

Decision (Section 62 – Grounds for reassessment of approval ERMA200223)

Date	2 September 2021
Application number	APP204212
Application type	Grounds for reassessment of an organism under section 62(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant	GE Free New Zealand
Date Application received	19 July 2021
Consideration date	18 August 2021
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee) ¹ : <ul style="list-style-type: none"> ▪ Dr Derek Belton (Chair) ▪ Peter Cressey
Purpose of the Application	To decide if there are grounds for the reassessment of approval ERMA200223

1. Summary of the decision

1.1. The Committee has decided under section 62 of the Hazardous Substances and New Organisms (HSNO) Act 1996 that there are no grounds for a reassessment of the approval to develop in containment genetically modified goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance (application number ERMA200223).

¹ The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the HSNO Act.

2. Purpose of the request

- 2.1. GE Free New Zealand in Food and Environment (GE Free NZ) requested under section 62(1)(a) of the Hazardous Substances and New Organisms Act 1996 (the Act) that the Authority consider whether there are grounds for reassessment of the controls approved in ERMA200223.
- 2.2. ERMA200223 was considered by a committee of the Authority of ERMA New Zealand. ERMA200223 was approved with controls on 13 April 2010, under section 45(1)(a) of the Act as a development of new organisms in containment.

3. Application and consideration process

- 3.1. The application was lodged on 12 March 2021, and formally received on 19 July 2021.
- 3.2. The Committee undertook its deliberations on 17 August 2021 and concluded on 18 August 2021.
- 3.3. The information that the Committee took into consideration included:
 - The application
 - Application Appendix 1: Cover letter to EPA
 - Application Appendix 2: Reassessment of ERMA200223
 - The EPA staff assessment report
- 3.4. The determination was made in accordance with section 62(2) of the HSNO Act. Decisions under section 62 of the HSNO Act have no statutory timeframe for completion, nor do they require public notification.
- 3.5. Under section 53 of the Act, there is no requirement to publicly notify a request for grounds for reassessment.

4. Legislative criteria considered

- 4.1. A decision as to whether there are grounds for reassessing any new organism is made under section 62(2) of the Act. This section provides that the Authority may decide that grounds exist to reassess a substance or organism after taking account the matters set out in section 62(2)(a), (aa) and (c).

Significant new information relating to the effects of the substance has become available (section 62(2)(a))

- 4.2. The applicant provided information that it considered to be new information regarding the existence of monoclonal antibodies used in cancer therapies, and which are being produced in the milk of cows developed under ERMA200223.

- 4.3. The EPA was already aware of this information, which was considered by the EPA as a component of the original application. The original ERMA200223 Decision-making Committee was aware at that time that the purpose of this work was to produce biosimilar alternatives to these anti-cancer drugs.
- 4.4. The Committee therefore considers that the information provided is not “significant new information”, as required in section 62(2)(a).

A change in controls under the Health and Safety at Work Act 2015 (section 62(2)(aa))

- 4.5. This factor is not relevant to this application.

Information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available (section 62(2)(c))

- 4.6. The applicant provided information that it considered to be evidence of a significant change of use under the approval, citing EPA correspondence that animals were being developed under ERMA200223 as a field test, while the approval was for development under conditions of outdoor containment.
- 4.7. The Committee notes that the EPA erroneously referred to the ERMA200223 approval as a field test in the cited correspondence. However, the Committee also notes that the ERMA200223 approval is for the development of cows, goats and sheep in outdoor containment, and that the approval holder continues to use it as such.
- 4.8. The applicant also provided information claiming that the approval holder is chronically non-compliant with the controls of the ERMA200223 approval, citing a number of MPI inspection reports dating from 1 March 2017 to 2 March 2020, as well as information provided in AgResearch’s Annual Reports to EPA.
- 4.9. The EPA was already aware of this information. The Committee noted that the information cited in the reports did not pertain to compliance with the controls of ERMA200223, and further noted that several of the cited reports stated specifically that the approval holder was in compliance with the controls of ERMA200223. The Committee also noted that information cited by the applicant from AgResearch’s Annual Reports was not in breach of the controls of ERMA200223.
- 4.10. The applicant also provided information claiming non-compliance with controls from approvals granted to AgResearch prior to the granting of the ERMA200223 approval.
- 4.11. The EPA was aware of the information, and of the fact that the animals developed and held under these approvals were legally transferred to be developed and held under ERMA200223, the controls of which superseded the controls of the now-expired earlier approvals.

4.12. The Committee therefore considers that the information provided does not constitute “a significant change in use” of the approved animals, or of the approval itself.

Other reasons for requesting a reassessment under section 62(2)

4.13. The Committee notes that the applicant provided information in support of its claims that the animal development work under ERMA200223 is being conducted without ethical oversight, and claims that the welfare of the animals is being neglected.

4.14. The Committee noted that the work under ERMA200223 is being carried out under full oversight of the Ruakura Animal Ethics Committee, evinced in quarterly reports provided within the AgResearch Annual Reports over the entire duration of the approval. The Committee also notes the Ethics Committee reports that the animals are well cared for.

4.15. The Committee therefore considers that the information provided does not constitute a lack of Ethics Committee oversight, which therefore does not constitute grounds for reassessment of ERMA200223.

5. Conclusion

5.1. The Committee considered whether each of the points raised by the applicant amounted to grounds for reassessment.

5.2. The Committee considers that the information available to it did not raise any grounds for reassessment.

5.3. In accordance with section 62(2) of the HSNO Act, and having regard to the relevant information, the Committee has decided that grounds do not exist for the reassessment of approval ERMA200223.



Dr Derek Belton
Chair, Decision-making Committee
Environmental Protection Authority

2 September 2021

Date