

Environmental Protection Authority Te Mana Rauhī Taiao

DECISION

22 January 2016

1. Summary

Substance	Ethanedinitrile (EDN)
Application code	APP202680
Application type	To import or manufacture a hazardous substance in containment under Section 31 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Draslovka a.s. formerly Lucebni zavody Draslovka a.s. (Referred to as Draslovka a.s.)
Purpose of the Application	To import ethanedinitrile (EDN), a fumigant, into containment for trials on timber/logs under commercial conditions
Unique identifier of substances	Ethanedinitrile (EDN)
Date application received	5 January 2016
Consideration date	22 January 2016
Considered by	The Chief Executive ¹ of the Environmental Protection Authority ("the EPA")
Decision	Approved with controls
Approval code	HSC100135

¹ The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

2. Background

- 2.1. The purpose of the application is to seek approval to import into containment EDN for use in fumigation trials on timber/logs.
- 2.2. In this instance EDN will be used to fumigate timber/logs in a contained trial, designed to replicate commercial conditions. The trial will rely on a sufficiently large buffer zone to satisfy the containment requirements.
- 2.3. The trial will generate data to demonstrate how EDN can be used for the intended purpose as a fumigant under New Zealand conditions. Levels of EDN released into the environment will be measured during the fumigation, upon ventilation when the fumigation is completed and for a period there-after.

3. Eligibility and consultation

- 3.1. The purpose of the application is to conduct 'research and development on any hazardous substance'; therefore I consider that the application qualifies for consideration as a containment approval under section 30(ba) of the Act.
- 3.2. WorkSafe New Zealand were advised of the application and invited to comment.

4. Hazardous properties and risks

4.1. The EPA has previously determined the hazard profile of EDN for approval HSC100070. The hazard classifications for EDN are set out in Table 1.

Hazard Endpoint	EDN
Flammability	2.1.1A
Acute toxicity (inhalation)	6.1B
Skin irritancy	6.3B
Eye irritancy	6.4A
Mutagenicity	6.6B
Reproductive/developmental toxicity	6.8B
Target organ toxicity	6.9B
Aquatic ecotoxicity	9.1A
Soil ecotoxicity	9.2B
Ecotoxicity to terrestrial vertebrates	9.3A
Ecotoxicity to terrestrial invertebrates	9.4A

Table 1: Hazard profile of EDN

- 4.2. I have reviewed the summary data and other information supplied by the applicant and consider that the information is sufficient to determine that any risks posed within the defined lifecycle of the substance in New Zealand can be managed through the application of containment controls.
- 4.3. The applicant has outlined the lifecycle of EDN as follows:
 - EDN will be imported as sea freight and in the form of a liquefied gas under pressure at 6 bar in ISO compliant 73I water capacity manganese steel cylinders (specified to 100-200 bar) fitted with AS 2473 compliant valves of high integrity (tied diaphragm) stainless steel, with the outlets fitted with a protective caps.
 - The EDN will be transported and stored at approved fumigant storage locations and under lock and key at the trial site. The storage areas will be open and well ventilated.
 - Draslovka a.s. will use up to 5 cylinders (250kg) of product for each trial.
 - Trial sites will allow for trials of the use of EDN under commercial scale conditions. Draslovka a.s. will carry out a risk assessment at each site before an EDN trial is conducted.
 - The risk assessment will include the provision of exclusion and buffer zones, signage, identification of neighbours and any special risk situations, signage/access and equipment to be used. Draslovka a.s. will ensure that the correct PPE is worn by those involved.
 - All trial applicators will hold NZ Approved Handler Certificate and Controlled Substance Licence (Fumigants).
 - A field trial plan will be produced and submitted to the EPA and Worksafe New Zealand 20 working days before each trial for review. This review is not an endorsement of the field trial plan but a review for any gaps or concerns.
 - Trials will not occur in adverse weather conditions.
 - Trials will be conducted with strict safety procedures including buffer zones. A buffer zone
 of 100 metres is required for non-occupational bystanders. This is referred to as the
 "safety zone."
 - Monitoring of air emissions and appropriate PPE will also be used to ensure the trials are completed safely.
 - EDN will be disposed of either via exportation or by incineration to produce carbon dioxide and nitrogen with the by-products recycled or disposed of.

Risks to the environment

4.4. I note that EDN could adversely affect the environment if an accident or failure to correctly follow procedures occurs during the lifecycle of the substance, resulting in a spill into the environment. If EDN was exposed to water or animals, adverse environmental effects could also occur. If released into the wider environment EDN has the potential to cause adverse effects.

4.5. I consider that, taking into account the containment controls in Appendix A and controls in place under other legislation, there are no significant risks to the environment from the importation and use of EDN in containment.

Risks to human health

- 4.6. I note that people could be adversely affected by EDN if an accident occurs that causes them to be exposed to the substance, such as an accident or failure to follow correct operational or disposure procedures. People who are not involved in the trial could be adversely affected if an EDN was used outside of containment or was not effectively contained, or if produce contaminated with EDN entered the human or animal food chain.
- 4.7. I note that the applicant is committed to running trials in a conservative manner to ensure worker safety. I also note that it is good practice to wear appropriate PPE to levels below the workplace exposure standards (WES value)² and generally less than 50% of the WES value. This is to protect workers who are more susceptible to the substance and to protect against sudden spikes in the concentration of the substance that would bring it above the WES value. Therefore, I would expect that the applicant will run the trials to this practice.
- 4.8. I consider that, taking into account the containment controls in Appendix A and controls in place under other legislation, there are no significant risks to human health from the importation and use of EDN in containment.

Risks to the relationship of Māori to the Environment

- 4.9. I have considered the potential Māori cultural impacts of this application. I note that the nature and hazard profile of the substance may give rise to the potential for cultural risk including the deterioration of aquatic taonga flora and fauna species and the environment.
- 4.10. I note that the applicant intends to consult with iwi prior to general release of the substance. I also note that the applicant intends to notify the appropriate authorities including the relevant iwi authorities in the region. Given the limited quantity of substances permitted to be used under this approval and the containment system proposed by the applicant, I consider that the effects Māori culture and their traditions will be negligible, and the approval of this application will not breach the Treaty of Waitangi.

Risk management

4.11. The applicant has provided a management plan to demonstrate how they intend to manage these risks, to ensure that EDN is contained and to address the containment requirements specified in Schedule 3 of the Act.

² The WES value is in the document described in the 7th Edition of "*Workplace Exposure Standards and Biological Exposure Indices* (http://www.business.govt.nz/worksafe/information-guidance/all-guidance-items/workplace-exposure-standards-and-biological-exposure-indices/workplace-exposure-standards-and-biological-indices-2013.pdf) Any reference to this document in these controls refers to any subsequent version approved or endorsed by the EPA.

5. Controls

5.1. I have set controls for EDN to mitigate the potential risks to human health and the environment, and to ensure that EDN is adequately contained in accordance with the matters set out in Schedule 3 of the Act. These controls are documented in Appendix A.

6. Decision

- 6.1. Pursuant to section 32 of the Act, I have considered this application to import hazardous substances in containment made under section 31 of the Act and have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology").
- 6.2. I and other members of the EPA staff met with two company directors of Draslovka a.s. on the1 December 2015 to discuss the regulatory process and Draslovka a.s. I do not believe this constitutes a conflict of interest.
- 6.3. I consider that, given the controls set for this substance, EDN can be adequately contained.
- 6.4. The application to import into containment EDN in containment the purpose of research and development is approved with controls as set out in Appendix A.

Date: 22nd January 2016

Chief Executive, EPA

Dr Allan Freeth

Appendix A: Controls

General

- 1. This approval expires on 22 January 2021.
- 2. This approval applies exclusively to, and is limited to, Draslovka a.s., who are referred to in the controls as the "approval user".
- 3. The approval user must ensure that no more than 500 kg of EDN is imported during the lifetime of this approval.
- 4. For each trial, the approval user must appoint a "field trial project lead" who is responsible for the overall conduct of a trial and compliance with these controls.
- 5. The approval user must ensure compliance with all controls, although they may contract other companies or individuals to carry out trials.
- 6. The approval user must ensure a field trial plan is produced and submitted to the EPA and Worksafe New Zealand at least 20 working days before each trial for review.³ This trial plan will include:
 - a. General location of the trial
 - b. Health and safety plan including
 - i. Levels of PPE worn
 - ii. Maintenance of the PPE to ensure it will remain effective
 - iii. Training of personal regarding PPE
 - c. Monitoring regime used in the trial including
 - i. Monitoring equipment to be used
 - ii. Maintenance of the equipment to ensure it will remain effective
 - iii. Training of personal regarding monitoring equipment
 - d. Specialist training for the use of EDN
 - e. First aid equipment available at the trial site

Packaging and information

- 7. The substance must be securely packed in suitable containers that comply with the Hazardous Substances (Compressed Gases) Regulations 2004.
- 8. The approval user must ensure that packages containing EDN are labelled in accordance with the Hazardous Substances (Identification) Regulations 2001; and the label must include
 - a. the name and contact details of a representative of the approval user;

³ The field trial plan should be sent to <u>technicall@worksafe.govt.nz</u> for Worksafe New Zealand and <u>notifications@epa.govt.nz</u> for the EPA

- b. instructions that after the trial, the remaining EDN must return to the approval user or an organisation nominated by the approval user.
- The approval user must ensure that a safety data sheet accompanies each EDN at all stages of its lifecycle in New Zealand. The safety data sheet must meet the documentation requirements of the Hazardous Substances (Identification) Regulations 2001, Hazardous Substances (Emergency Management) Regulations 2001 and the Hazardous Substances (Disposal) Regulations 2001.

Notification and Inspection

- 10. The EPA, Worksafe New Zealand, the Public Health Unit and the Regional Councils must be notified in writing of the trial. Notification will be provided no less than 10 working days before intended commencement of the trial and must include the following details:
 - a. Application number: APP202680;
 - b. HSNO approval number HSC100135;
 - c. Ethanedinitrile (EDN);
 - d. Address and GPS coordinates of the trial location;
 - e. Indicative start and completion dates (day/month/year) of the trial;
 - f. Field trial plan submitted in accordance to control 6 with any modifications noted.
- 11. The approval user must notify the EPA and Worksafe New Zealand the Public Health Unit and the Regional Councils
 - a. if the trial is going to be undertaken outside of the
 - i. notified indicative start and completion dates; or
 - ii. subsequent revised indicative start and completion dates;
 - b. within 24 hours after the decision to delay the trial has been made; and
 - c. of the revised indicative start and completion dates (day/month/year) of the trial.
- 12. The approval user must provide all records kept under this approval to the EPA within 3 working days of a request for the records being received in writing. This includes records of the location of the substance at each stage of the lifecycle from importation to disposal and monitoring results.

Field trial sites

- 13. The approval user must designate an area as the trial site for each trial, which may be all or part of a property or facility.
- 14. The trial site must include the following:
 - a. all preparation, storage and operational areas related to the study;
 - b. all necessary buffer zones.

- 15. The trial sites must be located to prevent any residential building or workplace which is not related to the research from being exposed to the substance.
- 16. The approval user must take measures to ensure that no person enters a trial site without the express permission of the field trial project lead or individual nominated by the field trial project lead. As a minimum, signs must be displayed at the entrances to the trial site that state:
 - a. an experimental fumigant is at the site; and
 - b. that the site is subject to a field trial of a hazardous substance; and
 - c. that unauthorised access to the site is not permitted; and
 - d. the telephone number of the approval user's representative on site.
- 17. The approval user must take measures to ensure that
 - a. all livestock is excluded from the trial site;
 - b. no beehives are present at the trial site; and
 - c. animals are excluded from the trial site to the extent that is reasonably practical.

Field trials

- 18. The approval user must ensure that the trials are undertaken in accordance with the field trial plan submitted with the notification before the trial under control 6.
- 19. The approval user must ensure that field trials do not go ahead under adverse weather conditions.
- 20. The approval user must ensure that each person involved with the trial has read, understands, and complies with:
 - a. the controls in this approval;
 - b. the field trial plan.
- 21. The approval user must notify immediate neighbours (any person whose property adjoins the perimeter of the safety zone) at least 24 hours prior to any trial. The notification should include the following information:
 - a. the intended date and time of the fumigation
 - b. the fact that EDN is being used as an experimental fumigant;
 - c. that unauthorised access to the site by people and animals are not permitted; and
 - d. the telephone number of the approval user's representative on site.

- 22. The field trial project lead must ensure that a 100 metre buffer zone⁴ from the logstack must be in place around all fumigation trials. This is known as the safety zone. Non-occupational bystanders are not permitted to be present in the safety zone.
- 23. The field trial project lead must not apply EDN under a tarpaulin unless the tarpaulin is:
 - a. in good repair without tears, rips or visible holes; and
 - b. made secure against likely weather conditions at the site; and
 - c. sealed with a border that is filled with heavy material.
- 24. The field trial project lead must ensure leak tests next to the log stack are performed at periodic intervals while the log stack is covered by tarpaulin.
- 25. A ventilation period can only commence after discharge of EDN into the logstack has finished. The ventilation period is in place for one hour after the concentration of EDN in than air is less than the workplace exposure standards (WES value)⁵ for EDN. The concentration of EDN must be recorded at multiple locations around the perimeter of the logstack at a distance of 1 metre. After this time, the trial is completed and the safety zone may be removed.
- 26. The approval user must monitor air emissions at the downwind edge of the safety zone of EDN.
 - a. If EDN levels at this monitoring location exceed an average of 1 ppm over a period of an hour during the trial, it will constitute a breach of containment and must be reported in accordance with control 42.
 - b. If EDN levels at this monitoring location exceed an average of 5 ppm over a period of an hour during the trial, it will constitute a serious breach of containment, the trial must stop immediately and it must be reported in accordance with control 41.
- The approval user must keep a record of application for EDN used under this approval. The record must meet the requirements specified in Regulation 6 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001.
- The approval user must ensure there is first aid equipment suitable for the use of EDN on site.
 This includes oxygen and appropriate equipment for use of oxygen.

Handling and personal protective equipment

- 29. Personal protective equipment that satisfies the requirements of Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 must be worn when handling the substance.
- 30. Personal protective equipment adequate to protect workers (including an appropriately protective breathing apparatus) must be worn by all people
 - a. discharging EDN; or

⁵ The WES value is in the document described in the 7th Edition of "Workplace Exposure Standards and Biological Exposure Indices (<u>http://www.business.govt.nz/worksafe/information-guidance/all-guidance-items/workplace-exposure-standards-and-biological-exposure-items/workpla</u>

⁴ an area extending outward in all directions from the perimeter of the logstack being fumigated.

indices/workplace-exposure-standards-and-biological-indices-2013.pdf) Any reference to this document in these controls refers to any subsequent version approved or endorsed by the EPA.

- b. in areas where the EDN concentration is at or exceeds the WES value. The PPE must be correctly in place when the concentration of EDN is at the WES value.
- 31. Any person handling or applying EDN must
 - a. be an approved handler and hold a Controlled Substance Licence (Fumigants); or
 - b. be working under the direct supervision of an approved handler that holds a Controlled Substance Licence (Fumigants).
- 32. Any person handling EDN must have training on safe usage of EDN.

Transport

33. The substance must be transported in compliance with any relevant requirements of the Land Transport Rule: Dangerous Goods 2005, the Civil Aviation Act 1990 or the Maritime Transport Act 1994.

Storage

34. The approval user must ensure that EDN is securely stored in facilities which meet the requirements of AS 4332:2004 "The storage and handling of gases in cylinders". In addition, storage of the substance must meet the requirements of the Hazardous Substances and New Organisms Act 1996 and the Resource Management Act 1991. Locked storage includes, but is not limited to, a secure laboratory.

Emergency management

35. The approval user must ensure that the trial sites, storage, use, transport and disposal of all EDN comply with the emergency management provisions prescribed by the Hazardous Substances (Emergency Management) Regulations 2001.

Disposal

- 36. The approval user must ensure that all EDN are disposed of in a manner compliant with the Hazardous Substances (Disposal) Regulations 2001.
- 37. The approval user must ensure that any logs/timber from the trial contain no detectable EDN as measured on the surface of the log before removal from the site.
- 38. The approval user must ensure that all empty cylinders of EDN are returned to the approval user at the expiry of this approval.
- 39. The approval user must ensure that at the expiry of this approval all EDN has been:
 - a. used; or
 - b. disposed of; or
 - c. contained in a laboratory with HSNO exempt status; or
 - d. are covered under a HSNO approval.

Breach of containment

- 40. Any person handling EDN must ensure that any material contaminated by a spill is either free of EDN or is collected and placed in a sealed container, and then returned to the approval user for disposal or decontamination.
- If for any reason a serious breach of containment under control 26(b) occurs, the approval user must immediately stop the trial, notify the fire department and Public Health Unit immediately, Worksafe New Zealand, Regional Councils and the EPA within 1 hour of the serious breach of containment being detected.
- 42. If for any reason a breach of containment occurs or when the controls are not followed, the approval user must notify Worksafe New Zealand and the EPA within 24 hours.