



Environmental  
Protection Authority  
*Te Mana Rauhi Taiao*

---

## UPDATED SCIENCE MEMO

---

### APP202804 – EDN

Substance database ID: 49330

CAS number 460-19-5

August 2021

## Executive Summary

This science memo is an updated version of the science memo generated in July 2018 (EPA 2018d) by the EPA.

Ethanedinitrile (EDN) is a compressed gas containing the active ingredient ethanedinitrile at a concentration of 1000 g/kg, at a minimum purity of 95%.

The active ingredient is new to New Zealand. The applicant seeks to have EDN approved for use as a fumigant for insect pests, nematodes and fungi in timber logs for export.

The active substance ethanedinitrile is approved in Australia, Malaysia and South Korea as a fumigant.

The proposed classification for EDN is Flammable Gas Category 1A, Gases under pressure Liquefied Gas, Acute inhalation category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1.

It is considered there is potential for significant exposure to people and the environment during the use phase of the lifecycle of EDN. The EPA has therefore undertaken quantitative risk assessments to assess the likely exposures to the substance under the use conditions proposed by the applicant. The initial risk assessment conducted for EDN is detailed in the July 2018 Science Memorandum (EPA 2018d). This updated science memo covers revisions to the risk assessment in light of the information that has become available since the July 2018 Science Memorandum was finalised, with a focus on the requirements of two draft SWIs approved in principle [(WorkSafe 2021b, WorkSafe 2021a, together the draft SWI (s))] generated by WorkSafe New Zealand ("WorkSafe"). 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.

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 bystanders in case of exceedance of the TELs outside the buffer zone determined by the '*Requirement for Specified Fumigants*' draft SWI (WorkSafe 2021b).

It is considered that the requirements of the draft SWI (s), are sufficient to reduce exposure levels for the uses covered by '*Requirement for Specified Fumigants*' draft SWI (WorkSafe 2021b) to a degree indicating that risks to the environment can be considered negligible.

Overall, it is considered that the risks to human health and the environment arising from the use of EDN are negligible with the requirements of the draft SWI (s) and the additional HSNO controls suggested.

## Standard terms and abbreviations

Abbreviation	Definition
ai	active ingredient
CAS #	Chemical Abstract Service Registry Number
DMC	Decision-Making Committee
EC	European Commission
EC <sub>50</sub>	Effective Concentration at which an observable adverse effect is caused in 50 % of the test organisms
g	Grams
GAP	Good Agricultural Practice
Kg	Kilogram
L	Litres
LC <sub>50</sub>	Lethal Concentration that causes 50% mortality
LD <sub>50</sub>	Lethal Dose that causes 50% mortality
M	Molar
m <sup>3</sup>	cubic metre
mg	Milligram
µg	Microgram
mol	mole(s)
PCBU	Person Conducting a Business or Undertaking
PES	Prescribed Exposure Standard
P <sub>ow</sub>	Partition coefficient between n-octanol and water
PPE	Personal Protective Equipment
ppm	parts per million (10 <sup>-6</sup> )
RQ	Risk Quotient
SWI	Safe Work Instrument
WES	Workplace exposure standard

## Table of Contents

<b>Executive Summary</b> .....	<b>2</b>
<b>Table of Contents</b> .....	<b>4</b>
<b>1. Introduction/Background</b> .....	<b>6</b>
<b>2. Hazardous properties</b> .....	<b>7</b>
<b>3. Risk assessment context</b> .....	<b>9</b>
<b>4. Human health risk assessment</b> .....	<b>9</b>
<b>5. Environmental risk assessment summary</b> .....	<b>10</b>
<b>6. Proposed controls</b> .....	<b>10</b>
<b>Appendix A: Identity of the active ingredient, use pattern and mode of action</b> .....	<b>11</b>
Identity of the active ingredient and metabolites .....	11
Regulatory status.....	12
Use pattern and mode of action .....	15
<b>Appendix B: Physico-chemical properties of ethanedinitrile</b> .....	<b>17</b>
<b>Appendix C: Mammalian toxicology</b> .....	<b>19</b>
<b>Appendix D: Environmental fate</b> .....	<b>20</b>
<b>Appendix E: Ecotoxicity</b> .....	<b>21</b>
Aquatic ecotoxicity.....	21
Ecotoxicity in soil .....	21
Ecotoxicity to terrestrial vertebrates .....	21
Ecotoxicity to bees and other terrestrial invertebrates .....	21
<b>Appendix F: Hazard classification of ethanedinitrile</b> .....	<b>22</b>
<b>Appendix G: Human health risk assessment</b> .....	<b>27</b>
Introduction and overview of the changes.....	27
Workplace Exposure Standards (WES) .....	32
Tolerable Exposure Limit (TEL).....	32
Maximum application rate .....	32
Uses envisaged .....	32
Release concentration.....	32
Exposure Assessment - Modelling .....	32
Exposure Assessment – Field studies/Monitoring .....	34
Risks to workers .....	34

Risks to bystanders or the general public ..... 36

Overall conclusions ..... 38

**Appendix H: Environmental risk assessment ..... 41**

    Aquatic risk assessment..... 41

    Terrestrial risk assessment ..... 42

    Conclusions of the ecological risk assessment..... 42

**Appendix I: Proposed controls ..... 43**

**Appendix J: References..... 44**

## 1. Introduction/Background

1. This application is to manufacture and/or import the substance EDN, containing 1000 g/kg ethanedinitrile (also known as oxalonitrile or cyanogen; CAS number 460-19-5) at a minimum purity of 95%.
2. Although initially intended for a use rate of 150 g/m<sup>3</sup> for 24 hours, the application rate has been revised by the applicant to a rate of 120 g/m<sup>3</sup> for 24 hours applied to logs under a sheet<sup>1</sup>, in a fumigation chamber, in a shipping container or a ship hold. Further details are available in Appendix A (Table 7).
3. A Science Memorandum (EPA 2018d) and a staff advice report (EPA 2018c) were generated for this application in July 2018. The science memo focussed on determining hazards, classification and associated human and environmental risks while the EPA Staff advice 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).
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 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 Regulations (GRWM). Two draft SWIs have been approved in principle (WorkSafe 2021b, WorkSafe 2021a). 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.
5. This updated science memo aims at highlighting the changes occurring following events related to the application. Most notably this includes the conclusions from the two rounds of joint expert conferencing (EPA 2018b, EPA 2018a), the various Decision-Making Committee (DMC) Direction and Minutes (EPA 2018e, EPA 2018f, EPA 2018g, EPA 2018h, EPA 2018i, EPA 2019e, EPA 2019a, EPA 2019b, EPA 2019c, EPA 2020a, EPA 2020b) and associated documents, and the content of the two approved-in-principle, draft Safe Work Instruments (draft SWI (s)) by WorkSafe (WorkSafe 2020b, WorkSafe 2020a, WorkSafe 2021b, WorkSafe 2021a).
6. The information sent by the applicant in response to DMC Direction and Minute 10 has also been considered (Draslovka 2020).
7. More details around the changes and additional documents generated since the 2018 hearing are available in the updated staff report (EPA 2021).

---

<sup>1</sup> Also referred to as application under tarpaulins. Tarpaulin is considered an equivalent term to sheet, being defined as a heavy-duty cover that has a low mass transfer coefficient for EDN and is waterproof and impenetrable.

8. The July 2018 Science Memorandum (EPA 2018d) is referred to and cross-referenced where relevant throughout this document.
9. More details about the use pattern of EDN and the regulatory status of ethanedinitrile can be found in Appendix A.
10. Physical and Chemical properties of EDN can be found in Appendix B.
11. Mammalian toxicological properties of EDN are reported in Appendix C. There are minimal changes to this section compared to the July 2018 Science Memorandum (EPA 2018d).
12. Environmental Fate properties of EDN have been reported in Appendix D.
13. Ecotoxicological properties of EDN have been reported in Appendix E.
14. Hazard properties and classification determination of EDN derived from its properties can be found under 2. Hazardous properties and Appendix F.
15. An updated human health risk assessment is provided in Appendix G. A summary is provided under section 4.
16. An updated environmental risk assessment and this is detailed in Appendix H. A summary is provided under section 6.
17. A list of suggested controls is provided in Appendix I.
18. A list of references is provided in Appendix J.

## 2. Hazardous properties

19. The updated hazard classifications<sup>2</sup> proposed for EDN are outlined in Table 1 and discussed in the respective appendices. Full details are included in Table 9 in Appendix F.

**Table 1: Proposed classification for EDN**

Hazard endpoint	EDN
Flammable gas	Category 1A
Gases under pressure	Liquefied gas
Acute inhalation toxicity	Category 2
Aquatic ecotoxicity - acute	Category 1; M-factor 10
Aquatic ecotoxicity - chronic	Category 1; M-factor 10

<sup>2</sup> According to GHS principles, adopted as the New Zealand classification system for hazardous substance on 30 April 2021

## Physical/chemical hazard classifications

### *Flammable gas, gases under pressure*

20. The lower and upper explosion limit reported for ethanedinitrile are 6 % and 32% by volume in air respectively. The original application form reported  $6.45 \pm 0.8$  to  $14.3 \pm 0.8$  vol.%. This meets the criteria for flammable gas Category 1A as the lower limit is less than 13% and the range is greater than 12 percentage points.
21. EDN is considered a liquefied gas under pressure (vapour pressure 5.16 bar at 21.1°C, see application form). This meets the classification criteria for gas under pressure.

## Toxicity hazard classifications

22. Ethanedinitrile is of relatively high acute toxicity to mammals and should be classified as acute inhalation toxicity Category 2. No evidence of dermal toxicity or dermal irritation was observed in acute exposure studies to the gas. Cyanide and cyanide compounds are not known to induce contact sensitisation. Ethanedinitrile is not classified as an eye irritant even though it induces an "irritation" sensation response to the eyes (and throat) in humans at ~16 ppm. The mechanism of this effect is through the direct stimulation of sensory nerves as opposed to direct tissue damage which is the basis for an eye irritation Category 2 classification. Results of genotoxicity studies conducted on ethanedinitrile were positive but deemed to likely be false positives associated with cellular toxicity due to CN<sup>-</sup> formation. Cyanide compounds are not considered to be genotoxic, carcinogenic, or reproductive/developmental toxicants.

## Ecotoxicity hazard classifications

### *Aquatic toxicity (acute and chronic)*

23. Ethanedinitrile is very ecotoxic in the aquatic environment and triggers a hazardous to the aquatic environment acute Category 1 classification. This classification is based on read-across test data from sodium cyanide (as per the Simon (2011) and Wenzel (2011) studies summarised in Tables 54 and 55, Appendix J of the 2018 Science Memorandum of EDN. Ethanedinitrile also triggers a hazardous to the aquatic environment chronic Category 1 classification, based on lack of clear evidence for ready biodegradability.

### *Soil toxicity*

24. The applicant proposes that ethanedinitrile is not toxic to soil organisms. 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.

#### *Terrestrial vertebrate toxicity*

25. 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.

#### *Terrestrial invertebrate toxicity*

26. 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 CN<sup>-</sup>, and is likely to trigger a hazardous to terrestrial invertebrates classification if the test data existed.

### 3. Risk assessment context

27. It is considered there is potential for significant exposure to people and the environment during the use phase of the lifecycle of EDN. The EPA has therefore undertaken quantitative risk assessments to assess the likely exposures to the substance under the use conditions proposed by the applicant. The initial risk assessment conducted for EDN is summarized in the July 2018 Science Memorandum (EPA 2018d). This reports covers the updates to the risk assessment with a focus on the requirements of the draft approved in principle SWI (s) generated by WorkSafe (WorkSafe 2021b, WorkSafe 2021a).
28. During the importation, manufacture, transportation, storage and disposal of EDN, the EPA considers that the proposed controls and other legislative requirements will sufficiently mitigate risks to a negligible level. This assessment takes into account the existing HSNO requirements around packaging, identification and disposal of hazardous substances. In addition, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand’s health and safety at work requirements all have provisions for the safe management of hazardous substances.

### 4. Human health risk assessment

29. WorkSafe is responsible for overseeing the Health and Safety at Work Act 2015 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 bystanders in case of exceedance of the TELs outside the buffer zone determined by the 'Requirement for Specified Fumigants' draft SWI (WorkSafe 2021b).

30. EDN contains two impurities of toxicological concern: hydrogen cyanide (CAS 74-90-8) 0.5% and carbon dioxide (CAS 124-38-9) 2.0%. Although these gases are highly toxic, the risk they present is of low significance given the higher concentration and high acute toxicity of EDN.

## 5. Environmental risk assessment summary

31. It is considered that with the draft SWI (s) (WorkSafe 2021b, WorkSafe 2021a), that risks to the environment would be considered negligible based on limited exposure.
32. 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. It should be noted that in order for any controls to be amended, the substance would need to be reassessed in accordance with the provisions of the Act.

## 6. Proposed controls

33. 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) approved in principle (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 HSNO Act to adequately manage the remaining risks to human health and the environment:

### *Proposed additional controls under HSNO*

- The following limit is set for toxicologically relevant impurities in the active ingredient ethanedinitrile used to manufacture this substance: Hydrogen cyanide: 1% v/v maximum
- The maximum application rate of this substance is 120 g of substance/m<sup>3</sup> over 24 hours
- A Tolerable Exposure Limit (TEL) of 0.034 ppm (=0.072 mg/m<sup>3</sup>) as a 24-hour average
- The substance can only be used for timber treatment fumigation under a sheet or in a shipping container.
- 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.

## Appendix A: Identity of the active ingredient, use pattern and mode of action

### Identity of the active ingredient and metabolites

General data on the active ingredient ethanedinitrile are provided in Table 2.

**Table 2: Identification of the active ingredient ethanedinitrile**

IUPAC name	Oxalonitrile (synonyms: Ethanedinitrile, Cyanogen)
CA name	Ethanedinitrile
Molecular formula	C <sub>2</sub> N <sub>2</sub>
CAS Number	460-19-5
Molecular weight (g/mol)	52.036
Structural formula	N ≡ C – C ≡ N
Purity	Min. 95% w/w The APVMA specifies a minimum purity of 860 g/kg minimum (APVMA 2017)
Significant impurities/additives	hydrogen cyanide (CAS 74-90-8): 0.5% (v/v); carbon dioxide (CAS 124-38-9): 2.0% (v/v) APVMA: hydrogen cyanide (50 g/kg maximum) and water 0.1 g/kg maximum (APVMA 2017)
Other international classification & labelling	<p><b>EU: Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)</b>            Flam. Gas 1; H220            Press. Gas            Acute Tox. 3; H331 (toxic if inhaled)            Aquatic Acute 1; H400            Aquatic Chronic 1; H410</p> <p><b>Safe Work Australia classification:</b>            Flam. Gas 1; H220            Press. Gas            Acute Tox. 3; H331 (toxic if inhaled)            Aquatic Acute 1; H400            Aquatic Chronic 1; H410</p> <p><b>Japan classification NITE (National Institute of Technology and Evaluation) (National Institute of Technology and Evaluation 2006)</b>            Flam. Gas 1; H220            Press. Gas; H280            Acute Tox. 2; H330 (Fatal if inhaled)            Eye irritation Cat 2A-2B; H319            STOT-SE Cat. 1; H370 (central nervous system)</p>

---

	STOT-SE Cat. 3; H335 (respiratory tract irritation) STOT-RE Cat. 2; H373 (nervous system) <sup>3</sup>
--	---

---

## Regulatory status

The regulatory status of ethanedinitrile in New Zealand and overseas is summarised in Table 3 to Table 6 below.

---

<sup>3</sup> No classification could be derived for aquatic toxicity

Table 3: Regulatory status of ethanedinitrile in New Zealand and Australia

Jurisdiction	New Zealand		Australia
Legislation	HSNO Act	ACVM Act	Agvet Code
Status	<b><u>Not approved</u></b> containment approvals granted	<b><u>Not approved</u></b>	<b><u>Approved in 2013</u></b> (Mixed function pesticide)

Table 4: Regulatory status of ethanedinitrile in the European Union and Japan

Jurisdiction	European Union		Japan
Legislation	Plant protection products Regulation 1107/2009	Biocidal products Regulation 582/2012	Agricultural Chemical Regulation Act
Status	<b><u>Not approved</u></b>	<b><u>Not approved</u></b>	<b><u>Not listed</u></b>

Table 5: Regulatory status of ethanedinitrile in North America

Jurisdiction	United States	Canada
Legislation	FIFRA	Pest Control Products Act
Status	<b><u>Not approved</u></b> Application received in March 2021 as a preventive wood preservative treatment (docket number: EPA-HQ-OPP-2021-0071)	<b><u>Not approved</u></b>

**Table 6: Regulatory status of ethanedinitrile in other jurisdictions**

Jurisdiction	South Korea	Malaysia	Russia
Legislation	Pesticide Control Act	Pesticides Act	
Status	<b><u>Approved in April 2019</u></b> Chemical	<b><u>Approved in December 2020</u></b> Fumigant	<b><u>Not approved</u></b> Application under review

In New Zealand, ethanedinitrile is not approved under the HSNO Act, although containment approvals have been granted (HSC100070, HSC100135 and HSC100191). HSC100191 was approved in 2019 and expires in February 2022. There is no approval of ethanedinitrile under the ACVM Act.

In Australia, ethanedinitrile is approved as a mixed function pesticide. This covers use for the fumigation of timber (Sterigas 1000™ fumigant) and strawberries (EDN Fumigas®) (see APVMA Product number P60096). The applicant has indicated that the approval of Sterigas is currently under review in Australia. The approval for timber treatment is at a rate of 50 g/m<sup>3</sup> for 6 hours exposure (fungi) and 50 g/m<sup>3</sup> for 10 hours exposure (insect pests of timber)

In the EU, ethanedinitrile is neither approved as a plant protection product under Regulation 1107/2009 or as a biocidal product under Regulation 582/2012. The applicant has indicated that they are in the process of submission in Czech Republic and that a critical use exemption was granted in 2018 in Europe as a sanitary treatment in the salvage harvesting of Norway spruce forests following attack by two bark beetle species (Draslovka 2020).

In Japan, ethanedinitrile is not included as an approved active ingredient on the list published by Food and Agricultural Materials Inspection Centre (FAMIC) on their website.

In the United States, ethanedinitrile is not approved. An application under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has been made in 2020 and received in 2021 [see registration docket (EPA-HQ-OPP-2021-0071)].

In Canada, ethanedinitrile is not approved under the Pest Control Products Act. The applicant has indicated that they are preparing for submission.

Ethanedinitrile was approved in South Korea in April 2019 under the tradename Sterigas (registration 96-Insecticide-45) for a rate of 50 g/m<sup>3</sup> for 24 hours. Ethanedinitrile was approved in Malaysia<sup>4</sup> in December 2020 under the tradename EDN for a rate of 50 g/m<sup>3</sup> for 10 hours. The applicant has indicated that evaluation is in progress in Russia with an application rate of 50 g/m<sup>3</sup> for 10 hours.

<sup>4</sup> <http://www.portal.doa.gov.my/racunberdaftar/welcome/detail/3772>

## Use pattern and mode of action

### Use pattern

The applicant seeks approval for the use of EDN, which contains the active ingredient ethanedinitrile at a concentration of 1000 g/kg (minimum purity 95%). EDN is proposed as a fumigant for the control of a wide range of wood insects, nematodes and fungi in timber logs to be exported out of New Zealand.

EDN will be imported in the form of a liquefied gas under pressure in 73L cylinders. The applicant seeks to have EDN approved for application as a fumigant under a sheet, in a fumigation chamber (or similar structure) on shore, in a shipping container, and in a ship's hold.

A maximum application rate of 120 g/m<sup>3</sup> of EDN for 24 hours is now proposed by the applicant [an application rate of 150 g/m<sup>3</sup> for 24 hours was considered in the July 2018 Science Memorandum (EPA 2018d)]. An updated and simplified use table is presented in Table 7.

### Mode of action

The mode of action of ethanedinitrile is described in the July 2018 Science Memorandum (EPA 2018d).

**Table 7: Updated and simplified list of intended uses for EDN**

Crop and/or situation (a)	Pests or group of pests controlled (b)	Mixture		Application	Maximum application rate per treatment	Remarks (h)	
		Type (c-e)	Conc. of ai (g/kg)	Method and kind (f-g)	g/m <sup>3</sup> min max		
Timber logs fumigation	Insect pests and pathogens on timber and logs	Gas	1000 g/kg (min 950 g/kg)	Directly applying EDN from the cylinder	120	24 hours treatment period equal to or above 10°C	
							under sheet
							in shipping container
							chamber or similar structures
	in ship's hold						

a Where relevant, the use situation should be described (e.g. fumigation of soil)

b e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds

c e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

d CropLife international, 2008. Technical Monograph no 2, 6th edition. Catalogue of pesticide formulation types and international coding system

e All abbreviations used must be explained

f Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, aerial, etc

g Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated. If spraying include droplet size spectrum,

h Remarks may include: Extent of use/economic importance/restrictions

## Appendix B: Physico-chemical properties of ethanedinitrile

The physico-chemical properties of ethanedinitrile are listed in Table 8.

**Table 8: Physical and chemical properties of ethanedinitrile**

Property	Reference	
Colour	Colourless	Application form
Physical state at 20°C and 1013 hPa	Gas	Application form
Melting point	-27.8°C at 101.325 kPa	Lide, D.R. CRC Handbook of Chemistry and Physics 88th Edition 2007-2008. CRC Press, Taylor & Francis, Boca Raton, FL 2007, p. 3-124
Boiling Point	-21.1°C at 101.325 kPa	Lide, D.R. CRC Handbook of Chemistry and Physics 88th Edition 2007-2008. CRC Press, Taylor & Francis, Boca Raton, FL 2007, p. 3-124
Odour Threshold	500 mg/m <sup>3</sup> (~235 ppm)	Ruth JH; Am Ind Hyg Assoc J 47: A-142-51 (1986)
Vapour density	1.8 (Air = 1)	National Fire Protection Guide. Fire Protection Guide on Hazardous Materials. 10th ed. Quincy, MA: National Fire Protection Association, 1991., p. 325M-29
Flash point	NA	Ethanedinitrile is a gas under normal conditions, the flashpoint is therefore not defined
Flammability	6 – 32 vol.% in air at 20°C and 101.3 kPa	APVMA approval summary National Fire Protection Guide. Fire Protection Guide on Hazardous Materials. 10th ed. Quincy, MA: National Fire Protection Association, 1991., p. 325M-29
	6.45 ± 0.8 -14.3 ± 0.8 (v/v)	Application form
Auto Flammability	Self-ignition temperature of ethanedinitrile is 850°C	Reach registration information.
Vapour pressure	520 kPa (21°C), 570 kPa (25°C)	Application form
Water Solubility (20°C)	9.75 g/L	Application form and Maxa, I.D. Physicochemical properties of cyanogen (EDN). University of Chemistry and Technology, Prague. 2016.
Log Pow	0.07	Application form

## Physical/chemical hazard classifications

### *Flammability, gases*

The lower and upper explosion limit reported for ethanedinitrile are 6 % and 32% by volume in air respectively. The original application form reported  $6.45 \pm 0.8$  to  $14.3 \pm 0.8$  vol.%

This meets the criteria for flammable gas Category 1A as the lower limit is less than 13% and the range is greater than 12 percentage points.

The self-ignition temperature for ethanedinitrile is 850°C and thus does not meet the definition of a pyrophoric gas. Ethanedinitrile is also stable under standard conditions. The classification can however not be downgraded to flammable gas Cat 1B as the lower flammability limit is not greater than 6% in air and no information on burning velocity is available. Ethanedinitrile is proposed to classify as flammable gas cat. 1A accordingly.

### *Gases under pressure*

EDN is present as a liquefied gas under pressure (vapour pressure 5.16 bar at 21.1°C, see application form). This meets the classification criteria for gas under pressure.

EDN does not trigger any other classification for physical hazards

## Appendix C: Mammalian toxicology

There are no changes to the mammalian toxicology information being provided. The same dataset has been used to derive the classifications under the GHS classification system as used to derive the previously applicable HNSO classification system. The conclusions presented in Appendix F of the July 2018 Science Memorandum (EPA 2018d) for EDN remain applicable. A summary of the human health classification for EDN is presented in Appendix F.

## Appendix D: Environmental fate

There are no changes to the Environmental Fate information being provided. The same dataset has been used to derive the classifications under the GHS classification system as used to derive the previously applicable HNSO classification system. The conclusions presented in Appendix F of the July 2018 Science Memorandum (EPA 2018d) for EDN remain applicable. However, a more detailed discussion on ready biodegradability is included below for classification purposes:

### **Position on ready biodegradability:**

Information on the potential for ready biodegradability of ethanedinitrile is inconclusive, as no test data are available. Ethanedinitrile dissociates by hydrolysis into hydrogen cyanide and cyanic acid. Although there is indication that hydrogen cyanide can dissipate quickly in the environment, it is considered that the information available does not allow for a clear conclusion to be drawn.

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.

This position is in line with the current applicable classification in the EU (aquatic chronic 1); see Table 2.

## Appendix E: Ecotoxicity

No new test data have been made available. The same data have been reviewed to derive classification according to GHS rules. The information as presented in the original July 2018 Science Memorandum (EPA 2018d) remains applicable.

The following section discusses how the classification for EDN under GHS rules have been derived.

### Aquatic ecotoxicity

Based on a 48-hour  $EC_{50}$  value of 12.4  $\mu\text{g}$  free CN/L to *Chironomus riparius*, the active ingredient ethanedinitrile is very toxic in the aquatic environment and triggers an acute aquatic category 1 classification. In the absence of information on the chronic toxicity and biodegradability, ethanedinitrile is also proposed to be classified as aquatic chronic category 1. This position is in line with the currently applicable EU harmonized classification (see Table 2).

### Ecotoxicity in soil

No reliable test data are available to determine ecotoxicity soil classification. It is noted that ethanedinitrile is registered in Australia as a soil fumigant against a full range of organisms including various micro-organisms, nematodes and weeds as a pre-plant treatment. Although the classification is proposed to be Not Determined (ND), it is expected that ethanedinitrile would be toxic to soil organisms.

### Ecotoxicity to terrestrial vertebrates

No changes apply and ethanedinitrile does not trigger classification.

### Ecotoxicity to bees and other terrestrial invertebrates

No changes apply and ethanedinitrile does not trigger classification, although given its use pattern as a fumigant targeting insects, toxicity would be expected.

## Appendix F: Hazard classification of ethanedinitrile

The updated hazard classification of ethanedinitrile is listed in Table 9.

**Table 9: Applicant and EPA classification of ethanedinitrile**

Hazard Class/Subclass	Classification		Method of classification		Remarks
	Applicant	EPA	Test Results	Read across	
<b><u>Physical/Chemical properties</u></b>					
<u>Explosives (class 1)</u>	NA	No	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Flammable gases</u>	2.1.1 A (Category 1)	Category 1A	<input type="checkbox"/>	<input type="checkbox"/>	The lower and upper explosion limit reported for ethanedinitrile are 6 % and 32% by volume in air respectively.
<u>Aerosols</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Oxidising gases</u>	No	No	<input type="checkbox"/>	<input type="checkbox"/>	Not an oxidising agent.
<u>Gases under pressure</u>	-	Liquefied gas	<input type="checkbox"/>	<input type="checkbox"/>	Liquefied gas vapour pressure 5.16 bar at 21.1°C as per application form
<u>Flammable liquids</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a liquid
<u>Flammable solids</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a solid
<u>Self-reactive substances and mixtures</u>	-	No	<input type="checkbox"/>	<input type="checkbox"/>	
<u>Pyrophoric liquids</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a solid
<u>Pyrophoric solids</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a liquid

Hazard Class/Subclass	Classification		Method of classification			Remarks
	Applicant	EPA	Test Results	Read across		
<u>Self-heating substances and mixtures</u>	-	ND	<input type="checkbox"/>	<input type="checkbox"/>		
<u>Substances and mixtures which, in contact with water, emit flammable gases</u>	-	ND	<input type="checkbox"/>	<input type="checkbox"/>		
<u>Oxidising liquids</u>	No	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a liquid	
<u>Oxidising solids</u>	No	NA	<input type="checkbox"/>	<input type="checkbox"/>	Not a solid	
<u>Organic peroxides</u>	No	ND	<input type="checkbox"/>	<input type="checkbox"/>	No functional groups present that could trigger classification	
<u>Corrosive to metals</u>	No	ND	<input type="checkbox"/>	<input type="checkbox"/>		
<u>Desensitised explosives</u>	-	NA	<input type="checkbox"/>	<input type="checkbox"/>		
<b><u>Toxic properties</u></b>						
Acute toxicity	oral	NA	NA	<input type="checkbox"/>	<input type="checkbox"/>	The substance is a gas and oral exposure is not a relevant route of exposure.
	dermal	No	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	LD <sub>50</sub> = >~10,000 ppm; Rabbits exposed to ~10,000 ppm ethanedinitrile for 8 hrs showed no evidence of toxicity indicating material is not dermally absorbed in significant amounts.

Hazard Class/Subclass	Classification		Method of classification			Remarks
	Applicant	EPA	Test Results	Read across		
	inhalation	6.1B <sup>5</sup>	Category 2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	LC <sub>50</sub> = ~136 ppm
<u>Skin corrosion/irritation</u>	No	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Rabbits exposed to ~10,000 ppm ethanedinitrile for 8 hrs showed no evidence of dermal irritation
<u>Serious eye damage/eye irritation</u>	No	ND	<input type="checkbox"/>	<input type="checkbox"/>		Although irritation of the eyes was observed in humans after a 6-8 min. exposure to 16 ppm ethanedinitrile, it was a sensory or neurological effect and not due to tissue damage. Sensory irritation is not a classifiable effect.
<u>Respiratory or skin sensitisation</u>	No	No	<input type="checkbox"/>	<input checked="" type="checkbox"/>		This effect is very unlikely as respiratory sensitisation was not observed in a chronic inhalation study with ethanedinitrile. Material is a gas and does not appear to penetrate the dermis. Sensitisation is also not a property associated with CN <sup>-</sup> or CN <sup>-</sup> generating compounds.
<u>Germ cell mutagenicity</u>	No	No	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Positive results from some studies on ethanedinitrile were deemed as false positives due to cytotoxicity. CN <sup>-</sup> , and cyanide compounds as a class, are not considered to be genotoxicants.

<sup>5</sup> 6.1B was proposed in the application form which corresponds to category 2 under GHS

Hazard Class/Subclass	Classification		Method of classification			Remarks
	Applicant	EPA	Test Results	Read across		
<u>Carcinogenicity</u>	No	No	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Results of a study on acetonitrile, a CN <sup>-</sup> generating compound, did not show evidence of tumour formation. CN <sup>-</sup> , and CN <sup>-</sup> generating compounds as a class, are not considered to be carcinogenic	
<u>Reproductive toxicity</u>	No	No	<input type="checkbox"/>	<input checked="" type="checkbox"/>	CN <sup>-</sup> , and CN <sup>-</sup> generating compounds as a class, are not considered to be reproductive toxicants.	
<u>Specific target organ toxicity – single exposure</u>	No	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	No specific target organ was identified in two 6-month inhalation studies with ethanedinitrile.	
<u>Specific target organ toxicity – repeated exposure</u>	No	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
<u>Aspiration hazard</u>	No	NA	<input type="checkbox"/>	<input type="checkbox"/>	The substance is a gas.	
<b><u>Ecotoxic properties</u></b>						
Aquatic ecotoxicity	Acute	9.1A	<b>Category 1</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Chronic		<b>Category 1</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Soil ecotoxicity		No	<b>ND</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EDN is approved as a soil fumigant in Australia and although no data is available, toxicity is expected
Terrestrial vertebrate ecotoxicity		NA	NA	<input type="checkbox"/>	<input type="checkbox"/>	Toxicity mechanism through inhalation, not oral route

Hazard Class/Subclass	Classification		Method of classification		Remarks
	Applicant	EPA	Test Results	Read across	
Terrestrial invertebrate ecotoxicity	NA	ND	<input type="checkbox"/>	<input type="checkbox"/>	No data available, but it is intended to control insect pests, therefore toxicity expected

-: No information provided by the applicant

NA: Not Applicable. For instance, testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible.

ND: Not determined due to a lack of test data or unreliable test data.

No: Not classified based on actual relevant data available for the substance or all of its components. The data are conclusive and indicate the threshold for classification is not triggered.

## Appendix G: Human health risk assessment

### Introduction and overview of the changes

The July 2018 Science Memorandum (EPA 2018d) provided a human health risk assessment with proposed controls based on a number of assumptions and data. The differences in the key parameters/data considered in the July 2018 Science Memorandum (EPA 2018d) and this updated science memo along with proposed controls are provided in the table below. The table includes brief comments about the changes, these are discussed in further detail under the respective sub-sections.

**Table 10: Key parameters/data considered in the 2018 and 2021 evaluation of EDN for human health risk assessment**

Parameter/dataset	July 2018 assessment (EPA 2018d)	Updated 2021 assessment	Comments
<b>Workplace Exposure Standard (WES)</b>	8-hour TWA Current 10 ppm & proposed: 2 ppm	8-hour TWA: 3 ppm (6.4 mg/m <sup>3</sup> ) Max: 5 ppm (10.6 mg/m <sup>3</sup> )	The value quoted in the July 2018 Science Memorandum (EPA 2018d) corresponds to the WES value initially proposed by WorkSafe during their 2018 consultation. WorkSafe has further considered these values and updated the 8-hour average and ceiling concentrations. These are the prescribed exposure standard (PES) in the draft SWI(s).
<b>Tolerable Exposure Limit (TEL)</b>	24-hour TWA 0.034 ppm (0.072 mg/m <sup>3</sup> )	24-hour TWA 0.034 ppm (0.072 mg/m <sup>3</sup> )	The TEL value used in the 2018 Science Memorandum (EPA 2018d) was later discussed and confirmed in an expert conferencing joint witness statement (EPA 2018b). This value is not given in the draft SWI (s) and is therefore proposed to be set as a control under s77A
<b>Maximum application rate</b>	150 g/m <sup>3</sup> over 24 hours	120 g/m <sup>3</sup> over 24 hours	The maximum application rate of 150 g/m <sup>3</sup> over 24 hours initially proposed by the applicant in their application form has been lowered to 120 g/m <sup>3</sup> . This maximum application rate has been used by WorkSafe for the development of their draft SWI (s). The application rate is not specifically mentioned in the draft SWI (s) and is therefore proposed to be set as a control under s77A
<b>Uses covered</b>	Timber logs fumigation under a sheet	Timber logs fumigation under a sheet Timber logs fumigation in a shipping container	Although the applicant has asked for further uses, namely ship's holds and chambers/structures, this type of use is not covered by

Parameter/dataset	July 2018 assessment (EPA 2018d)	Updated 2021 assessment	Comments
			the draft WorkSafe SWI (s) considered further in the context of this application. This is proposed to be set as a control under s77A
<b>Modelling data considered</b>	<p>Applicant generated modelling (Sullivan Environmental Consulting Incorporated 2018a)</p> <p>Review of applicant's modelling (Graham Environmental Consulting Limited 2018)</p>	<p>Applicant generated modelling (Sullivan Environmental Consulting Incorporated 2018a)</p> <p>Review of applicant's modelling (Graham Environmental Consulting Limited 2018)</p> <p>Additional modelling conducted by applicant ahead of 2018 hearing (Sullivan Environmental Consulting Incorporated 2018b)</p> <p>Expert conferencing Joint Witness Statement on Air Concentration Dispersion Modelling (EPA 2018a)</p> <p>Advice from EPA consultant on EDN air dispersion modelling (Graham 2018)</p> <p>Additional modelling commissioned by WorkSafe (Todoroski Air Sciences Property Limited 2019)</p>	<p>Modelling results from the applicant (Sullivan Environmental Consulting Incorporated 2018a) were reviewed by Dr Bruce Graham who produced a report with recommendations (Graham Environmental Consulting Limited 2018). The EPA July 2018 Science Memorandum (EPA 2018d) is based on this latter report.</p> <p>WorkSafe began developing the draft SWI (s) in 2019 and commissioned a report from Todoroski Air Sciences Property Limited (Todoroski Air Sciences Property Limited 2019) as part of that process.</p> <p>Following the publication of the EPA Addendum to the Staff Report in 2019 (EPA 2019d), the DMC agreed for further information to be provided while reiterating that modelling in itself it is likely not to be sufficient.</p>

Parameter/dataset	July 2018 assessment (EPA 2018d)	Updated 2021 assessment	Comments
		Modelling for port of Tauranga (Sullivan Environmental Consulting Incorporated 2020) performed by applicant in response to DMC Direction & Minute 09 (EPA 2019c) and 10 (EPA 2020a)	
<b>Monitoring/field data considered</b>	None considered	<p>USA Worker Safety trial reports (three reports)</p> <p>New Zealand fields trial data</p> <p>Commercial scale trials in the Czech Republic</p> <p>A rationale for justification for not using Scrubbing, destruction, or recapture equipment during the ventilation of ethanedinitrile</p> <p>Information about a new EDN monitor developed for use during fumigations</p>	No field studies or monitoring information was summarised in the July 2018 Science Memorandum (EPA 2018d). The DMC expressed its desire to obtain data on ambient environmental monitoring of EDN from appropriately scaled fumigation. This information has been provided to WorkSafe as part of their SWI development.
<b>Concentration before release of the sheet (tarp)</b>	Average concentration: 700 ppm (1.5 g/m <sup>3</sup> )	700 ppm	This parameter has been fixed by the draft SWI (WorkSafe 2021b) as part of the ventilation requirements, such as the ventilation does not begin until the concentration of EDN in the enclosed space is 700 ppm or less. As this parameter is fixed by the draft SWI

Parameter/dataset	July 2018 assessment (EPA 2018d)	Updated 2021 assessment	Comments
			(WorkSafe 2021b), it is not considered necessary to set this value as an additional control under the Act.
<b>Minimum buffer zones for workers without specific protective equipment</b>	10 m from a single log pile source 20 m from a multiple log pile source	No specific distance set	The relevant draft SWI (WorkSafe 2021b) defines 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. Further details below.
<b>Minimum buffer zones for bystanders</b>	120 m	50 m  In addition, it is proposed to include a minimum distance of 120 m between the fumigation site and sensitive areas.	WorkSafe's draft SWI (WorkSafe 2021b) requires that the substance is used by PCBUs in a manner that that does not result in a concentration in the air exceeding the TEL at any point on the boundary of the 50 m buffer zone set for workers.  To allow for the possibility that these requirements are not adhered to (i.e. exposure level exceeding the TEL), and to protect more sensitive populations and/or populations that be unable to evacuate themselves in case of breaches of the TEL being reported, it is proposed to set an additional control that fumigations using ethanedinitrile (EDN) should not be carried out within 120 m of any sensitive site where the public may lawfully be present. This distance is to be measured from the perimeter of the enclosed space.

## Workplace Exposure Standards (WES)

The values quoted in the July 2018 Science Memorandum (EPA 2018d) correspond to the initially proposed WES value during their 2018 consultation. WorkSafe has further considered these values and updated the 8-hour average and ceiling concentrations. These are the prescribed exposure standard (PES) in the draft SWI(s).

## Tolerable Exposure Limit (TEL)

The value used in the July 2018 Science Memorandum (EPA 2018d) was later discussed and confirmed in expert conferencing joint witness statement (EPA 2018b). This is proposed to be set as a control under s77A.

## Maximum application rate

The maximum application rate of 150 g/m<sup>3</sup> over 24 hours initially proposed by the applicant in their application form has been lowered to 120 g/m<sup>3</sup>. This maximum application rate has been used by WorkSafe for the development of their SWI (s). This is proposed to be set as a control under s77A.

## Uses envisaged

Although the applicant has asked for further uses, namely ship's holds and chambers/structures, this type of use is not covered by the WorkSafe draft SWI (s). 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."*

In the subsequent WorkSafe targeted consultation document (WorkSafe 2020b), WorkSafe also allowed for the use of EDN in shipping containers. Use restrictions in line with the draft SWI (s) are proposed to be set as controls under s77A.

## Release concentration

It is noted that 700 ppm concentration proposed in the July 2018 Science Memorandum has been used as a parameter in the draft SWI (WorkSafe 2021b) developed by WorkSafe.

## Exposure Assessment - Modelling

As mentioned in the July 2018 Science Memorandum (EPA 2018d), modelled post-fumigation air concentration levels to ethanedinitrile in treating logs were completed by the applicant (Sullivan Environmental Consulting Incorporated 2018a). This was then reviewed by Dr Bruce Graham on

behalf of the EPA (Graham Environmental Consulting Limited 2018). The conclusions of the July 2018 Science Memorandum (EPA 2018d) are based on those two modelling reports and further details are included in the 2018 Science Memorandum.

Further work related to air concentration dispersion modelling was later conducted by the applicant, who provided revised air dispersion modelling (Sullivan Environmental Consulting Incorporated 2018b) prior to the August 2018 hearing. This topic was discussed during the hearing with no final position on the validity of the modelling being reached. In order to discuss the parameters of the models, a round of expert conferencing between the EPA and applicant's representatives was conducted on the topic of air dispersion modelling and a joint witness statement produced (EPA 2018a). As a number of issues were not finalised, the DMC asked for further clarifications and further advice from the EPA consultant (Graham 2018) and discussions with the EPA consultant occurred (EPA 2018i).

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.”*

As part of the development of the WorkSafe Safe Work Instrument (SWI) for EDN, WorkSafe commissioned further air dispersion modelling (Todoroski Air Sciences Property Limited 2019).

In response to the EPA Addendum to the Staff Report (EPA 2019d), the applicant has requested the possibility of providing additional modelling. The DMC granted this request (EPA 2019c, EPA 2020a) and further modelling was provided (Sullivan Environmental Consulting Incorporated 2020) with updated parameters in line with modelling commissioned by WorkSafe (Todoroski Air Sciences Property Limited 2019).

As mentioned in the DMC Direction and Minute 9 (EPA 2019c):

- *“...air dispersion modelling undertaken on behalf of the applicant has significant inherent uncertainty, and alone, is an unreliable basis for decision-making. The DMC has indicated its desire for ambient environmental monitoring of EDN from appropriately-scaled fumigation trials to address this uncertainty. For this reason, the DMC is not inclined to use air dispersion modelling as the sole basis for making a decision without compelling evidence of safety and agreement by all parties. Provision of further modelling that provides no improvement on this situation (other than to provide some comparative numbers for use*

*scenarios other than log stack fumigation) is unlikely to significantly progress the understanding of the risks associated with this application.”*

As noted and evidenced above, air dispersion modelling depends on a number of variables and in itself is not sufficient to provide sufficient characterization of the risks associated with EDN fumigation. Results from field trial data was also considered and has been discussed below in further details. The EPA has not directly reviewed the extra modelling work generated following the July 2018 Science Memorandum (EPA 2018d) but has focused its analysis on the draft SWI (s) generated by WorkSafe that took into consideration further modelling work (WorkSafe 2020a, WorkSafe 2020b) as well as field/monitoring data (see below).

## Exposure Assessment – Field studies/Monitoring

No field studies or monitoring information was summarised in the July 2018 Science Memorandum (EPA 2018d). As noted above in the modelling section, the DMC has requested field studies or monitoring data to be provided in relation to the application. This includes the following information:

- USA Worker Safety trial reports (three reports).
- New Zealand fields trial data.
- Commercial scale trials in the Czech Republic
- A rationale for justification for not using Scrubbing, destruction, or recapture equipment during the ventilation of ethanedinitrile
- Information about a new EDN monitor developed for use during fumigations.

The EPA notes that this information has been provided to WorkSafe as part of their SWI development which has been considered alongside the applicant's and their own modelling (Todoroski Air Sciences Property Limited 2019).

The EPA has not reviewed in detail the information related to the exposure assessment (modelling and monitoring) provided following the July 2018 Science Memorandum (EPA 2018d) but considers, as this information has been integrated into WorkSafe's development of the draft SWI (s) (WorkSafe 2020a, WorkSafe 2020b) now approved in principle, that the amount of information on the exposure assessment of ethanedinitrile within the parameters considered is sufficient to propose measures mitigating the risks to workers potentially exposed to EDN (see below for further details).

## Risks to workers

In the July 2018 Science Memorandum (EPA 2018d), it was determined, based on the modelling information at an application rate of 150 g/m<sup>3</sup> 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.

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.

After an initial public consultation (WorkSafe 2020a) and a further targeted consultation period (WorkSafe 2020b), these draft SWI (s) (WorkSafe 2021b, WorkSafe 2021a) have since then 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.

The affected area is defined as follows in the relevant draft SWI:

- (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”*

The 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”*

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

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). This is approximated in Figure 1, page 40.

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.

The EPA suggests the addition of controls that ensures 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/m<sup>3</sup> over 24 hours
- The substance can only be used for timber treatment fumigation under a sheet or in a shipping container

## Risks to bystanders or the general public

The July 2018 Science Memorandum (EPA 2018d) proposed a 120 m buffer zone for bystanders based on the results of the modelling results available at the time (see Table 10). This considers a chronic and continuous type of exposure reflective of individuals who may be residing near a fumigation operation.

As noted above, 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 witness statement (EPA 2018b).

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”.

In relation to bystanders, 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.”*

In addition, the draft SWI 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.”*

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.”*

These provisions are tentatively represented in Figure 1, page 40.

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 to the buffer zone. Further details are available in WorkSafe’s published documents (WorkSafe 2020b, WorkSafe 2020a).

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

It is noted that this position relies on PCBUs meeting their obligations. 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.”*

The exposure level is defined as below:

**“exposure level** means the concentration of EDN in the air recorded at the monitoring location”

The monitoring location is defined 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”

These provisions are approximated in Figure 1, page 40.

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 5 working days of the exposure level being recorded.*

To allow for the possibility that these requirements are not adhered to (i.e. exposure level exceeding the TEL), and to protect more sensitive populations and/or populations that 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:

- 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.

In addition to the controls proposed to be set in relation to risks to works, 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/m<sup>3</sup>) as a 24-hour average

## Overall conclusions

Overall, it is considered that with the proposed controls in place, the risks to workers and the general public from the use of EDN will be negligible.

A simplified schematic interpretation of the draft SWI and additional proposed controls is included in Figure 1.

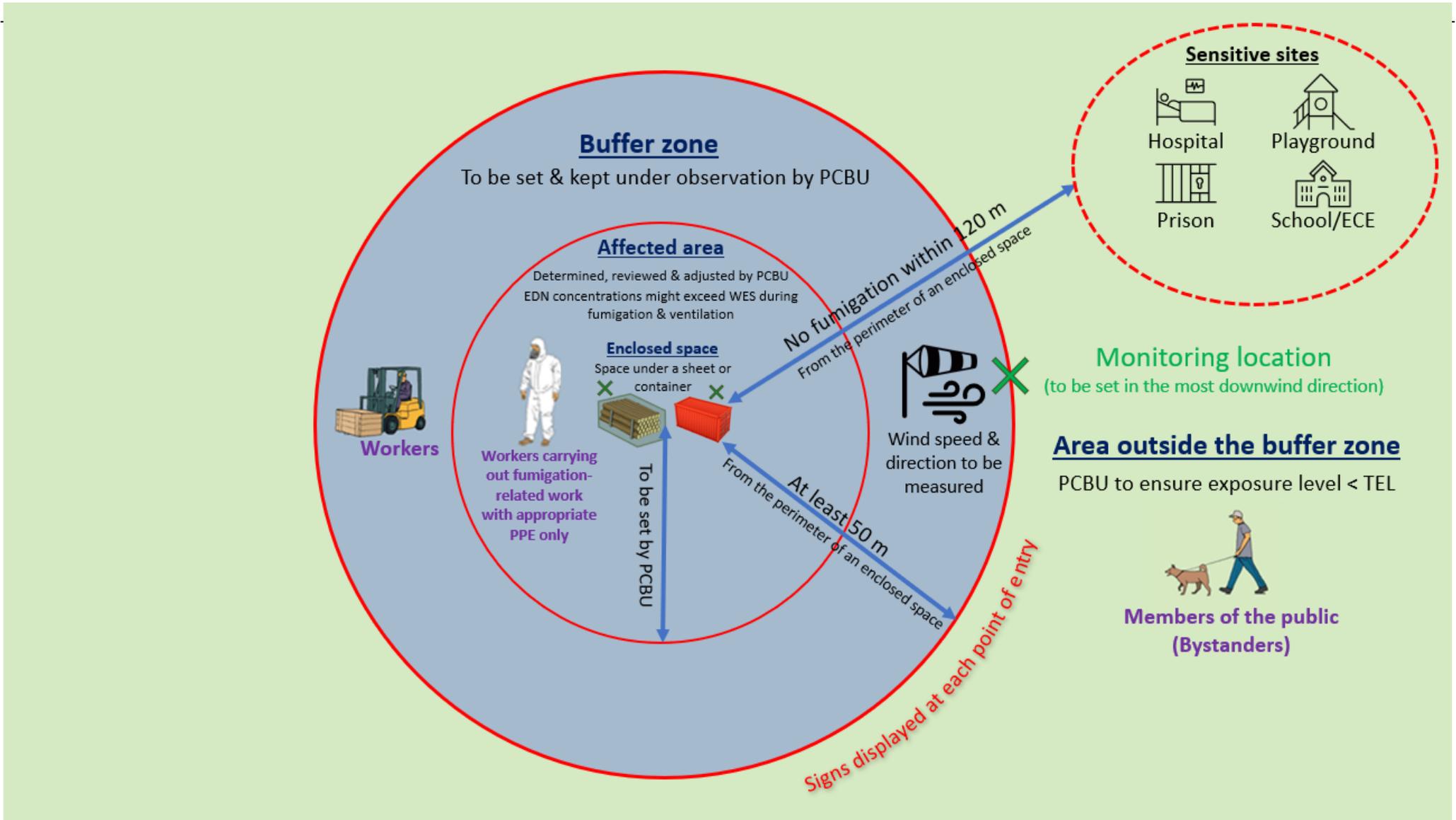


Figure 1: simplified representation of controls and measures applicable to EDN fumigation operations (distances not to scale)

## Appendix H: Environmental risk assessment

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.

This section looks at updates to the risk assessment where this is required.

### Aquatic risk assessment

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.”*

Given the ventilation/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).

## Terrestrial risk assessment

### Soil organisms

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.

### Terrestrial vertebrates (birds)

The July 2018 Science Memorandum (EPA 2018d) included the following control:

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

The applicant has provided a rationale as to why this control was not required (Draslovka 2020). They argued that ports are not suitable locations for waterbird colonies and provided a list of bird species potentially present in the vicinity of the ports of Tauranga, Napier and Northport. In addition, the EPA notes that the draft SWI (WorkSafe 2021b) sets a number of requirements that would limit potential exposure to birds such as ventilation requirements and obligations imposed to the PCBU to monitor and enforce WES values in the affected area and TEL outside of the buffer zone. These measures are considered to also provide a level of protection to birds.

Overall, it is considered that the addition of this control is not necessary.

## Conclusions of the ecological risk assessment

The conclusions of the July 2018 Science Memorandum (EPA 2018d) were that, based on low exposure, the direct risks to aquatic organisms, terrestrial vertebrates and invertebrates were considered negligible with the proposed controls in place.

It is considered that the controls proposed in Appendix I of the July 2018 Science Memorandum (EPA 2018d) are no longer necessary as these are better addressed by the requirements described in the draft SWI. These will further reduce exposure levels for non-target organisms outside of the treatment areas.

## Appendix I: Proposed controls

A whole revised set of controls is provided in the updated Staff Report.

- A maximum application rate of 120 g/m<sup>3</sup> over 24 hours
- A Tolerable Exposure Limit (TEL) of 0.034 ppm (=0.072 mg/m<sup>3</sup>) as a 24-hour average
- The substance can only be used for timber treatment fumigation under a sheet or in a shipping container
- The following limit is set for toxicologically relevant impurities in the active ingredient ethanedinitrile used to manufacture this substance: Hydrogen cyanide: 1% v/v maximum
- 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.

## Appendix J: References

APVMA (2017, 25 March 2019). "Standard for ethanedinitrile active constituent." 2021, from <https://apvma.gov.au/node/27071>.

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 EPA Staff Report - Application for approval to import EDN for release - APP202804.

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.

National Institute of Technology and Evaluation (2006). "GHS Classification Result - Oxalonitrile." Retrieved 04/06/2021, 2021, from <https://www.nite.go.jp/chem/english/ghs/06-imcg-0773e.html>.

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.