on ethanedinitrile and other cyanide-containing substances
 - the full composition of EDN
 - physico-chemical properties of EDN;
 - The submissions (see details in sections 5 and 6, a full list of submitters can be found in the Staff Report (EPA 2018c));
 - Information received from or published by WorkSafe
 - initial advice released in 2018 (WorkSafe 2018)
 - The public consultation document released in February 2020 (WorkSafe 2020a).
 - The targeted consultation document released in July 2020 (WorkSafe 2020b).
 - draft SWI '*Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021*' (WorkSafe 2021b).
 - draft SWI '*Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for Ethanedinitrile)* (WorkSafe 2021a).
 - Initial EPA Staff Evaluation and Review Report (EPA 2018c) and Science Memorandum (EPA 2018d);

- Expert conferencing information on the TEL and air concentration and dispersion modelling, including the two joint expert witness statements (EPA 2018b, EPA 2018a);
- The Addendum to the Staff Report (EPA 2019d);
- The cultural risk assessment (refer EPA 2018c);
- The Direction and Minutes of the DMC (EPA 2018e, EPA 2018f, EPA 2018g, EPA 2018h, EPA 2018i, EPA 2019e, EPA 2019a, EPA 2019b, EPA 2019c, EPA 2020a, EPA 2020b) and documents submitted in response to these Direction and Minute, including information sent by the applicant (Draslovka 2020).
- The updated Science Memorandum (EPA 2021)
- Other available information, including various air concentration dispersion modelling reports (Graham 2018, Graham Environmental Consulting Limited 2018, Sullivan Environmental Consulting Incorporated 2018b, Sullivan Environmental Consulting Incorporated 2018a, Todoroski Air Sciences Property Limited 2019, Sullivan Environmental Consulting Incorporated 2020).

3.20. All additional, publicly available, information that has been received since 20 August 2018 is available on the EPA website.

4. Hazardous properties

- 4.1. The EPA classified the hazard profile of EDN as detailed in Table 3; this is described in more detail in Appendix F of the updated Science Memorandum (EPA 2021). Please note: the proposed HSNO classifications have been updated since the EDN hearing to the Global Harmonized System (GHS) for classification following the adoption of that system by the EPA in April 2021.
- 4.2. Physico-chemical, mammalian toxicology and ecotoxicology studies were provided for ethanedinitrile and for cyanide-containing compounds. Information from these studies was used to classify the substance.

Table 3: Applicant and EPA hazard classifications of EDN

Hazard Endpoint	Applicant classification	EPA classification (GHS)
Flammability	2.1.1A	Flammable gas Category 1A
Gases under pressure	-	Liquefied gas
Acute toxicity (inhalation)	6.1B	Acute inhalation toxicity Category 2
Aquatic ecotoxicity – acute	9.1A	Hazardous to the aquatic environment acute Category 1; M-factor 10

Hazard Endpoint	Applicant classification	EPA classification (GHS)
Aquatic ecotoxicity - chronic		Hazardous to the aquatic environment chronic Category 1; M-factor 10

- 4.3. Information on the potential for ready biodegradability of ethanedinitrile is inconclusive, as no test data are available. For classification purposes, it is therefore considered that ethanedinitrile is not readily biodegradable, although, it can be expected that ethanedinitrile (and the resulting hydrogen cyanide) would be degraded quickly in the environment. EDN is not expected to bioaccumulate and is not considered to persist in the environment.
- 4.4. The applicant proposes that ethanedinitrile is not toxic in the soil environment. The EPA disagrees as no reliable test data are available to make that conclusion. Furthermore, ethanedinitrile is approved for use as a soil fumigant (in the product EDN Fumigas®) in Australia by the Australian Pesticides and Veterinary Medicines Authority (APVMA). As such, it is considered highly likely that ethanedinitrile is toxic to soil organisms, and a hazardous to soil organisms classification is likely to apply. The ecotoxicity of ethanedinitrile to soil organisms could not be determined in this instance however, due to a lack of test data.
- 4.5. The applicant proposes that a hazard classification for ecotoxicity to terrestrial vertebrates is not applicable (“NA”) since ethanedinitrile is a gas and oral exposure is not a relevant route of exposure. Since hazard classification for terrestrial vertebrates is only concerned with toxicity to terrestrial vertebrates via the oral route of exposure, the EPA is in agreement with the applicant’s conclusion, and accepts that a hazardous to terrestrial vertebrates classification is not applicable to ethanedinitrile.
- 4.6. The applicant proposes that a hazard classification for ecotoxicity to bees and other terrestrial invertebrates is also not applicable (“NA”). The EPA disagrees with this conclusion since no reliable test data are available to make that conclusion. In addition, it seems conceivable that it could be possible to expose bees to ethanedinitrile. As such, the EPA disagrees with the applicant’s proposal and considers instead that ecotoxicity to terrestrial invertebrates could not be determined (“ND”). It is considered highly likely however that ethanedinitrile is toxic to bees and other terrestrial invertebrates based on its conversion to cyanide (CN⁻), and is likely to trigger a hazardous to terrestrial invertebrates classification if the test data existed.

5. Submissions – pre-hearing

- 5.1. After the initial submission process, prior to the EDN hearing, 43 submissions were received for this application (see the Staff Report (EPA 2018c) for the full list of submitters, including their views on EDN as well as the EPA’s response).

6. Submissions on new information provided during the adjournment of the hearing

- 6.1. Stakeholders in Methyl Bromide Reduction (STIMBR) provided a summary of new information (submitted on the day of the Wellington hearing on 21 August 2018) with regards to a potential ammonia issue during the fumigation process, raised by the containment field trials at Tokoroa in April 2016. STIMBR commissioned Plant and Food Research to undertake the testing. The summary report states that ammonia was not identified in the headspace above the EDN-treated log samples, and though researchers at Plant and Food Research stated that an odour could be detected when EDN application rates exceed 50 g/m³, they noted that the compounds contributing to the odour were difficult to determine. STIMBR stated in the summary report that the odour was unlikely to be EDN or HCN due to their distinctive smell, and taking the toxicity of EDN into consideration, it was considered unlikely that the odour would be harmful.
- 6.2. The hearing for EDN has been adjourned since the end of proceedings (in Rotorua) on 29 August 2018. During this period, there have been five further opportunities for parties to submit written feedback on new information that was received and made publicly available by the EPA. This new information concerned the two rounds of expert conferencing on TELs and air concentration dispersion modelling, and to respond to the request by the DMC for further information in Direction and Minute 6 (EPA 2019e), Direction and Minute 8 (EPA 2019b) and Direction and Minute 11 (EPA 2020b).
- 6.3. Some submissions echoed those previously submitted to the EPA, including the importance of the forestry industry in New Zealand and that EDN is a good alternative fumigant to methyl bromide.
- 6.4. The first two opportunities for submitters to provide written comments (during the adjournment of the hearing) occurred after the joint expert statements (in response to Direction and Minute 2 (EPA 2018f)) were made available on the EPA website, along with the new information from the applicant and STIMBR that was provided to the EPA on 20 August 2018 and 21 August 2018, respectively.
- 6.5. The third opportunity for submitters to provide written feedback occurred after the DMC issued Direction and Minute 6 (EPA 2019e) on 28 January 2019, for further information after the teleconference minutes (with DMC and the EPA consultant, Dr Bruce Graham in attendance) and supporting documentation was made available on the EPA website. Direction and Minute 6 (EPA 2019e) received nine responses, including one from the applicant and one from Worksafe.
- 6.6. The fourth opportunity for submitters to provide written feedback on the additional information submitted by the applicant occurred after the DMC issued Direction and Minute 8 (EPA 2019b). Direction and Minute 8 received one response.

- 6.7. Responses from submitters to Direction and Minute 2 (EPA 2018f), Number 6 (EPA 2019e) and Number 8 (EPA 2019b) raised a number of points, including the conservatism of the TEL (0.034 ppm as a 24 hour average) and that ship hold use should be included in the scope of the application. Some submitters thought more modelling should be carried out to determine the air dispersion of EDN, as well as determining the effects on human health and the environment. Other submitters reported on the frustrations resulting from the delayed decision of EDN. One submitter stated that evaluating recapture of EDN would be beneficial, while another submitter questioned whether liquid phase hydrogen cyanide from moisture under the tarpaulin or sheet had been overlooked by the EPA. Two submitters also mentioned that the amount of time it took to remove tarpaulins from log stacks was likely overstated in reports, based on observational accounts. The submitter responses for Direction and Minute 2 (EPA 2018f), Number 6 (EPA 2019e) and Number 8 (EPA 2019b) can be found in full in the Addendum to the Staff Report (EPA 2019d) and on the EPA website.
- 6.8. The DMC issued another Direction and Minute 11 (EPA 2020b) to allow submitters an opportunity to respond to new information submitted by the applicant to the DMC under Direction and Minute 10 (EPA 2020a). The EPA received five responses.
- 6.9. Responses from submitters for Direction and Minute 11 covered similar topics to the previous submissions received prior to the hearing and during the hearing adjournment.
- 6.10. Additionally, the Bay of Plenty Regional Council (BOPRC) believed that the air dispersion modelling should be independently reviewed and that EDN concentration measurement data should be made available to regulators. BOPRC also suggested that the explosivity of EDN, especially in ship's holds had not been fully assessed.
- 6.11. BOPRC also wished for regulators (including Regional Councils and WorkSafe) to be informed on the monitoring that will be used to verify compliance and boundary limits, while STIMBR's submission wanted the EPA to review monitoring after a year of fumigation in order to revisit controls, including those for buffer zones and EDN concentration allowances.
- 6.12. Matariki Forests stated that they believed EDN fumigation could be carried out in more locations than is currently permissible for other fumigation activities.
- 6.13. STIMBR and Red Stag Timber emphasised that they felt the TEL was extremely conservative, while Tauranga Moana Fumigant Action Group (TMFAG) had little confidence in the TEL value due to the lack of knowledge on the health effects of EDN and noted that "*exposure levels should be set significantly higher*"².

² Considered by the EPA to be meant as "significantly lower". Responses from STIMBR and Red Stag for Direction and Minute 11 can be found in full on the EPA website.

- 6.14. Red Stag Timber also noted that the buffer zone limits from the initial Science Memorandum (EPA 2018d) were too conservative. Furthermore, STIMBR noted the *“the buffer of 20m for unprotected workers is not needed if, as has been proposed to WorkSafe, a risk management approach managed by the fumigator is prescribed in the SWI.”*
- 6.15. STIMBR outlined their preference for ship’s hold to be included in the EDN use and noted that they believed WorkSafe’s reluctance to include ship hold fumigation in their draft SWI was driven by the EPA, stating *“WorkSafe appears to have felt constrained by the advice formulated by EPA staff”*.
- 6.16. STIMBR has stated that they do not believe audiometric and respiratory system health checks proposed by WorkSafe were necessary based on a report provided by the applicant. However, they did want to reiterate that they supported health checks when there was clear evidence to do so.
- 6.17. TMFAG requested as part of their submission that instantaneous and short time exposure limits should be set for EDN.
- 6.18. A number of submitters noted their frustrations at the delay in the decision for EDN.
- 6.19. The submitter responses for Direction and Minute 11 can be found in full on the EPA website. See section 3 for a brief overview of the timeline of submissions.

EPA response

- 6.20. The EPA notes that the applicant has submitted information not included with their initial application during the application process, including prior to the hearing and during the adjournment of the hearing. The analysis of this information along with the creation of the draft SWI (s) for EDN, has added to the time required to process and progress this application.
- 6.21. With regards to the potential ammonia odour following fumigation, STIMBR has provided a summary report to the EPA (this report is available on the EPA website). The summary report findings were inconclusive. Furthermore, the EPA maintains that no data have been provided to the EPA that would quantify how much ammonia is present at the end of a fumigation.
- 6.22. With regards to further modelling as commented on by the BOPRC, STIMBR and Red Stag, the EPA notes that no further modelling will be conducted at this time. However, during the SWI process, WorkSafe commissioned a report from Todoroski Air Services (“Todoroski”) on air dispersion modelling (Todoroski Air Sciences Property Limited 2019). The Todoroski report covers such aspects as identifying whether a 50 m buffer zone for workers is adequate for log stack ventilation, to identify how long the buffer zone should be in place, and to identify the effects of ventilation depending on the time of day. The report also takes into consideration fumigation in ship holds.

- 6.23. The Todoroski report concluded that “[r]estricting ventilation to daytime hours reduces the spatial extent of the potential impact [of EDN]” (page 56 of the Todoroski report). WorkSafe has set a requirement in their draft SWI related to fumigation requirements (WorkSafe 2021b) that ventilation must take place between the hours of sunrise and sunset to align with this conclusion.
- 6.24. With regards to the buffer zone comments from submitters, the EPA notes that WorkSafe have proposed a buffer zone of at least 50 m in the draft SWI related to fumigation requirements (WorkSafe 2021b), also stating that the PCBU must ensure the TEL is not exceeded at the boundary of the buffer zone. This differs from the initial proposal from the EPA for a buffer zone of 20 m for workers and 120 m for the general public. A detailed overview of the rationale behind the setting of the buffer zone definition and its associated entry requirements is given in the WorkSafe public consultation document (WorkSafe 2020a) and targeted consultation document (WorkSafe 2020b).
- 6.25. In response to BOPRC wishing to be informed of the monitoring that will be used to verify compliance and boundary limits, the EPA notes that record-keeping, monitoring and reporting requirements are set by WorkSafe and are featured in the draft SWI related to fumigation requirements (WorkSafe 2021b).
- 6.26. In response to STIMBR and Red Stag commenting on the conservatism of the TEL, and with TMFAG not having confidence in the TEL value, the EPA notes that there has been expert conferencing on the matter and both experts signed an agreed statement that included the TEL for EDN (EPA 2018b).
- 6.27. With regards to EDN use in a ship’s hold, the EPA considered that there was a lack of study data to support ship hold fumigations during the initial quantitative risk assessment. WorkSafe commissioned a report that included air dispersion modelling and considered ship hold use during the consultation process (WorkSafe 2020a). However, WorkSafe concluded:
- “... the requirements that would be required to manage the risk of fumigation are likely to be impracticable for the locations where fumigation would take place.*
- On this basis we are proposing to restrict fumigation with EDN to fumigation under sheets only and not to allow fumigation in a ship’s hold.”*
- 6.28. In the subsequent WorkSafe public consultation document (WorkSafe 2020a) and targeted consultation document (WorkSafe 2020b), WorkSafe also allowed for the use of EDN in a shipping container.
- 6.29. With regards to the audiometric and respiratory health checks, given these checks relate to activities in the workplace, the EPA accepts WorkSafe’s advice on the health monitoring requirements for workers.

- 6.30. With regards to potentially non-compliant activities (if the substance is approved and draft SWI (s) are given legal effect) compliance, monitoring and enforcement activities can address any such activity.
- 6.31. In response to TMFAG's request for short-term exposure limits, the EPA notes that the risk to members of the public from this type of exposure was considered negligible. See the Human health effects in section 7 for further information.

7. Risk assessment

- 7.1. During the importation, manufacture, transportation, storage, and disposal of this substance, it is expected that exposure to people or the environment is unlikely to occur and that the proposed controls and other legislative requirements will sufficiently mitigate the risks associated with these stages of the substance lifecycle to a negligible level. These include the existing Hazardous Substances Notices around packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's health and safety at work requirements.
- 7.2. In contrast, it is considered that there is the potential for exposure to humans and the environment to occur during the use phase of the substance. Therefore, a human health and environmental risk assessment was carried out. In this assessment, the above controls and legislative requirements were taken into account when identifying controls to mitigate risks associated with use of the substance.
- 7.3. It should also be noted that WorkSafe is responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations and has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. The assessment undertaken by the EPA has been done on the basis that the draft SWI (s) will take legal effect in their current form.

Use pattern

- 7.4. EDN is a gas containing ethanedinitrile (at a minimum of 95% purity) and is intended to be used as a fumigant to control insect pests and pathogens on timber and logs.
- 7.5. Although initially intended for a use rate of 150 g/m³ for 24 hours, the application rate has been revised by the applicant to a rate of 120 g/m³ for 24 hours applied to logs under a sheet, in a fumigation chamber, in a shipping container or a ship's hold.

Effects from fire

- 7.6. EDN is a flammable gas and therefore presents potential risks from fire, including harm to human health, property damage, wider communities and surrounding environments.

- 7.7. EDN is proposed to be classified as flammable gas Category 1A and therefore prescribed controls will apply. It is considered that these controls and requirements under other legislation will manage the risks associated with the flammability of EDN to a negligible level.
- 7.8. As the agency responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations, WorkSafe has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. The EPA has therefore sought WorkSafe's views in line with Section 11(2A) of the Act. WorkSafe provided advice in August 2018 (WorkSafe 2018), that they were concerned about fumigation in shipping containers and ship holds as they were likely to contain non-intrinsically safe³ ignition sources, and that a flammable atmosphere exists during EDN fumigation.
- 7.9. The EPA notes that fumigation may only occur under a sheet or in a shipping container as described in the draft SWI (s) developed by WorkSafe, and that the draft SWI (s) include signage requirements to prevent unintended ignition of the substance. Given this, the EPA considers that the risk of fire during log fumigation under a sheet or in a shipping container is negligible if prescribed and additional HSNO controls and requirements of the draft SWI(s) (once given legal effect) are followed.

Human health effects

- 7.10. The human health risk assessment conducted prior to the EDN hearing (EPA 2018d) was based on toxicity study data and air concentration dispersion modelling provided by the applicant (Sullivan Environmental Consulting Incorporated 2018a) and reviewed by Dr Bruce Graham (Graham Environmental Consulting Limited 2018) for the EPA. This modelling simulates how the EDN gas will disperse in the atmosphere based on a number of assumptions and data. The modelling initially provided only considered fumigation under sheets.
- 7.11. Further information regarding the initial modelling can be viewed in the EPA Science Memorandum (EPA 2018d) and the Staff Report (EPA 2018c), and can be found in Dr Graham's report (Graham Environmental Consulting Limited 2018).
- 7.12. The updated Science Memorandum (EPA 2021) provides an overview of the differences in the key parameters and data considered in the July 2018 Science Memorandum (EPA 2018d) and this updated assessment (see Table 10 of the updated Science Memorandum).
- 7.13. Key parameters and data include the maximum application rate considered for EDN, the release concentration before ventilation, Workplace Exposure Standard values (WES),

³ Intrinsic safety is a protection technique for safe operation of electrical equipment in hazardous areas by limiting the energy, electrical and thermal, available for ignition.

Tolerable Exposure Limit (TEL), the range of uses envisaged, modelling information and field studies and monitoring information.

Risks to Workers

- 7.14. In the July 2018 Science Memorandum (EPA 2018d), it was determined, based on the modelling information at an application rate of 150 g/m³ for 24 hours, that a minimum distance of 10 m or 20 m from the treated log stacks is required to ensure levels under the WES value applicable at the time, based on a release concentration before ventilation of 700 ppm.
- 7.15. WorkSafe provided advice in August 2018 (WorkSafe 2018), proposing they develop two SWI (s) giving effect to provisions of the General Risk and Workplace Management (GRWM) Regulations.
- 7.16. After an initial public consultation (WorkSafe 2020a) and a further targeted consultation period (WorkSafe 2020b), these draft SWI (s) have since been generated and approved in principle, while considering extra information related to the fumigation and ventilation parameters, as well as modelling and monitoring information. The draft SWI related to fumigation requirements (WorkSafe 2021b) in particular, includes the determination of an affected area, surrounding the enclosed space where fumigation occurs.
- 7.17. The affected area is defined as follows in the draft SWI (WorkSafe 2021b):
- (a) *“an area within which one or more workplace exposure standards for EDN is or may be exceeded during fumigation and ventilation; and*
 - (b) *includes an enclosed space”*
- 7.18. The draft SWI further provides requirements for entry into the affected area as follows:
- “For the purposes of regulation 13.46(4)(a) of the Regulations, a PCBU with management or control of EDN that the PCBU uses for fumigation must—*
- (a) *for each fumigation, determine, review and, if necessary, adjust the affected area having regard to—*
 - (i) *the particular circumstances of the fumigation; and*
 - (ii) *information obtained from monitoring data; and*
 - (b) *ensure that—*
 - (i) *no person enters or remains in the affected area at any time, other than in the following circumstances*
 - (A) *the certified handler referred to in regulation 14.16(2)(a)(i) of the Regulations (as modified by clause 11) is satisfied that the affected area is safe for the person to enter:*

(B) the person is a worker carrying out fumigation-related work; and
(ii) no worker carrying out fumigation-related work enters or remains in the affected area unless—

(A) the worker wears personal protective equipment in accordance with regulation 13.8 of the Regulations; and

(B) the personal protective equipment is suitable to ensure the worker is not exposed to levels of EDN above the workplace exposure standards”

7.19. There is no size or dimension prescribed for the affected area and its setting needs to be ensured by the PCBU.

7.20. The EPA notes that the setting of fixed buffer zones for workers from the treatment area without wearing appropriate PPE (as proposed in the July 2018 Science Memorandum) has been replaced with the designation of this affected area by WorkSafe in their draft SWI (WorkSafe 2021b).

7.21. The EPA notes that the responsibility and jurisdiction for the setting of controls and requirements to manage adverse effects of a substance in the workplace rest with WorkSafe.

7.22. The EPA suggests the addition of controls that ensure that EDN is used in accordance with the requirements of the draft SWI (s) generated by WorkSafe, namely:

- A maximum application rate of 120 g/m³ over 24 hours
- The substance can only be used for timber treatment fumigation under a sheet or in a shipping container

Risks to members of the general public

7.23. The July 2018 Science Memorandum (EPA 2018d) proposed a 120 m buffer zone for members of the public based on the results of the modelling results available at the time. This considers a chronic and continuous type of exposure reflective of individuals who may be residing near a fumigation operation.

7.24. As noted in section 3, the 24 hour average TEL for ethanedinitrile which was initially proposed has been confirmed through the joint expert conference on that topic with the produced expert witness statement (EPA 2018b).

7.25. As noted by the DMC in their Direction and Minute 8 (EPA 2019b), the creation of SWI (s) by WorkSafe would “*enable the HSNO DMC to consider if adequate workplace requirements are in place and to enable the assessment of any residual risk arising to public health in light of these workplace requirements being known*”.

7.26. In relation to members of the public, the EPA notes that the draft SWI related to fumigation (WorkSafe 2021b) includes the following measure under 'Exposure standards and limits':

"12 Modified requirement for tolerable exposure limit

For the purposes of regulation 13.46(4)(b) of the Regulations, regulation 13.17 applies as if subclause (1) were replaced with the following:

"(1) A PCBU with management or control of work using a class 6 substance must ensure that it is not used in a manner that results in—

- (a) in the case of fumigation using EDN, a concentration of the substance in the air at any point on the boundary of the buffer zone that exceeds the tolerable exposure limit set for that medium; and*
- (b) in every other case, a concentration of the substance in an environmental medium that exceeds the tolerable exposure limit set for the medium."*

7.27. In addition, the draft SWI (WorkSafe 2021b) defines buffer zone as per below:

"Buffer zone means an area extending outward in all directions from the perimeter of an enclosed space being fumigated to a distance of at least 50 metres."

7.28. Entry to the buffer zone is further restricted as per below:

"7 Entry to buffer zone to be restricted

- (1) "For the purposes of regulation 13.46(4)(a) of the Regulations, a PCBU with management or control of EDN that the PCBU uses for fumigation must ensure that no member of the public is in the buffer zone during the buffer zone period.*
- (2) Despite subclause (1), if a buffer zone extends over water, the PCBU must ensure so far as reasonably practicable that—*

- (a) the buffer zone is kept under observation; and*
- (b) if a member of the public enters the buffer zone, the member of the public moves out of the buffer zone as soon as is reasonably practicable."*

7.29. As noted above, the EPA had originally determined that a distance of 120 m from the treatment area was necessary in order to reach 24-hour average EDN concentrations below the TEL value of 0.034 ppm (based on a higher application rate and multiple source). In the draft SWI (WorkSafe 2021b), WorkSafe requires a buffer zone to be set at a minimum distance of 50 meters around the enclosed space where fumigation takes place. Requirements are also

established in terms of setting and monitoring exposure levels and entry for the buffer zone. Further details are available in WorkSafe's published documents (WorkSafe 2020b, WorkSafe 2020a).

7.30. Provided the requirements described in the draft SWI (WorkSafe 2021b) are adhered to, it is considered that the risks to members of the public would be negligible, as concentrations outside of the buffer zone would be maintained below the TEL at all times.

7.31. It is noted that this position relies on PCBUs meeting their obligations at all times. The draft SWI (WorkSafe 2021b) also includes provisions for notification of breaches of TELs concentrations:

"13 Additional requirement to notify recorded exposure level

For the purposes of regulation 13.46(4)(a) of the Regulations, if the exposure level recorded for a ventilation exceeds the tolerable exposure limit for EDN, the PCBU must notify WorkSafe and the relevant medical officer of health as soon as practicable but within 5 working days of the exposure level being recorded."

7.32. The exposure level is defined in the draft SWI (WorkSafe 2021b) as below:

"exposure level means the concentration of EDN in the air recorded at the monitoring location"

7.33. The monitoring location is defined in the draft SWI (WorkSafe 2021b) as below:

"Monitoring location, in relation to a buffer zone, means the point on land at the edge of the buffer zone that is in the most downwind direction from the enclosed space being ventilated"

7.34. Scenarios under which the TEL could be exceeded are therefore considered as part of the draft SWI (WorkSafe 2021b). As the TEL proposed for EDN relates to long-term continuous chronic exposure, a brief and discrete exceedance of the value is not considered to result in appreciable effects. It is also noted, that in case of exceedances, the draft SWI indicates that the *"PCBU would need to notify WorkSafe and the relevant medical officer as soon as practicable but within five working days of the exposure level being recorded"*.

7.35. To allow for the possibility that these requirements are not adhered to (ie exposure level exceeding the TEL), and to protect more sensitive populations or populations that might not be in a position to evacuate themselves in case of breaches of the TEL being reported, the EPA suggests the addition of a further exclusion zone around sensitive sites:

- Fumigations using ethanedinitrile (EDN) should not be carried out within 120 m of any sensitive site where the public may lawfully be present. Sensitive sites include

schools, playgrounds, Early Childhood Centres (ECE), prisons or place of detention, hospitals or long-term care facilities where members of the public who may be unable to evacuate themselves could be present. The distance should be measured from the perimeter of the enclosed space.

7.36. In addition to the controls proposed to be set in relation to risks to workers, the EPA also suggests the addition of a control setting the TEL value:

- A Tolerable Exposure Limit (TEL) of 0.034 ppm (=0.072 mg/m³) as a 24-hour average

Monitoring

7.37. A discussion around monitoring of EDN was included in the Staff Report (EPA 2018c) which noted that the applicant initially proposed using an electrochemical gas analyser for monitoring EDN exposures and that this instrument had an operating range of 1 to 50 ppm and a repeatability of 2 ppm. Therefore, this instrument was only considered marginally suitable for monitoring against the WES values 3 and 5 ppm and it would not be suitable for monitoring against any exposure limits lower than that, like the proposed TEL.

7.38. It was also noted in the 2018 Staff Report (EPA 2018c) that no other suitable instruments had been identified for the continuous monitoring levels of EDN in air below 1 ppm, and it was likely that the only viable options would involve the collection of gas samples, either in gas containers or on absorption tubes, followed by analysis in a suitably qualified laboratory.

7.39. Further information pertaining to the discussion on monitoring of EDN prior to the hearing can be found in the Staff Report (EPA 2018c).

7.40. In the draft SWI related to fumigation (WorkSafe 2021b), produced during the hearing adjournment, WorkSafe does not suggest any specific monitoring instrument, however, the draft SWI does state that each fumigation using EDN is to be continuously monitored by sampling tubes equipped with meters to allow readings to be taken from outside the affected area, and that records must be kept on the type of monitoring equipment used. It also states that the PCBU is responsible for the monitoring of the TEL, and adjusting the buffer zone to ensure the TEL is not breached.

Impurities

7.41. Information on manufacturing impurities was provided by the applicant. As a result of this information a control is proposed to limit the amount of hydrogen cyanide present in ethanedinitrile to less than 1% v/v, where v/v means volume of hydrogen cyanide per volume of ethanedinitrile.

Human health risk assessment summary

7.42. WorkSafe is responsible for overseeing the Health and Safety at Work Act 2015 (HSW) and associated regulations and has responsibility for assessing that the HSW requirements are adequate to manage the risks from the substance in the workplace. The draft SWI (s) have been prepared to achieve that end. The EPA proposes that controls are set to ensure that the substance will be used in line with the requirements of the draft SWI (s). In addition, the EPA proposes that an additional control is set to protect members of the public in case of exceedance of the TELs outside the buffer zone determined by the draft SWI related to fumigation (WorkSafe 2021b).

Environmental effects

- 7.43. The July 2018 Science Memorandum (EPA 2018d) provided an environmental risk assessment with proposed controls based on a number of assumptions and data. Since then, draft SWI (s) setting a number of requirements have been approved in principle for EDN (WorkSafe 2021b, WorkSafe 2021a). Although the draft SWI (s) (and the intended use patterns) are designed to address risks related to workers, they also contribute to reducing potential exposure levels outside of the fumigation area, and therefore address risks to the environment.
- 7.44. An overview of the updates to the risk assessment in light of these requirements being known is provided in the updated Science Memorandum (EPA 2021).

Risks to aquatic organisms

- 7.45. The risks associated with the exposure of EDN to aquatic species was evaluated in the EPA Science Memorandum (EPA 2018d) and the Staff Report (EPA 2018c).
- 7.46. The following paragraphs were included in the July 2018 Science Memorandum (EPA 2018d) in relation to the aquatic risk assessment:

“Any risk to aquatic species from use of EDN is considered limited on the basis of low potential for exposure, especially under windy conditions that are expected to provide the mechanical turbulence to disperse the fumigant, and also the turbulent water conditions that appear to be unfavourable for partitioning. As such, based on the use pattern, it is considered that there is no exposure pathway between EDN and the aquatic environment.

On the basis that ethanedinitrile has the potential to be present over water bodies in the vicinity of fumigation sites, it would be prudent to ensure that fumigations are not conducted under still conditions that could result in an inversion, where it is more likely that EDN could move into water. As such, the following label restraint should be added:

- *Atmospheric conditions should be monitored and ethanedinitrile should not be vented under very low wind speed conditions (less than 5 km/h), or under inversion conditions.”*

- 7.47. Given the ventilation and monitoring requirements and other requirements set under the draft SWI related to fumigation requirements (WorkSafe 2021b), it is considered that that the initial label restraint is no longer necessary as the provisions laid out in the draft SWI would address the issue initially highlighted by reducing potential exposure. The applicant has also argued that very low wind speed conditions or inversion conditions would not typically occur in port locations where sea breezes are always expected (Draslovka 2020).
- 7.48. With the prescribed and proposed controls in place, the risk to aquatic organisms is considered negligible.

Risks to earthworms and other soil organisms

- 7.49. The risk to soil organisms is considered to be negligible as EDN will be used in an environment where soil organisms are unlikely to be present due to the high proportion of concrete and asphalt surfaces at industrial locations such as ports. However, the EPA notes that while ethanedinitrile has a Not Determined (“ND”) classification for soil toxicity, it is highly likely to be toxic to soil organisms, and has been approved in Australia as a soil fumigant. Therefore, it is expected that toxicity to soil organisms could occur if the use pattern is modified. The EPA has proposed an additional control stating that the substance must only be used as a fumigant for timber and logs for export under a sheet or in a shipping container, this will further mitigate exposure of soil organisms to a negligible level.

Risks to non-target plants

- 7.50. No changes relative to the initial Science Memorandum (EPA 2018d) and Staff Report (EPA 2018c) apply, and the risk to non-target plants is still considered to be negligible, as non-target plants are unlikely to be found in the surroundings of a port where EDN is used. Furthermore, EDN will quickly volatilise and dissipate in the atmosphere.

Risks to birds

- 7.51. There is a risk to birds from inhalation of EDN, either when the sheet is removed or through a leak during fumigation. This risk has not been fully assessed as there is no reliable estimate of exposure of birds to EDN during fumigation activities.
- 7.52. The Science Memorandum (EPA 2018d) and the Staff Report (EPA 2018c) included the following control:

- *“Fumigations conducted at port locations must be undertaken only at locations where water bird colonies are not known to exist.”*

7.53. It is considered that some of the risk associated with this data gap is mitigated by the fumigations occurring at ports, which are undesirable locations to most species of birds (except sea birds). In the response to Direction and Minute 10 (EPA 2020a) the applicant also provided some rationale as to why this control was not required (Draslovka 2020). Additionally, the EPA notes that the draft SWI related to fumigation (WorkSafe 2021b) sets a number of controls, such as ventilation requirements and obligations of the PCBU to monitor and enforce WES values in the affected area and the TEL outside of the buffer zone, that would limit potential exposure to birds. These measures are considered to also provide a level of protection to birds. Therefore, the addition of the above control is no longer considered necessary.

Risks to pollinators and non-target arthropods

7.54. It is considered highly likely that EDN will be toxic to bees or other terrestrial invertebrates as it is intended to kill insect pests in logs. Non-target terrestrial invertebrates, particularly native species, are unlikely to be found at port locations during EDN ventilation, and the likelihood of exposure is expected to be low, with the risks likely to be negligible with proposed controls in place. This conclusion is unchanged from the July 2018 Staff Report (EPA 2018c).

Ozone depleting potential (ODP)

7.55. Ethanedinitrile is not listed as an ozone depleting substance under the Montreal Protocol.

Global warming potential

7.56. No Global Warming Potential has been provided for EDN. There is uncertainty regarding the rate of degradation of ethanedinitrile in the atmosphere, and there is insufficient information to calculate the time-integrated radiative forcing of ethanedinitrile with respect to carbon dioxide. EDN is not listed as a greenhouse gas in the Climate Change Response Act 2002.

Environmental risk assessment summary

7.57. The EPA considers risks to the environment to be negligible provided that the use is restricted to the fumigation of logs and timber at port locations, under a sheet or in a shipping container and the draft SWI (s) take legal effect in their current form.

7.58. It is considered that the controls for wind speed restriction and bird colony locations proposed in the Science Memorandum (EPA 2018d) and the Staff Report (EPA 2018c) are no longer necessary as these are better addressed by the requirements suggested in the draft SWI related to fumigation (WorkSafe 2021b), and that these measures will further reduce exposure levels for non-target organisms outside of the treatment areas.

Summary of the Cultural Risk Assessment

- 7.59. Kaupapa Kura Taiao (KKT, the EPA's Māori Policy and Operations team) considered the potential impacts of EDN on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the Act in 2018. A cultural risk assessment (CRA) was summarised in and appended to the Staff Report (EPA 2018(c)).
- 7.60. KKT have considered the conclusion in the CRA - that potential risks of EDN to Māori interests are likely to be negligible in terms of Māori cultural beliefs and environmental frameworks - in light of the draft SWI (s) and proposed controls under the Act. These developments do not change the CRA's conclusion. It is important to note that there have not been substantial changes to the use pattern or application rates since the CRA was completed in 2018.
- 7.61. The hazard classifications specified in the CRA (2018 Staff Report, Appendix B, page 49) should now be read as:

Ngā kōmakatanga mōrearea (Hazard classifications)

Flammable gas - Category 1A

Acute inhalation toxicity - Category 2

Hazardous to the aquatic environment acute - Category 1

Hazardous to terrestrial environment - hazardous to soil organisms

Hazardous to terrestrial environment - hazardous to terrestrial vertebrates

Hazardous to terrestrial environment - hazardous to terrestrial invertebrates.

8. Assessment of risks to society, the community and the market economy

- 8.1. The risks to society, the community and the market economy were outlined in the Staff Report (EPA 2018c). These risks concerned exposure of EDN to the general public. The 2018 Staff Report (EPA 2018c) mentioned the potential for scrubbing and recapture of EDN, however, this control is no longer being considered based on the information gathered from WorkSafe and outlined in their draft SWI (s).
- 8.2. There are several other controls and requirements proposed by the EPA and in the draft SWI (s) produced by WorkSafe that will manage these risks. These controls will include a requirement that the concentration under a sheet or in a shipping container be below a certain level before ventilation can begin, and the application of a buffer zone for protecting the public, will manage the risk of the general public being exposed to unsafe levels of EDN. Thus, with

the proposed controls in place this is considered highly unlikely that the general public will be exposed to EDN, with the residual risk non-negligible but low in magnitude.

9. New Zealand's international obligations

- 9.1. The Staff Report (EPA 2018c) has previously addressed New Zealand's international obligations for EDN and noted that EDN is a proposed alternative to methyl bromide for the fumigation of logs and timber. Methyl bromide is classed as an ozone-depleting substance under the Montreal Protocol, and New Zealand has obligations to phase out, reduce and monitor substances that deplete the ozone layer. Any alternatives, such as EDN, that have the potential to reduce New Zealand's reliance on methyl bromide have the potential to help New Zealand meet its obligations under the Montreal Protocol.
- 9.2. This information remains unchanged and further information on New Zealand's international obligations can be found in the Staff Report (EPA 2018c).

10. Assessment of costs

- 10.1. The assessment of costs were considered in the Staff Report (EPA 2018c). In this report, it was indicated that existing fumigation hardware, such as that used by methyl bromide, could be repurposed for EDN without significant modification. Therefore, it is estimated that EDN fumigations could be conducted at similar cost to current methyl bromide fumigations. It was also noted that although monitors capable of measuring low levels of EDN would need to be purchased, the potential costs of using EDN were not likely to be significant in terms of their overall impact.
- 10.2. In the 2018 Staff Report (EPA 2018c), it noted that there was some uncertainty around the costs of scrubbing and recapture of EDN, however as WorkSafe no longer require the scrubbing and recapture of EDN this uncertainty has been negated.
- 10.3. It was also noted that there was uncertainty regarding the costs associated with the monitoring requirements that will apply to EDN, both monitoring the concentration of EDN in the environment and health monitoring. WorkSafe have produced two draft SWI (s) that outline requirements for monitoring EDN and workers' health (WorkSafe 2021b, WorkSafe 2021a), both of which will be the responsibility of the PCBU.

11. Assessment of benefits

- 11.1. The benefits of EDN were outlined in the Staff Report (EPA 2018c). These benefits are not considered to have changed since the report was released.

12. The effects of the substance being unavailable

- 12.1. If EDN were not available there would be fewer tools available for the phytosanitary treatment of forest products pre-export. This could have significant consequences for the forestry industry in New Zealand if it is unable to meet trading partners' phytosanitary requirements.

13. Uncertainties

- 13.1. Some uncertainties outlined in the Staff Report (EPA 2018c) remain, such as, potential uncertainty regarding whether the models used for the risk assessment reflect what will occur when EDN is used commercially at a port, and the appropriateness of this modelling to assess risks at smaller ports.
- 13.2. Some uncertainty also remains over the efficacy of EDN at temperatures below 10°C, however it should be noted that this has no impact on either the human health or environmental risk assessments of the substance.
- 13.3. There was some uncertainty on whether WorkSafe would require the scrubbing and recapture of EDN. This has been resolved and scrubbing and recapture will not be required by WorkSafe.
- 13.4. There was also uncertainty regarding the amount of ammonia present at the end of EDN fumigation and whether this poses a risk to workers or the environment. STIMBR commissioned Plant and Food Research to develop a protocol to identify which compounds are present in treated wood after log fumigations with EDN and to determine the potential compounds causing wood odour following EDN fumigations. While ammonia was not identified in the headspace above EDN-treated logs, a definitive answer on the possible compounds causing the post-fumigation smell associated with EDN fumigated logs could not be provided (report was submitted to the EPA on 21 August 2018).
- 13.5. With regards to the modelling at ports, WorkSafe commissioned a report on air dispersion modelling from Todoroski (Todoroski Air Sciences Property Limited 2019) which calculated the buffer zones required for EDN use and recommended restricting ventilation of EDN to daytime hours. This is reflected in draft SWI related to fumigation (WorkSafe 2021b) proposed by WorkSafe.
- 13.6. In the draft SWI related to fumigation (WorkSafe 2021b), WorkSafe propose that each fumigation must be continuously monitored by sampling tubes, though they have not specified the type of device to be used or how the PCBU is to ensure the monitoring of the TEL beyond the 50 m buffer zone. This is indicative of an outcomes-based measure rather than a prescriptive control and the EPA is comfortable that compliance with and enforcement of these requirements would be managed effectively.

14. Controls

14.1. The EPA considers that the prescribed controls would manage a number of the identified risks to human health and the environment. It is considered that the requirements identified in the draft SWI (s) (WorkSafe 2021b, WorkSafe 2021a) would allow for the identified risks to be mitigated to a negligible level for the uses covered by those draft SWI (s). In line with the proposed requirements of the draft SWI (s), the EPA proposes to set additional controls under Section 77 and Section 77A of the Act to adequately manage the remaining risks to human health and the environment..

Exposure limits

14.2. A Tolerable Exposure Limit (TEL) of 0.034 ppm on a 24 hour average basis is proposed by the EPA. This is equivalent to 0.072 mg ethanedinitrile/m³. This TEL value has been finalised in the joint expert witness statement (EPA 2018b) [in response to Direction and Minute 2 (EPA 2018f)].

14.3. The EPA is required to set acceptable daily exposure (ADE) and potential daily exposure (PDE) values for new active ingredients that may become present in food, drinking water or other environmental media. This is to allow the EPA or other government departments to set standards or guideline values for food, drinking water or other media where necessary. However, as ethanedinitrile is not expected to become present in food or drinking water ADE and PDE values have not been proposed.

14.4. The prescribed controls allow for Environmental Exposure Limits (EELs) to be set for any component in a substance. With the proposed controls in place, the risks to the environment are expected to be negligible. Therefore, no EEL values are proposed at this time.

14.5. WorkSafe New Zealand has proposed new Workplace Exposure Standard (WES) values for EDN:

- An average airborne concentration of 3 ppm (6.4 mg/m³) calculated over an 8 hour work period;
- A maximum airborne concentration of 5 ppm (10.6 mg/m³) at any time during that work period.

Additional controls and variations to prescribed controls – pre-hearing

14.6. Prior to the EDN hearing held in August 2018, there were a number of additional controls proposed by the EPA under section 77A of the Act, as well as requirements from WorkSafe to manage potential risks. These can be found in both the Science Memorandum (EPA 2018d) and EPA Staff Report (EPA 2018c).

14.7. During the EDN hearing adjournment, the applicant had the opportunity to further comment on the proposed controls for EDN (in a response to Direction and Minute 10). The applicant provided feedback on the controls and proposed some changes [(Draslovka 2020) summary in Table 4]:

Table 4: Suggested changes to controls proposed by applicant

Control	EPA's initial proposed control	Applicant's proposed control
Maximum application rate	The maximum application rate of this substance is 150 g of substance/m ³	The application rate of this substance is 120 g of substance/m ³
Use restriction	This substance must only be used as a fumigant for timber and logs for export under tarpaulins	This substance must only be used as a fumigant for timber and logs for export under a tarpaulin, in a container or a ship's hold.
Use restriction	Atmospheric conditions must be monitored and EDN must not be vented under very low wind speed conditions (less than 5 km/h) or under inversion conditions	The removal of the use and label control stating "Atmospheric conditions should be monitored and ethanedinitrile should not be vented under very low wind speed conditions (less than 5 km/h) or under inversion conditions."
Use restriction	Fumigations must be undertaken only at locations where water bird colonies are not known to exist	The removal the use restriction stating "Fumigations conducted at port locations must be undertaken only at locations where water bird colonies are not known to exist." Applicant proposes a permission control which would enable the EPA to request a site specific risk assessment from the users, including the location of, and species present of, nearby bird colonies and their distance to the treatment site, and how potential risks will be managed.

Control	EPA's initial proposed control	Applicant's proposed control
Buffer zone	EPA proposed the buffer zone of 20 m for workers and 120 for members of the public	The buffer zone for unprotected workers be set as 20 m and the buffer zone for the public be set 30 m (with an endpoint concentration of 700 ppm).
Adaptive management – buffer zone	-	The applicant proposes, after one full year or 1000 fumigations (whichever is the latter) that the EPA and WorkSafe consider the data in consultation with the industry's nominee, and, either confirm the buffer, or, if necessary, reset the maximum buffer zone distance (ie extend, or reduce the buffer) at 1 metre beyond which the TEL or the WES have not been exceeded.

14.8. The EPA acknowledges the proposed control changes from the applicant and has taken them under consideration.

Additional controls and variations to prescribed controls – during hearing adjournment

14.9. The following additional controls are proposed under section 77A of the Act to manage the risks of use of EDN.

Maximum application rate

14.10. The maximum application rate of EDN is 120 g EDN/m³ over 24 hours.

Use restriction

14.11. This substance must only be used as a fumigant for timber and logs for export under a sheet or in a shipping container.

14.12. Fumigations using ethanedinitrile (EDN) should not be carried out within 120 m of any sensitive site where the public may lawfully be present. Sensitive sites include schools, playgrounds, Early Childhood Centres (ECE), prisons or place of detention, hospitals or long-term care facilities where members of the public who may be unable to evacuate themselves could be present. The distance should be measured from the edge of the enclosed space.

Label

14.13. The maximum application rate and use restrictions must be included on the label for this substance.

Maximum Impurity

14.14. 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

14.15. The TEL set for ethanedinitrile is 0.034 ppm (0.072 mg/m³) calculated over a 24 hour average period.

Additional WorkSafe requirements – during hearing adjournment

14.16. There are a number of requirements that fall under the jurisdiction of WorkSafe [see WorkSafe's assessment (WorkSafe 2018) and draft SWI (s) (WorkSafe 2021b, WorkSafe 2021a) for these requirements].

14.17. During the EDN hearing adjournment, WorkSafe produced two draft SWI (s), '*Health and Safety at Work (Hazardous Substances—Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021*' (WorkSafe 2021b) and '*Health and Safety at Work (General Risk and Workplace Management—Exposure and Health Monitoring Requirements for*

Ethanedinitrile) *Safe Work Instrument 2021*' (WorkSafe 2021a), and have now been approved in principle. These draft SWI (s) outline a number of requirements for EDN, including:

- Health monitoring for workers;
- Definition of an affected area, to be determined, reviewed and adjusted if necessary by a PCBU, in which WES values (8-hour average of ceiling value) is or may be exceeded. Entry in that affected area is restricted;
- Definition of a buffer zone – an area extending outward in all directions from the perimeter of an enclosed space being fumigated to a distance of at least 50 metres;
- Entry restrictions into buffer zone;
- Fumigations using EDN to be carried out in an enclosed space (defined as the space under a sheet or in a shipping container);
- Air quality monitoring;
- Ventilation requirements, including the concentration of EDN in an enclosed space must be no more than 700 ppm prior to ventilation;
- Record keeping.

15. Overall evaluation and recommendation

- 15.1. The EPA considers that risks to human health from the use of EDN as a fumigant for logs and timber prior to export to be negligible when used in accordance with the controls and requirements proposed by the EPA and WorkSafe.
- 15.2. WorkSafe have now provided draft SWI (s) for the use of EDN. The assessment undertaken by the EPA has been based on the draft SWI (s) taking legal effect in their current form. The requirements outlined in these draft SWI (s), along with the controls proposed by the EPA, will help mitigate the risks to workers, member of the public, and the environment to a negligible level.
- 15.3. It is considered that EDN is not likely to pose significant potential risks and impacts on Māori interests if appropriate controls are assigned to EDN. Furthermore, the benefits of EDN outweigh its risks from a Māori perspective.
- 15.4. It is considered that there are potentially significant benefits associated with the approval of EDN. These have been assessed as having a high level of benefit.
- 15.5. Overall, it is considered that the potential benefits of the substance (EDN) outweigh the risks to the environment, if used in accordance with the appropriate controls and requirements. The risks of the substance to human health have been considered by the EPA as being negligible if proposed controls and requirements set by the EPA and WorkSafe are followed.

15.6. The EPA recommends approving EDN for import or manufacture under section 29 of the Act with the prescribed and additional controls listed in Appendix A, in line with the requirements of the draft SWI (s).

Appendix A: Proposed controls for EDN

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

Code	HSNO Act	Control
Application rate	Section 77A	The maximum application rate of this substance is 120 g of the substance/m ³ (over 24 hours)
Use restriction	Section 77A	<p>This substance must only be used as a fumigant for timber and logs for export under a sheet or in a shipping container.</p> <p>Fumigations using ethanedinitrile (EDN) should not be carried out within 120 m of any sensitive site where the public may lawfully be present. Sensitive sites include schools, playgrounds, Early Childhood Education (ECE) centres, prisons or place of detention, hospitals or long-term care facilities where members of the public who may be unable to evacuate themselves could be present. The distance should be measured from the perimeter of the enclosed space.</p>
Label	Section 77 variation to Labelling Notice	<p>The substance label must include the following statements, or words to the same effect:</p> <ul style="list-style-type: none"> This substance must only be used as a fumigant for timber and logs for export under a sheet or in a shipping container; Fumigations using the substance should not be carried out within 120 m of any sensitive site where the public may lawfully be present. Sensitive sites include schools, playgrounds, Early Childhood Education (ECE) centres, prisons or place of detention, hospitals or long-term care facilities where members of the public who may be unable to evacuate themselves could be present. <p>The application rate must be included on the label.</p>
Max impurity	Section 77A	<p>The following limit is set for the toxicologically relevant impurity in the active ingredient, ethanedinitrile, used to manufacture this substance:</p> <p>Hydrogen cyanide: 1% v/v maximum</p>
Tolerable exposure limit (TEL)	Section 77A	The TEL set for ethanedinitrile is 0.034 ppm (0.072 mg/m ³) calculated over a 24 hour average period.

HSW HS Requirements

Note: these controls are not set for the substance under this approval but apply in their own right under the HSW Act and HSW (HS) Regulations according to the classification of the substance. They are listed here for information purposes only.

Control code	Regulation	Control description	Extra information
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	The proposed PES: Average airborne concentration of 3 ppm (6.4 mg/m ³) calculated over an 8 hour work period; Maximum airborne concentration of 5 ppm (10.6 mg/m ³) at any time during that work period
HSW14	Part 14	Fumigants	
HSW15	Part 15	Gases under pressure	
HSW16	Part 16	Requirements for tank wagons and transportable containers	
HSW17	Part 17	Requirements for stationary container systems	
HSW19	Part 19	Tracking hazardous substances	
SWI-14	N/A	Requirements for Specified Fumigants	

Control code	Regulation	Control description	Extra information
SWI	N/A	Exposure and Health Monitoring Requirements for Ethanedinitrile	

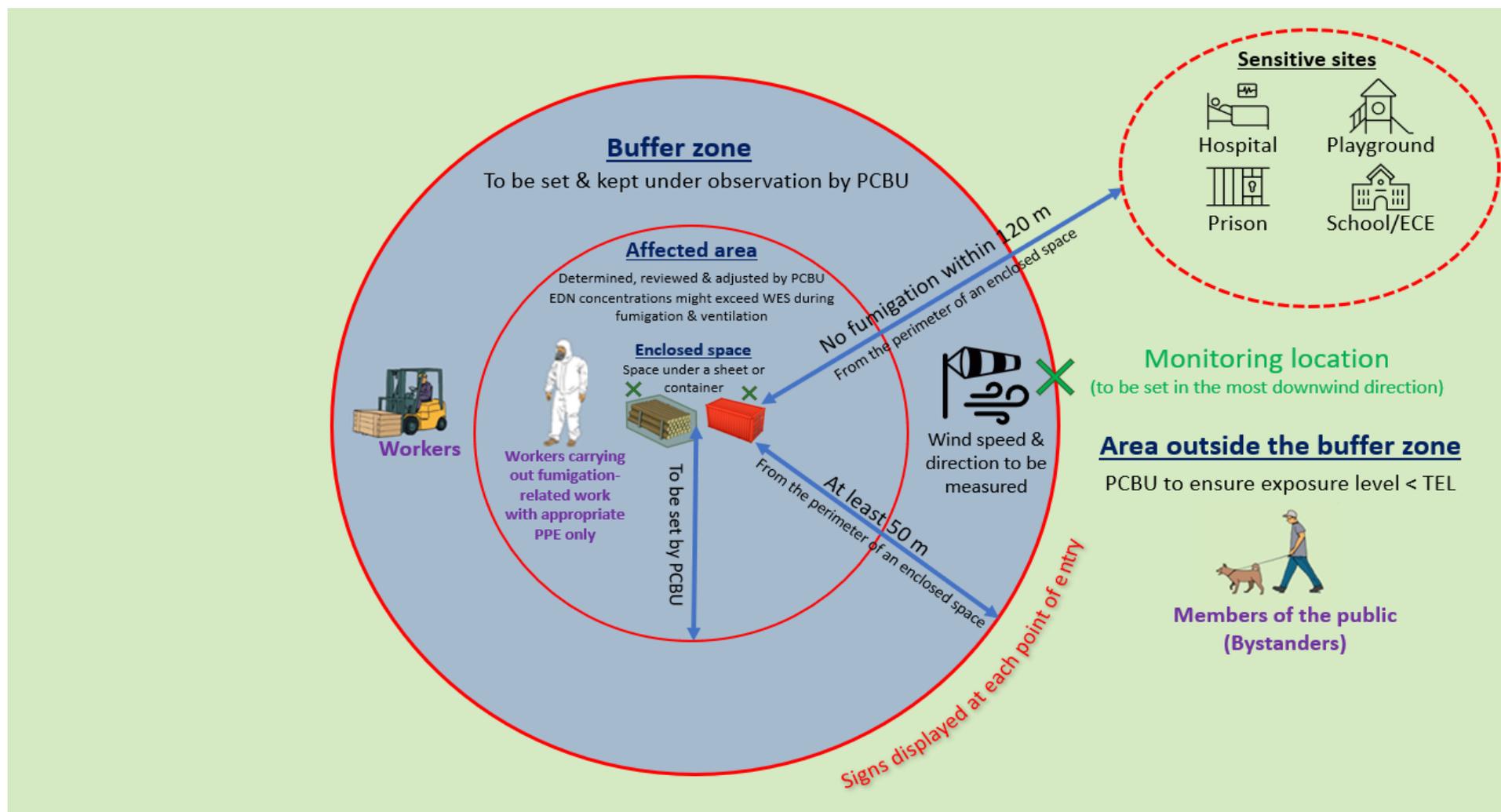


Figure 1: simplified representation of controls and measures applicable to EDN fumigation operations (distances not to scale)

Appendix B: Full list of submitters

The full list of submitters can be found in the Staff Report (EPA 2018c). No additional submitters have been added to this list.

Appendix C: list of references

Draslovka (2020). Draslovka's reponse to the WGT010 Direction and Minute of the Decision-making Committee - 18 February 2020 73.

EPA (2018a). APP202804 - Ethanedinitrile - Expert Conferencing Joint Witness Statement - Topic: Air Concentration Dispersion Modelling: 7.

EPA (2018b). APP202804 - Ethanedinitrile - Expert Conferencing Joint Witness Statement - Topic: Tolerable Exposure Limits: 12.

EPA (2018c). EPA Staff Report - Application for approval to import EDN for release: 65.

EPA (2018d). Science Memo - APP202804 - EDN: 121.

EPA (2018e). WGT01 - Direction & Minute of the Decision-Making Committee - Regards Application APP202804; to import for release EDN (Ethanedinitrile) . a fumigant for use on timber/logs under commercial conditions: 1.

EPA (2018f). WGT02 - Directions and Minutes of the Decision-Making Committee - Regards Application APP202804; to import for release EDN (Ethanedinitrile) . a fumigant for use on timber/logs under commercial conditions: 3.

EPA (2018g). WGT03 - Directions and Minutes of the Decision-Making Committee - Regards Application APP202804; to import for release EDN (Ethanedinitrile) . a fumigant for use on timber/logs under commercial conditions: 2.

EPA (2018h). WGT04 - Directions and Minutes of the Decision-Making Committee - Regards Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions: 1.

EPA (2018i). WGT05 - Directions and Minutes of the Decision-Making Committee - Regards Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions: 5.

EPA (2019a). Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions - WGT007: Direction and Minute of the Decision-Making Committee - 05 April 2019: 5.

EPA (2019b). Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions - WGT008: Direction and Minute of the Decision-Making Committee - 14 June 2019: 4.

EPA (2019c). Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions - WGT009: Direction and Minute of the Decision-Making Committee - 11 December 2019: 3.

EPA (2019d). EPA Addendum to the Staff Report - Application for approval to import EDN for release - APP202804: 38.

EPA (2019e). WGT06 - Directions and Minutes of the Decision-Making Committee - Regards Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions: 3.

EPA (2020a). Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions - WGT010: Direction and Minute of the Decision-Making Committee - 18 February 2020: 3.

EPA (2020b). Application APP202804; to import EDN (Ethanedinitrile), a fumigant for use on timber/logs under commercial conditions - WGT011: Direction and Minute of the Decision-Making Committee - 31 March 2020: 2.

EPA (2021). Updated Science Memo - APP202804 - EDN: 45.

Graham, B. (2018). Advice to the EPA following expert conferencing on EDN air concentration dispersion modelling: 1.

Graham Environmental Consulting Limited (2018). Review of an Assessment of Ethanedinitrile for Log Fumigation - Report to the Environmental Protection Authority: 13.

Sullivan Environmental Consulting Incorporated (2018a). Air Concentration Dispersion Modeling Assessment of Ethane dinitrile (EDN) Concentrations in Tauranga Port, New Zealand.

Sullivan Environmental Consulting Incorporated (2018b). Air Concentration Dispersion Modeling Assessment of Ethanedinitrile (EDN) Concentrations in Tauranga Port, New Zealand.

Sullivan Environmental Consulting Incorporated (2020). Dispersion Modeling of Ethanedinitrile Airborne Concentrations Associated with Timber Fumigation at the Port of Tauranga, New Zealand.

Todoroski Air Sciences Property Limited (2019). Air Dispersion Modelling - Ethanedinitrile: 97.

WorkSafe (2018). APP202804 - WORKSAFE ADVICE - WorkSafe advice on the application for approval to import and use ethanedinitrile as a phytosanitary treatment of wood products: 22.

WorkSafe (2020a). Public consultation - Safe Work Instrument Specifying Requirements for Using Ethanedinitrile (EDN): 16.

WorkSafe (2020b). Targeted consultation on revised proposals - Safe Work Instrument Specifying Requirements for Using Ethanedinitrile (EDN): 10.

WorkSafe (2021a). Health and Safety at Work (General Risk and Workplace Management - Exposure and Health Monitoring Requirements for Ethanedinitrile) Safe Work Instrument 2021 - DRAFT: 2.

WorkSafe (2021b). Health and Safety at Work (Hazardous Substances - Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021 - DRAFT: 15.