To obtain a determination of whether an organism is a new organism

Send to Environmental Protection Authority preferably by email (neworganisms@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)
Payment must accompany final application; see our fees and charges schedule for details.

Gallid alphaherpesvirus 1 (infectious laryngotracheitis virus)

AviPro LT®
Infectious Laryngotracheitis Vaccine for Chickens

Submitted by
Pacificvet Limited
Christchurch

Application Number
APP203608

Date
Completing this application form

1. This form is used when you wish to apply for a statutory determination under section 26 of the Hazardous Substances and New Organisms (HSNO) Act 1996 as to whether or not an organism is a new organism (i.e. whether the organism is regulated under the HSNO Act or not).

2. If you wish to make an application for approval of for use of a new organism, a different form will have to be used. All forms are available on our website.

3. It is recommended that you contact an Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Advisor can assist you with any questions you have during the preparation of your application.

4. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.

5. Any extra material that does not fit in the application form must be clearly labelled and cross-referenced, and included with the application form when it is submitted.

6. Please add extra rows/tables where needed.

7. You must sign the final form (the EPA will accept electronically signed forms) and pay the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an “approved customer”, you must have submitted more than one application per month over the preceding six months, and have no history of delay in making payments, at the time of presenting an application.

8. Information about application fees is available on the EPA website.

9. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

10. Commercially sensitive information must be included in an appendix to this form and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form and cross reference to where that information is located in the confidential appendix.

11. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.

12. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.
## Definitions

### Genetically Modified Organism (GMO)

Any organism in which any of the genes or other genetic material:
- Have been modified by *in vitro* techniques, or
- Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques

### New Organism

A new organism is an organism that is any of the following:
- An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998;
- An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation;
- An organism for which a containment approval has been given under the HSNO Act;
- An organism for which a conditional release approval has been given under the HSNO Act;
- A qualifying organism approved for release with controls under the HSNO Act;
- A genetically modified organism;
- An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand;
- An organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970. This does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus

A new organism does not cease to be a new organism because:
- It is subject to a conditional release approval; or
- It is a qualifying organism approved for release with controls; or
- It is an incidentally imported new organism
1. Applicant details

1.1. Applicant

Company Name: (if applicable) Pacificvet Limited
Contact Name: Kent Deitemeyer
Job Title: Joint Managing Partner
Physical Address: 3 Hickory Place, Christchurch
Postal Address (provide only if not the same as the physical): PO Box 16-129, Hornby, Christchurch 8441
Phone (office and/or mobile): 03 349 8438
Fax: 03 349 8863
Email: Kent@pacificvet.co.nz

1.2. New Zealand agent or consultant (if applicable)

Company Name:
Contact Name:
Job Title:
Physical Address:
Postal Address (provide only if not the same as the physical):
Phone (office and/or mobile):
Fax:
Email:
2. Information about the organism

2.1. Name of organism
Identify the organism as fully as possible

Organism name:

*Gallid alphaerpesvirus 1* (infectious laryngotracheitis virus).

The name of *Gallid alphaerpesvirus 1* was adopted by the ICTV in 2016. Previously, the virus was identified as *Gallid herpesvirus 1* or *Gallid herpesvirus type 1*. These names persist in the literature. The ICTV provide the following justification for the change: 'It is proposed that subfamily-specific prefix be added to the word “herpesvirus” in all species names. Nothing else in the names would change. This would bring clarity as to which subfamily a species belongs, particularly since many animals are are associated with species in different subfamilies, and it can be difficult to remember which species is in which family.’

Briefly describe the biological characteristics of the organism:

*Gallid alphaerpesvirus 1* is a member of the genus *Iltovirus*, subfamily *Alphaherpesviridae* of the *Herpesviridae* family within the order *Herpesvirales* (1).

The chicken is the natural host of *Gallid alphaerpesvirus 1* (GaHV-1). GaHV-1 is the cause of infectious laryngotracheitis (ILT), a disease of chickens. Infections have been identified in pheasants and peafowl.

The natural portals of entry for GaHV-1 are through the upper respiratory and ocular routes. Egg transmission has not been demonstrated. Direct bird-to-bird transmission occurs more readily from acutely infected birds than through contact with clinically recovered carrier birds (1).

2.2. Regulatory status of the organism

Is the organism that is the subject of this application also the subject of:

- An innovative medicine application as defined in section 23A of the Medicines Act 1981?
  - ☐ Yes  ☑ No

- An innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997?
3. Evidence regarding whether the organism meets the definition of a new organism

Does the organism meet the definition of a new organism under the HSNO Act?

For example, does it belong to a species that was not present in New Zealand before July 29 1998? Is it a genetically modified organism? etc.

Describe the evidence you have to support this view, providing supporting materials in an appendix as appropriate.

*Gallid alphaherpesvirus 1* is not a new organism in New Zealand.

Infectious laryngotracheitis virus was present in New Zealand as early as 1957 (2), (3). The presence of GaHV-1 in New Zealand was confirmed in 1976 (4). There have been reports of infectious laryngotracheitis in New Zealand in the MPI publication *Surveillance* since 1992 (5), (6), (7), (8), (9), (10).

A live attenuated infectious laryngotracheitis vaccine Laryngo-Vac® registered pursuant to the ACVM Act 1997 No. A3151 has been marketed continuously in New Zealand since 1976 (11). Laryngo-Vac® comprises the Cover strain of GaHV-1 (12).

Pacificvet Limited seeks to register a live attenuated vaccine AviPro® LT under the ACVM Act 1997. AviPro® LT contains the Hudson strain of GaHV-1 (12).

According to Garcia et al.; "Based on the phylogenetic grouping and the timeline of isolation, the Cover strain (circa 1958) most likely originated from the Hudson strain (circa 1933)” (13).
REFERENCES


4. Checklist

This checklist is to be completed by the applicant

<table>
<thead>
<tr>
<th>Application</th>
<th>Comments/justifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act</td>
<td>☑ Yes ☐ No (If No, please discuss with an Advisor to enable your application to be further processed)</td>
</tr>
<tr>
<td>Confidential data as part of a separate, identified appendix</td>
<td>☐ Yes ☑ No</td>
</tr>
<tr>
<td>Supplementary optional information attached:</td>
<td></td>
</tr>
<tr>
<td>• Copies of additional references</td>
<td>☑ Yes ☐ No</td>
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<tr>
<td>• Relevant correspondence</td>
<td>☐ Yes ☑ No</td>
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<tr>
<th>Administration</th>
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<tbody>
<tr>
<td>Are you an approved EPA customer?</td>
<td>☐ Yes ☑ No</td>
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<tr>
<td>If Yes are you an:</td>
<td></td>
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<tr>
<td>Applicant: ☑ Yes</td>
<td></td>
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<tr>
<td>Agent: ☐ No</td>
<td></td>
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<tr>
<td>If you are not an approved customer, payment of fee will be by:</td>
<td></td>
</tr>
<tr>
<td>• Direct credit made to the EPA bank account (preferred method of payment)</td>
<td>☐ Yes ☑ No</td>
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<tr>
<td>Date of direct credit:</td>
<td>☐ Yes ☑ No</td>
</tr>
<tr>
<td>☐ Payment to follow</td>
<td></td>
</tr>
<tr>
<td>• Cheque for application fee enclosed</td>
<td>☐ Yes ☑ No</td>
</tr>
<tr>
<td>☐ Payment to follow</td>
<td></td>
</tr>
<tr>
<td>Electronic, signed copy of application e-mailed to the EPA</td>
<td>☑ Yes</td>
</tr>
</tbody>
</table>
## Signature of applicant or person authorised to sign on behalf of applicant

- I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.
- I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Signature]</td>
<td>14 June 2018</td>
</tr>
</tbody>
</table>

## Request for information waiver under section 59 of the HSNO Act

- I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request:
Appendices and referenced material (if any) and glossary (if required)

See References listed in Section 3.