Environmental Protection Authority
Te Mana Rauhī Taiao

Memorandum

To:	Dr Louise Malone (chair), Dr Kerry Laing
Copy to:	Dr Clark Ehlers, Gayle Holmes, [redacted]
From:	[redacted]
Date:	21 August 2019
Subject:	APP203865: application to determine if there are grounds for reassessment of soluble concentrate containing 520 to 540 g/L hydrogen cyanamide

Background

The substance

1. The substance named "soluble concentrate containing 520 to 540 g/L hydrogen cyanamide" ("the substance") was approved under the Hazardous Substances and New Organisms (HSNO) Act on 01 August 2006, following the decision on a Chief Executive initiated reassessment application (reference: HRC05001). The approval number of the substance is HRC000001.
2. The substance is marketed in New Zealand as a plant growth regulator, used to promote uniform and increased bud break and flowering of kiwifruit and earlier concentrated flowering of apples, being applied at a particular stage of the growing cycle to overcome the effects of mild or variable winter temperatures.
3. Six products containing the substance are registered with the Ministry for Primary Industries' Agricultural Compounds and Veterinary Medicines group (ACVM): Hi-Cane (registration number P003566), Treestart (P007333), Hortcare Hi-break (P007018), Synergy HC (P007840), Gro-Chem HC50 (P005858), and Cyan (P007190).
4. The substance is classified as follows:

   6.1C (All), 6.1C (O), 6.1D (D), 6.1D (I), 6.3A, 6.4A, 6.5B, 6.8B, 6.9A (All), 6.9A (O), 9.1D (All), 9.1D (F), 9.1D (A), 9.1D (C), 9.3B, 9.4C.
5. The controls that apply to the substance include default controls applicable to a substance having these hazard classifications, as well as a number of additional or varied controls.
6. In the 2006 reassessment decision, it was stated that exposure to bystanders could occur through spray drift and it was recommended that the Environmental Risk Management Authority (ERMA, the Environmental Protection Authority's (EPA's) predecessor) monitor the reporting incidents over the following five years to assess the effectiveness of changes in technology and the impact of the regulatory controls. The 2012 HSNO Monitoring Report (see link in the Appendix) concluded that it can be assumed hydrogen cyanamide was being used more safely than it was before the reassessment. In addition, it concluded that these monitoring requirements

were not controls as such, and were not as successful as the monitoring controls set for other substances.

Application process

7. Mr John Levers lodged an application for grounds for reassessment of “Hi-Cane hydrogen cyanamide” in February 2019.

8. The applicant did not specify exactly which controls he would like to amend. He is mainly concerned by the human health impact of the substance on bystanders, and its environmental effects on terrestrial vertebrates and invertebrates. He attached a letter explaining on which basis he would like the substance to be reassessed.

9. The applicant is seeking grounds to reassess the substance on the basis of:
    - significant new information relating to the effects of the substance
    - availability of another substance with similar or improved beneficial effects and reduced adverse effects
    - information showing a significant change of use of the substance
    - information showing a significant change in the quantity of the substance manufactured or imported.

10. The EPA requested further information for this grounds application in June 2019. The applicant sent a link (see Appendix) to a European Food Safety Authority (EFSA) publication on the active ingredient cyanamide, a synonym of hydrogen cyanamide. The document is named “Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide”. The EPA therefore considered this document as part of the application.

11. The application was formally received on 15 July 2019.

Legislative basis

12. Section 62(2) of the Act states:

> *(2) Where any request has been made under subsection (1), the Authority may decide that grounds exist to reassess that substance or organism after taking into account that-*
>
> *(a) significant new information relating to the effects of the substance or the organism has become available; or*
>
> *(aa) a change in any controls under the Health and Safety at Work Act 2015; or*
>
> *(b) another substance with similar or improved beneficial effects and reduced adverse effects has become available; or*
>
> *(c) information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available.*

13. Thus, while the EPA has a discretion to decide whether there are grounds for reassessment, it is essential that at least one of the factors in section 62(2)(a) to (c) exist, and it is mandatory to take into account that factor when deciding whether there are grounds for reassessment.

Assessment

Effects of the substance

14. The applicant considers that there is significant new information about the effects of the substance to justify grounds being granted. The applicant's original application does not provide sufficient evidence to justify this claim. In response to a request for further information, the applicant provided the EFSA document "Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide".

15. A Draft Assessment Report (DAR) containing the initial evaluation of cyanamide was published by EFSA in June 2006 (see Appendix). The representative formulated product used for the evaluation was "Dormex", a soluble concentrate which contains 520g/L cyanamide. The DAR formed the basis of a European Commission Decision of 18 September 2008 to remove cyanamide from Annex I to Council Directive 91/414/EEC. This lead to the withdrawal of authorisations for plant protection products containing that active ingredient in the European Union.

16. Subsequently, a resubmission application was made in Europe to include cyanamide in Annex I again. An Additional Report evaluated the resubmission dossier, including data provided in response to issues identified in the DAR. It was published by EFSA in January 2010 (see Appendix).

17. The document provided by the applicant contains the peer review conclusions on this additional report. Indeed, the European Commission asked EFSA to conduct a focused peer review in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology on the additional report. This process did not lead to a change of decision by the European Commission.

18. The original DAR was published the same month as the decision on the EPA's reassessment application. The European Commission decision was published two years after the ERMA reassessment decision. It was therefore not possible for these documents to be taken into account in the decision process on the reassessment, and we consider them to be new information.

19. In the EFSA Peer Review document provided by the applicant, the critical areas of concerns are the operator and bystander exposure estimates which exceed the Acceptable Operator Exposure Level (AOEL), as well as the potential for groundwater exposure. A high risk to birds was also identified but the risk assessment could not be finalised on the basis of the available data. We consider that this is significant new information about the effects of the substance.

20. The EPA has supplemented the information provided by the applicant by conducting a review of the approval status of hydrogen cyanamide in other regulatory jurisdictions: it is approved in Australia, the United States of America (USA), and Canada; it is still approved as a biocidal product in Europe.

21. In June 2019, the European Chemical Agency (ECHA) released a public consultation on potential candidates for substitution for cyanamide as a biocidal product. They classify it as carcinogen category 2 and toxic for reproduction category 2. The classifications mean ECHA consider cyanamide to have endocrine disrupting properties, and it is currently undergoing an endocrine disruptor assessment under the Biocidal Products Regulation in Europe.

22. The Australian label for Dormex (a cyanamide-containing product) indicates it is suspected of causing cancer and causes severe skin burns (see link in Appendix). The USA label for Dormex also states the product is corrosive. The substance is also classified as skin corrosive in Europe, different from the EPA classification as skin sensitive 6.3A.

23. The ECHA, USA and Australian information are also considered to be significant new information about the effects of the substance.

Use and quantity

24. The applicant proposes that an indication from the kiwifruit industry that they are going to triple production in the next ten years means that the use of the substance will also triple. He reports that he considers that the controls on the substance are not being followed. He considers that these are evidence that there has been a significant change in the substance's use and quantity.

25. As the change in the quantity used has not already occurred, the EPA consider this information as not relevant for this application. The information presented in the application about compliance with controls is also not relevant for this application.

Alternatives

26. The applicant states that kiwifruit representatives (apparently from New Zealand Kiwifruit Growers Incorporated) have told him that there are alternatives to the substance, and that those alternatives are not as good. He speculates that they are not being used because of cost. No information is provided on these alternatives. As such, there is insufficient information upon which to conclude whether there are suitable alternatives or not.

Risk and cost-benefit assessment

27. An assessment of the risks to human health and the environment has not been conducted as part of this Grounds for Reassessment application.

28. Similarly, assessments of the benefits of the substance and the costs of it being, or not being, available have not been conducted as part of this application.

29. If it is decided that grounds for reassessment exist then these aspects may need to be considered when evaluating any subsequent application for a reassessment of the substance.

Cultural assessment

30. We have considered the principles of the Treaty of Waitangi. There are no issues to be addressed in the context of this application. We will revisit this matter in any subsequent application for a reassessment of the substance.

International obligations

31. No international obligations are considered relevant to the substance.

Recommendation

32. The application has been assessed against the criteria under section 62 of the Act. The information presented in the application does not satisfy the factors under sections 62(2)(b) or s

62(2)(c) of the HSNO Act. We consider, however, that the EFSA document “Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide” is significant new information relating to the effects of the substance under section 62(2)(a) of the HSNO Act.

33. Taking this into account, the draft decision document concludes that grounds exist for the reassessment of soluble concentrate containing 520 to 540 g/l hydrogen cyanamide (HRC000001). This is provided in draft form and can be amended as necessary to reflect the outcome of your consideration.

34. To assist in your consideration, the following documents have been provided:
    - the application form
    - the European Commission Decision concerning the non-inclusion of cyanamide in Annex I to Council Directive 91/414/EEC
    - the USA label for the product Dormex
    - the draft decision for APP203865.

35. Please advise if you require any additional information.

Appendix: Linked references

Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide, 2010

https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1873

Additional report to the DAR, January 2010

Cyanamide_additional report_01_Vol1 (January 2010)_public.pdf
Cyanamide_additional report_03_Vol3_Contents (January 2010)_public.pdf
Cyanamide_additional report_04_Vol3_B1 (January 2010)_public.pdf
Cyanamide_additional report_05_Vol3_B2 (January 2010)_public.pdf
Cyanamide_additional report_06_Vol3_B3 (January 2010)_public.pdf
Cyanamide_additional report_07_Vol3_B4 (January 2010)_public.pdf
Cyanamide_additional report_08_Vol3_B5 (January 2010)_public.pdf
Cyanamide_additional report_09_Vol3_B6 (January 2010)_public.pdf
Cyanamide_additional report_10_Vol3_B7 (January 2010)_public.pdf
Cyanamide_additional report_11_Vol3_B8 (January 2010)_public.pdf
Cyanamide_additional report_12_Vol3_B9 (January 2010)_public.pdf
Cyanamide_additional report_13_Vol3_B10 (January 2010)_public.pdf

Draft Assessment Report (DAR), June 2006:

Cyanamide_DAR_01_Vol_1_public.pdf
Cyanamide_DAR_02_Vol_2_public.pdf
Cyanamide_DAR_03_Vol_3_B1-B5_public.pdf
Cyanamide_DAR_04_Vol_3_B6_part1_public.pdf
Cyanamide_DAR_05_Vol_3_B6_part2_public.pdf
Cyanamide_DAR_06_Vol_3_B6_part3_public.pdf
Cyanamide_DAR_07_Vol_3_B8_public.pdf
Cyanamide_DAR_08_Vol_3_B7_public.pdf
Cyanamide_DAR_09_Vol_3_B9_public.pdf
Cyanamide_DAR_10_Vol_3_appendices_public.pdf

Monitoring the effectiveness of the Hazardous Substances and New Organisms Act, July 2012

https://www.epa.govt.nz/assets/RecordsAPI/5d05b47597/Monitoring-the-effectiveness-of-the-HSNO-Act-2012.pdf

ECHA webpage: public consultation on potential candidates for substitution

https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution/-/substance-rev/23418/term?_cldee=bWljaGFlbC5iZXJhcmRvenppQGVwYS5nb3Z0Lm56&recipientid=lead-91d8a05ef5c1e8118105005056952b31-d4540ec5f37e4854a3ce18fca44182f5&esid=9d9b09b8-0aae-e911-810f-005056b9310e

Australian label for Dormex

https://cdn.nufarm.com/wp-content/uploads/sites/22/2018/05/06182420/5223-Dormex-16Dec2017.pdf