

# Legal memorandum

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**To:** Decision-making Committee for APP202804  
**Copy to:** Lauren Fleury, Manager – HSNO & Chris Hill, GMHSNO  
**From:** Kendyl Oates, Senior Solicitor  
**Date:** 20 December 2021  
**Subject:** EPA’s written response to STIMBR’s legal submissions

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This legal memorandum has been prepared in response to Direction & Minute 16 – APP202804 and reflects the specific facts and circumstances of APP202804.

## Purpose

1. In Direction & Minute 16 the DMC directed the EPA to prepare a written response to the written copy of STIMBR’s legal submissions read out at the hearing on 25 November 2021.
2. Those legal submissions were provided to the EPA on Monday, 6 December 2021 and comprised a Memorandum of Counsel for STIMBR which attached a document entitled *Talking Notes for STIMBR Presentation to DMC, 25 November 2021* and noted that the transcript itself provides a complete written record of STIMBR’s oral submissions (together, **STIMBR’s legal submissions**).
3. This response addresses the key aspects of STIMBR’s legal submissions but does not address the following matters: what is to be treated with EDN or a HSNO approval having national effect or the concluding paragraph of the *Talking Notes*.
4. This memorandum has been prepared by the EPA Legal Team.

## Summary of advice

5. We have reviewed STIMBR’s legal submissions and remain of the view that, based on the current information, it is not open to the Decision-making committee (**DMC**) to grant an approval under the Hazardous Substances & New Organisms Act 1996 (**HSNO**) that would permit use of EDN in ship holds.
6. Together the Health and Safety at Work Act 2015 (**HSWA**) (and associated regulations) and HSNO form the complete regulatory framework for a substance like EDN that will be used in a workplace. STIMBR’s legal submissions refers to a “circularity” between the separate regulatory elements. The EPA considers that these elements are sequential or linear, not circular. Controls under HSWA are directly relevant to the DMC’s assessment of the EDN application. That is why, as STIMBR notes, the DMC adjourned the first part of the hearing to allow WorkSafe time to develop the draft Safe Work Instruments (**draft SWIs**).

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7. We do not consider there to be any “jurisdictional bar” to granting an approval that would permit use of EDN in ship holds. Rather, we consider that there is insufficient information regarding the risks and mitigations/controls of using EDN in a ship’s hold before the DMC; there is no real-world data on use in ship holds and the draft SWI’s do not mitigate the adverse effects of that use.<sup>1</sup>
8. Decision making under HSNO must be based on evidence. The DMC cannot issue an approval that would permit use in a ship’s hold without sufficient evidence regarding that use.
9. HSWA already requires that a SWI be in force for EDN to be used in a workplace – the “condition” proposed by STIMBR simply reflects the law as it stands. However, the effect of that approach would be to circumvent the EPA conducting a proper assessment of risks to the environment and bystanders, thereby undermining the regulatory regime.
10. STIMBR’s legal submissions refer to matters it identifies as factors in WorkSafe’s internal decision-making processes. These are not relevant to the DMC’s consideration of the application. The DMC must focus squarely on the outcome of WorkSafe’s statutory processes as they currently stand.
11. HSNO expressly contemplates and provides for scenarios where HSWA controls on an approved substance change. This means, that if EDN were approved under HSNO (with controls that prohibit use in ship holds) and WorkSafe develop a SWI at a later date, the controls on EDN could be reassessed. This approach would ensure risks to the environment and bystanders are adequately assessed and managed.

## Discussion

### *The regulatory framework for hazardous substances used in a workplace is sequential*

12. It is useful to lay out the broader regulatory context at the outset of this response, as it is key to the issues that will be addressed. Separate statutory processes under HSWA and HSNO are designed to work together to form the complete regulatory framework for use of a specific hazardous substance (like EDN) in a workplace.
13. WorkSafe, as the agency responsible for overseeing the HSWA and associated regulations, is responsible for assessing that the HSWA requirements are adequate to manage the risks from the substance in the workplace. The EPA is responsible for approving the import or manufacture of new hazardous substances and specifying controls to manage risk and to safeguard people and the environment.
14. STIMBR’s submissions delineate between WorkSafe’s and EPA’s respective roles, noting that *“the role of the EPA...is not to duplicate WorkSafe’s role, but to take account of the work that WorkSafe has done”*. The EPA agrees with that proposition. However, STIMBR also submits that the DMC approve use in ship holds on the basis of what WorkSafe may

do in the future (ie develop an SWI). We do not consider that approach is open to the DMC.

15. STIMBR's legal submissions refers to "circularity" between the separate regulatory elements (eg the SWIs and a HSNO approval). We consider that these elements to be sequential or linear, not circular.
16. It is appropriate and necessary for WorkSafe and the EPA to have regard to the remit and decisions of the other when carrying out their statutory functions, with HSWA matters being determined (for example, by an in principle approval of draft SWIs) before a HSNO approval (or reassessment) is decided. This is reflected in:
  - a. EPA staff concluding when the first part of the hearing was convened in 2018 that the lack of air dispersion modelling for ship holds and a lack of real-world data from ship hold trails prevented them from making a proper risk assessment of the use of EDN in ship holds (as noted in STIMBR's submission); and
  - b. the DMC's decision to adjourn the hearing in 2018 so that a SWI relating to the management of the risks of EDN in workplaces could be developed; and
  - c. the reassessment provisions of HSNO (detailed at paragraph 36 below).
17. The draft SWIs, that have been agreed in principle, must inform the DMC's consideration of the application, including the identification of any risks to the environment or bystanders together with relevant HSNO controls. The updated EPA Staff Report and Science Memo were prepared on the basis the draft SWIs would take legal effect in their current form.

*Is there a jurisdictional bar for a conditional approval permitting use of EDN in ship holds?*

18. STIMBR submits that it is open to the DMC to grant approval for EDN on the condition that the substance could not be used in ship holds until there is a SWI in force in relation to that use (**conditional approval**). At the hearing, STIMBR orally submitted that there was no "jurisdictional bar" to the DMC issuing a conditional approval.<sup>2</sup>
19. We have interpreted STIMBR's reference to a "jurisdictional bar" to mean an express statutory provision stipulating that the DMC has no lawful power to issue a conditional approval like the one proposed by STIMBR. There is no provision in HSNO that expressly precludes a conditional approval (though nor is there a provision expressly providing for a conditional approval).
20. We do not consider the concept of a jurisdictional bar to be relevant here. Rather, it is the application of HSNO that leads to the conclusion that a conditional approval is not open to the DMC - without sufficient information (including a draft SWI, in circumstances where one will be required in order for the substance to be used under HSWA) about the risks and mitigations of using EDN in ship holds, it is not open the DMC to approve EDN without controls that prohibit that specific use.

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<sup>2</sup> Refer to pages 103 - 104 - Transcript of Proceedings, EPA Hearing, APP202804 – EDN- Virtual Hearing on 25 November

### *A HSNO approval must be based on relevant evidence*

21. It is useful to consider aspects of decision making under HSNO in more detail and address some aspects of the EPA legal advice dated 18 November 2021.
22. In order to make a decision on the EDN application section 29(1) of HSNO requires the DMC to take into account matters including any controls which may be imposed on the substance to mitigate any risks that have been identified. There is inadequate information about both the risks of using EDN in ship holds and any controls that may apply before the DMC. We note that:
- a. while STIMBR's submissions refer to the applicant potentially obtaining real-world data for ship holds there is no real-world data on ship hold fumigations currently before the DMC. It is not possible to consider controls that would manage risks where specific risks have not been evaluated/assessed;
  - b. the draft SWIs do not mitigate the adverse effects of the use of EDN in ship holds – such use is excluded from the draft *Health and Safety at Work (Hazardous Substances – Requirements for Specified Fumigants) Amendment Safe Work Instrument 2021* (refer clause 3 (b)); and
  - c. the EPA Updated Staff Report 2021 and Updated Science Memo 2021 were written on the basis that the draft SWIs would take legal effect in their current form. Accordingly, neither of these documents considered detailed data or information about the use of EDN in ships holds, including risks and any potential controls to mitigate adverse effects.
23. Controls under HSWA must be applied to the use of EDN in a workplace – this is not disputed, nor is the fact that a ship hold will always be a workplace. HSWA controls are directly relevant to the consideration of an approval under HSNO, hence the first adjournment. A HSNO approval cannot authorise use where the risks have not been adequately assessed (either by the DMC or by WorkSafe in the course of developing a SWI).
24. We consider STIMBR's submission that risks to workers "*have already been comprehensively address by the in principle SWI*" to be too broad. The Updated EPA Staff Report 2021 concluded that the draft SWIs will adequately manage the risk to workers *for the uses permitted by the SWI* – not for any use of EDN.
25. WorkSafe has, through its statutory process, determined that use of EDN will be restricted under HSWA. The rationale for excluding use in ship holds is set out in *Safe Work Instrument Specifying Requirements for Using Ethanedinitrile (EDN)* (dated February 2020) and was referred to in WorkSafe's presentation.<sup>3</sup> Broadly, based on the information

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<sup>3</sup> At the hearing on 25 November 2021, WorkSafe advised the hearing that "*...we did consider ship hold fumigations but at the time we developed the safe work instrument very little to no data was available on ship hold fumigations. And our own modelling that we commissioned did suggest that the buffer zones that would be required for ship hold fumigations would be too large to be practicable*" – refer page 48 - Transcript of Proceedings, EPA Hearing, APP202804 – EDN- Virtual Hearing on 25 November 2021

available to WorkSafe it concluded that the requirements to manage risk were considered likely to be impracticable.

26. Yet, STIMBR submits that it anticipates that controls in the draft SWIs could or would remain the same for a SWI covering use in ship holds. That cannot be predetermined. Different uses of EDN may lead to different risk profiles, each requiring specific consideration as to whether any identified requirements/controls under HSWA would appropriately mitigate associated risks, and in turn whether the HSWA controls appropriately mitigate risks to the environment and bystanders, or whether additional controls under HSNO may be required. To assess risk, the specifics of any controls, like a SWI must be known.
27. A decision under HSNO cannot be properly made based on speculation about the outcome of a separate statutory process. It is necessary for the DMC to weigh relevant evidence that is currently before it to determine what controls may apply to a substance under HSNO. Clause 12 of the HSNO Methodology Order requires the nature of adverse effects to be taken into account when assessing risks. Risks must have been assessed in order for a HSNO approval to permit a specific use.
28. The real impact of such an approach given the information before the DMC would be to preclude the assessment of risks of that use to the environment and people (outside the workplace) which is required under HSNO.
29. It is important to note that section 7 of HSNO requires the DMC to take into account the need of caution in managing adverse effects where there is scientific or technical uncertainty about those effects. The lack of real-world data on the risks of EDN being used in ship holds means there is uncertainty regarding risks and mitigations.
30. Mechanisms to address use in ship holds in the future are addressed at paragraphs 34 to 38 below.

#### *Matters internal to WorkSafe are not relevant considerations for the DMC*

31. The complementary roles of WorkSafe and the EPA are addressed at paragraphs 12 to 14 above. STIMBR outlined its understanding of two reasons why the draft SWIs do not cover ship holds in its submission. The first of these reasons (absence of real-world data from ship hold tests) is dealt with above.
32. The other reason advanced by STIMBR is that “*WorkSafe restricted its consideration because it thought the EPA was not likely to include ship holds in its approval*”. While there is no evidence before the DMC to support that assertion, WorkSafe’s internal decision-making processes are not a relevant consideration for the DMC. The draft SWIs must be taken on their face alongside other evidence that is before the DMC.
33. STIMBR submits that if a conditional approval were granted, if WorkSafe were to develop a SWI to cover ship holds, it would have the certainty of knowing what the TEL is. Although an agreement has been reached on the TEL value through expert conferencing, the TEL has not been set yet (this would be done in a HSNO approval). This has not been an impediment to the development of the draft SWIs. In any event, this is not a relevant consideration for the DMC in deciding on the application.

### *Addressing use in ship holds in the future*

34. While we consider that the DMC cannot issue an approval without controls that prohibit use in ship holds based on the information before it, such controls could be amended in the future.
35. It is open to WorkSafe to develop a SWI for use of EDN in a ship's hold, as STIMBR submit. WorkSafe addressed this in its presentation to the hearing.<sup>4</sup> Such a step is a separate statutory process entirely in the hands of WorkSafe. However, the outcome would have a bearing on steps that could then be taken under HSNO.
36. HSNO expressly contemplates and provides for scenarios where HSWA controls on an approved substance change. Section 62 addresses grounds for reassessment of a substance. The grounds decision maker is permitted to take “*a change in any controls under the Health and Safety at Work Act 2015*” into account (under section 62(2)(aa)) when considering whether there are grounds to reassess a substance. Further, section 63C provides:

#### **Modified reassessment to change controls in other cases**

(1) Despite anything to the contrary in this Act, the Authority may reassess a hazardous substance in accordance with this section if the Authority considers that—

(a) a reassessment of the hazardous substance under section 63 is not appropriate because the reassessment will involve only a specific aspect of the approval; and

(b) the amendment is not a minor or technical amendment to which section 67A applies; and

(c) **the reassessment is necessary because of a change in the** hazard classification system, controls in regulations, EPA controls, or **controls under the Health and Safety at Work Act 2015**.

**(emphasis added)**

37. STIMBR submits that a conditional HSNO approval would avoid the need for a further HSNO assessment following the development of a SWI for use of EDN in a ship's hold and that a conditional approval would mean industry could rely on it without further delay. This is not a relevant consideration on which the DMC can base an approval (including controls). As noted above, the effect would be to circumvent the regulatory regime because the risks of EDN from use in ship holds to the environment and people (outside the workplace) cannot be determined without knowing what the HWSA controls are (or would be).
38. If EDN is approved under HSNO, and a SWI for use in ship holds is developed at a later date, HSNO processes are not likely to be unduly complex or time-consuming (although the outcome of these processes cannot, of course, be predetermined). We note that different legislative and regulatory settings around methyl bromide means the modified reassessment process for that substance is not necessarily a useful comparator.

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<sup>4</sup> Refer to page 84, Transcript of Proceedings, EPA Hearing, APP202804 – EDN- Virtual Hearing on 25 November 2021

## Conclusion

39. An approval under HSNO must be based on evidence. Currently there is insufficient information before the DMC to enable the adequate assessment of the risks of and mitigations for using EDN in ship holds. The DMC cannot rely on the outcome of a separate statutory process that WorkSafe may run in the future (to assess and mitigate the risks of EDN in a workplace) in order to determine risks and appropriate mitigations of that use under HSNO. Accordingly, it is not open to the DMC to approve the import or manufacture EDN without controls that prohibit use in ship holds.

This advice has been peer reviewed by Celia Haden, Principal Solicitor.

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