Staff Assessment Report

Application APP203065: to release a live attenuated vaccine strain of Infectious Bronchitis Virus - Poulvac Bron Vic S

January 2017

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<td>Rapid Assessment for Release of a Qualifying Organism</td>
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<td>Applicant</td>
<td>Pacificvet Limited</td>
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<td>Purpose</td>
<td>To release Avian Infectious Bronchitis Virus (Vic S strain) as a live attenuated vaccine for poultry</td>
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Summary and Recommendations

This application seeks approval to introduce Infectious Bronchitis Virus (IBV) in the form of a live attenuated vaccine (Vic S strain) for use against infectious bronchitis in New Zealand poultry.

The current bespoke live attenuated vaccine, registered under the ACVM Act 1997 as Pacificvet Infectious Bronchitis New Zealand (IBNZ) ‘A’ Strain Vaccine (A004552), is nearing an end of manufacturing and ACVM registration for a replacement vaccine is being sought to secure future supply and avert a welfare risk to the industry. The replacement vaccine to be registered, Poulvac Bron Vic S made by Zoetis USA, is closely related to the current Pacificvet IBNZ ‘A’ vaccine.

Section 38I of the HSNO Act provides for a rapid assessment of applications seeking the release of qualifying organisms, where a qualifying organism is a new organism that is or is contained in a veterinary medicine. Release under section 38I of another IBV vaccine strain (Massachusetts serotype, #1263 strain) in the form of the vaccine known as Poulvac IB MM or Zoetis Bron-Mass vaccine, was approved by the EPA on the 6th March 2015 (APP202377) with controls. This Staff Assessment Report considers the current application against the criteria set out in section 38I of the Act as a qualifying organism.

The dosage of the Poulvac Bron Vic S live attenuated vaccine and routes of administration (via drinking water, eye drop or aerosol) is highly unlikely to have significant adverse effects on the health of the public or any valued species.

It is highly improbable that the Poulvac Bron Vic S could form an undesirable self-sustaining population and would have significant adverse effects on the health of the public, or any valued species, or natural habitats, or the environment.

We recommend the application be approved subject to the proposed controls.
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1. **This Document**

1.1. This Staff Assessment Report has been prepared by EPA staff to assist the decision-maker in considering application APP203065. It contains information from the applicant, and other readily available sources. It also sets out the criteria for considering the application under the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act).

2. **The Application**

2.1. The applicant, Pacificvet Limited, seeks approval to import and release Avian Infectious Bronchitis Virus (Vic S strain) contained within a live attenuated vaccine for infectious bronchitis (IB), for use in commercial flocks of layer and broiler chickens.

2.2. The application was formally received on the 15th December 2016, under section 34 of the Act, seeking approval for release or release from containment a new organism.

2.3. The current stock of Pacificvet IBNZ ‘A’ strain vaccine is becoming unavailable as the master seed virus used for production has become non-viable for further vaccine production.

2.4. The applicant intends to supply the closely related vaccine Poulvac Bron Vic S at multiple commercial poultry farms throughout New Zealand where lyophilised live attenuated vaccine will be stored, transported and used in accordance with the manufacturer’s instructions.

**The Organism**

2.5. The organism to be assessed is: Avian Infectious Bronchitis Virus (Vic S strain)

2.6. Order: Nidovirales, Family: Coronaviridae, Subfamily: Coronavirinae
Genus: Gammacoronavirus, Species: Avian coronavirus
Accepted common name: Avian Infectious Bronchitis Virus (Vic S strain).

2.7. Other coronaviruses within this genus are known to infect turkeys, ducks, pheasants, teal and geese, as well as Beluga whales and bottlenose dolphins (Reddy et al, 2015; Jackwood and de Wit, 2013).

2.8. The organism constitutes a live attenuated vaccine known as the Poulvac Bron Vic S made by Zoetis USA as a bespoke product for Australia.

3. **Background**

**Infectious Bronchitis Virus**

3.1. IBV is an enveloped, single stranded, positive-sense RNA virus with a genome length of approximately 27.6 kb and contains at least 10 open reading frames (Reddy et al, 2015; Cavanagh, 2007).

3.2. IBV has a high mutation frequency with genetic diversity generated by point mutations, insertions, and deletions in the genome and through genetic recombination, all of which occur naturally during viral
replication (Cavanagh, 2007). Recombination amongst IBV populations plays a major role in generating new genetic types and strains of the virus (Thor et al, 2011).

3.3. IBV exists in many different antigenic and genotypic forms known as variants with some geographically widespread and others more geographically restricted (Sjaak de Wit et al, 2011). Australia and New Zealand have their own indigenous IBV variants through geographical isolation (Valastro et al, 2016; Ignjatović J and Sapats S, 2000).

**IBV-associated disease**

3.4. Infectious bronchitis (IB) is a significant infectious disease in chickens worldwide. It is ubiquitous in countries where chickens are reared intensively, and is a major cause of economic losses in the poultry industry. Although primarily a respiratory pathogen, IBV can also infect epithelial cells in the kidney, oviduct and gastrointestinal tract and manifests itself as respiratory, reproductive or renal disease. IBV infections often increase susceptibility to secondary bacterial infections or increase the damage caused by primary respiratory pathogens (McLachlan, 2016; Awad et al, 2014; Jackwood and de Wit, 2013).

3.5. There is extensive antigenic variation, and variation in virulence and tropism between isolates of IBV from different geographic regions. Different strains present a variety of clinical manifestations ranging from respiratory disease and reproductive disorders, to nephritis (inflammation of kidneys) and poor egg production and quality. In IBV-infected flocks, the morbidity rate (disease incidence) can reach 100%, but the mortality rate depends on factors including the virulence of the strain, presence of secondary infections, flock age, immune status, management and environmental factors (Awad et al, 2014; Jackwood and de Wit, 2013).

3.6. IBV has an incubation period of 24 to 48 hours, and viral spread occurs rapidly among chickens in a flock by aerosol and mechanical means. During the acute phase of disease, the virus is shed into the respiratory tract, and subsequently into the environment by coughing birds. Virus is also shed in faeces, where it can survive for long periods. Contact with infected chickens is the most likely source of infection, along with faeces, feed and drinking water contaminated by faeces. Contaminated litter, footwear, clothing, utensils, equipment and personnel are also potential sources for indirect transmission (Awad et al, 2014; Ignjatović and Sapats, 2000).

3.7. The signs of IB include: coughing and snicking (upper respiratory clicking noise); nasal discharge; depression; reduced quantity and quality of eggs; silent layers (layers with underdeveloped oviducts, which appear normal but do not lay eggs); acute mortality due to gout related kidney infection and failure; condemnation due to secondary *Escherichia coli* infections (Awad et al, 2014; Jackwood and de Wit, 2013).

3.8. IBV is listed by the World Organisation for Animal Health (OIE) as a notifiable terrestrial disease. The OIE consider that ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.
3.9. New IBV types, subtypes and variants, whether the result of mutations, recombination, or both, continue to emerge, making control of IBV extremely challenging (Jackwood and de Wit, 2013).

IBV in New Zealand

3.10. Current knowledge of IBV in New Zealand is dated. It has been noted that contemporary epidemiologic study is necessary to provide information on which to base current decisions on IBV control (McLachlan, 2016). In comparison to other countries, there are relatively few variant IBV strains in New Zealand.

3.11. IBV was first detected in New Zealand in the 1960s, and four serotypes (A, B, C, and D) were subsequently isolated and described as distinct from those present in other countries (Lohr, 1977 and 1976). The viral strain ‘A’ was subsequently developed as a vaccine using an attenuated wild type ‘A’ strain by Juergen Lohr that has been historically in use in New Zealand (Bernardi, 2008).

3.12. A molecular comparison between these historical strains and four further field strains (K32, K43, K87 and T6) present in New Zealand showed a restricted genetic range with a high level of sequence similarity between the New Zealand strains and the Australian Group I strains (which includes the Vic S strain), suggesting the New Zealand strains represent a distinct geographical isolate that may have been introduced from Australia or vice versa (McFarlane and Verma, 2008; Valastro et al, 2016).

3.13. The IBV strains found in New Zealand are considered different from those found in other countries, particularly as they are not as virulent as the “classic” or virulent strains that affect the poultry industry elsewhere (Bernardi, 2008). The respiratory effects of New Zealand field strains appear to be mild, which is consistent with the experimental observations, but severe uraemia (urea in blood) has been observed in chicks that were deliberately chilled following inoculation with some isolates (Howell, 1992). The effects of IBV on commercial layers in New Zealand are primarily on egg number and egg quality (Bernardi, 2008).

3.14. The main serotypes and virulent strains that are found in many other countries are not found in New Zealand. Consequently exotic strains of IBV are listed as unwanted organisms under the Biosecurity Act (1993) (Date determined 1998-08-21).

3.15. A HSNO Act approval for the importation into containment of exotic vaccine strains of IBV was granted in 2007 (Application NOC07004). The approval was required to fulfil Ministry for Primary Industries (MPI) requirements to enable a live attenuated IBV vaccine to be imported into containment in New Zealand, for export to Fiji and other Pacific nations.

3.16. A HSNO Act approval for the importation and release with controls of an IBV live attenuated virus of for another IBV vaccine strain (Massachusetts serotype, #1263 strain) in the form of the vaccine known as Poulvac IB MM or Zoetis Bron-Mass vaccine, was given by the EPA on the 6th March 2015 (APP202377).
3.17. An inactivated (dead) IBV vaccine is also registered for use in New Zealand (ACVM A8021) based on a Massachusetts serotype. Live attenuated vaccine can be used to “prime” the flock before the use of an inactivated viral strain for long lasting immunity (Bernardi, 2008).

3.18. In contrast to other countries where the number of IBV variants makes control of IBV infections a complex and evolving target, New Zealand has a relatively limited number of viral strains resulting in control measures significantly different from elsewhere in the world (McLachlan, 2016; Bernardi, 2008).

Host range of IBV

Farmed birds

3.19. Within the genus Gammacoronavirus, chickens are the primary and most significant hosts of IBV, and all ages of chickens are susceptible, but the disease is most severe in chicks (Jackwood and de Wit, 2013). Chickens are not the only host for IBV, although it is possible that IBV may only cause disease in this species (Jackwood and de Wit, 2013; Cavanagh, 2007).

3.20. Farmed pheasants and turkeys have also been shown to be natural hosts of IBV-like coronaviruses; it is possible that certain strains of IBV are able to infect farmed pheasants (Jackwood and de Wit, 2013; Ignjatović and Sapats, 2000).

Wild birds

3.21. The role of wild birds in the persistence and spread of IBV is unknown. Wild birds may act as reservoirs and long-distance vectors of Gammacoronaviruses including IBV, and IBV-like viruses (Quinteros et al, 2016, Jackwood and de Wit, 2013). The impact of live attenuated poultry vaccines and the spillover to wild bird populations is increasingly recognised as an area that requires more research (Devlin et al, 2016).

3.22. A three-year study of the role of wild birds as reservoirs for avian coronaviruses in Korea found coronavirus in 14 waterfowl of 1473 individual birds tested, but concluded that the coronaviruses they isolated were genetically distinct from IBV (Kim and Oem, 2014). A study of IBV-like coronaviruses in wild birds in Poland found a 3.5% incidence of coronaviruses, with the virus detected in ducks, geese, mute swans, gulls and pheasants (Domanska-Blickarz et al, 2014).

3.23. A study of avian coronaviruses in wild bird populations in England examined 441 birds of 42 species; and found coronavirus associated with wildfowl and waders, noting that the birds associated with coronaviruses appeared healthy (Hughes et al, 2009). An investigation into the prevalence of avian respiratory disease including IBV in Burkina Faso, found no IBV in the small number of wild birds studied (Tarnagda et al, 2011).

Non-avian species

3.24. Non-avian species are not susceptible to natural infection with IBV, and there is no record of IBV infecting a non-avian species naturally. Avian Infectious Bronchitis has no known human health
significance (Jackwood and de Wit, 2013). Under experimental conditions, suckling mice, rabbits and guinea-pigs have been infected through intra-cerebral inoculation (Ignjatović and Sapats, 2000). A primate cell line (Vero) has been experimentally infected with IBV (Beaudette strain) and propagated, and the adapted strain shown to be capable of further propagation in human liver and lung cancer cell lines (Tay et al, 2012).

Control of IBV

3.25. Vaccination is the only practical means of controlling IBV and it is used around the world in the intensive poultry industry although the nature of IBV and its high rates of recombination and mutation make this a particularly difficult task (Jackwood and de Wit, 2013; Ignjatović and Sapats, 2000).

3.26. Other control methods such as exclusion have not been successful, however flock management methods such as ’all-in/all-out’ operations, cleaning and disinfection between batches are actively used to minimise infection rates. Breeding to increase resistance is not practised, although infection outcomes may differ between different chicken lines (Ignjatović and Sapats, 2000).

IBV Vaccines

3.27. The generally accepted strategy for control of IBV is to use vaccine strains that are similar to those found in a particular geographic area. However this is not always possible as there may not be vaccines available for the prevalent strains (Awad et al, 2014).

3.28. The emergence of variant strains of IBV, through mutation and recombination, means that vaccination programmes employed by the poultry industry have not eliminated the disease. There are a range of vaccines available. The most frequently used vaccines are based on Massachusetts (Mass) strains (Ignjatović and Sapats, 2000), and many countries only allow live vaccine strains of the Massachusetts type (OIE, 2013). However new vaccines are becoming available as new variant strains become predominant, and in some cases vaccines containing multiple IBV serotypes are used.

3.29. Live attenuated vaccines represent IBV strains that have been passaged in embryonated chicken eggs, or thermally treated, to achieve a reduction in virulence for the respiratory tract; the resulting vaccine can be mild or virulent depending on the level of attenuation (OIE, 2013).

3.30. It has been noted that “The use of live attenuated vaccines carries a risk of residual pathogenicity associated with vaccine back-passage in flocks. However, proper mass application will generally result in safe application of live vaccine” (OIE, 2013).

3.31. Furthermore, the indiscriminate use of live vaccines, especially other exotic variants not previously present is strongly discouraged (Ignjatović and Sapats, 2000), and it has been suggested that live vaccines from other parts of the world should not be introduced if prevailing endemic strains are of a different serotype or genetic lineage.

3.32. Genetic recombination of vaccine strains and wild type strains can occur (Thor et al, 2011; Wang et al, 1993). Therefore it is best practice to mass-immunise (mass application) all chicks in a flock. 
concurrently, to minimise ‘back passaging’ of the vaccine virus, thus reducing the potential for recombination or reversion to virulence (Ignjatović and Sapats, 2000; OIE, 2013). In addition, vaccination using the manufacturer’s recommended dosage will help reduce the potential for back-passage reversion that can result from fractional dose application (OIE, 2013).

3.33. Inactivated vaccines are usually given after “priming” with a live vaccine. They are used in layers and breeders, administered by subcutaneous inoculation at 13 to 18 weeks of age, and in pullets that have been previously primed with a live vaccine. They provide high and uniform levels of antibodies that persist for longer, and protect against a reduction in egg production (Ignjatović and Sapats, 2000).

The Vic S strain IB vaccine

History and use of Vic S in Australia

3.34. The first IBV vaccine produced and used in Australia was the ‘Vic S’ vaccine since the recognition of IBV in Australian chicken flocks in the 1960s and was developed from a field strain that caused renal and respiratory disease in young chickens (Hewson et al, 2012).

3.35. Pacificvet is proposing the introduction of the live attenuated vaccine Poulvac Bron Vic S for use by the New Zealand poultry industry. The vaccine is derived from an Australian strain of IBV and attenuated by serial passage in embryonated eggs. A vaccine master seed was established at passage 38. Its continuing supply is unlikely to be an issue. The vaccine is currently registered by Zoetis Australia Pty Ltd for use in Australia (APVMA Product Number: 39006).

3.36. The bespoke vaccine was selected by Pacificvet because it is widely used in Australia and the vaccine is most closely related to the IBNZ ‘A’ strain (Valastro et al, 2016; Macfarlane and Verma, 2008). The New Zealand ‘A’ vaccine strain used for the currently registered vaccine, shares 99.5% nucleotide and 98.7% amino acid homology with the Vic S strain as determined by sequence analysis of the S1 glycoprotein gene (Verma and McFarlane, 2008). This would suggest that that the New Zealand strains may have been introduced from Australia or vice versa.

3.37. The applicant considers that the use of a live attenuated vaccine strain is unlikely to cause the emergence of a more virulent or resistant strain due to the recommended entire flock vaccination programme and mass application techniques (OIE, 2013) recommended by Pacificvet Limited.

3.38. The vaccine is also considered to be safe and of a low virulence having been attenuated through 38 passages to create the master seed bank. Since 2005, more than 350 million doses of the vaccine have been used in Australia (see Application section 6.4). Live IBV vaccines are required to pass the safety test set out by the OIE, requiring chickens to be inoculated with 10 times the recommended dosage, and observed for 21 days, with no serious clinical signs or deaths from causes attributable to the vaccine (OIE, 2013).

3.39. Live attenuated IBV is temperature sensitive, and will only survive for a few days at room temperature although longer periods at cooler temperatures have been reported (Jackwood and de Wit, 2013). It is
easily inactivated by common disinfectants such as 70% ethanol, chloroform, or 1% phenol; and is more stable at low pH than high pH (Ignjatović and Sapats, 2000).

3.40. The applicant notes (section 6.4) that there is no evidence that the vaccine strain remains viable in the environment to provide repeat exposure to the vaccine strain, there is no evidence of spread of the vaccine strain to non-vaccinated birds, and there is no record of the Vic S vaccine strain being shown to mutate and recombine with field strains.

3.41. The applicant notes (see Section 3.1) that the affinity of the Vic S strain vaccine to the various field strains in New Zealand is not precisely known although the close genetic relationship between the currently registered and effective Pacificvet Infectious Bronchitis NZ ‘A’ strain vaccine and the Vic S strain would suggest that the Poulvac Bron S Vic S vaccine is assumed to be similarly effective.

3.42. Given the very unlikely situation of a reversion to virulence of the live attenuated vaccine or that the vaccine did mutate or recombine with a wild type strain, the applicants have noted that it is likely the original vaccine would remain effective (Section 5).

Potential for recombination

3.43. Phylogenetic evidence is emerging that live attenuated viruses used in the poultry industry (including IBV) are resulting in recombined wild type and vaccine viruses (Devlin et al, 2016).

3.44. A recent Australian study provides preliminary evidence that recombination events occur between wild type IBV strains, the Vic S vaccine strain and another unknown avian coronavirus (Quinteros et al, 2016). Next Generation Sequencing of the whole genome of IBV strains in Australia, rather than the S1 gene commonly sequenced, was undertaken and a comparative study indicated that it is likely that IBV vaccine strains may have played a significant role in inter-clade recombination events in Australia that have occurred multiple times. This study raised the possibility that, due to the high reliance on live attenuated vaccines in Australia, there is a high probability that co-infection with a field strain and a vaccine strain could occur that would allow for such recombination events.

3.45. Molecular analysis comparing S1 genes among early IBV isolates from New Zealand and more recent field isolates indicated that it was possible that the isolates of one group may have been derived from the attenuated vaccine strain in use in New Zealand at the time (Ramneek et al, 2005).

4. Consultation with Māori (Kaupapa Kura Taiao)

4.1. The application was reviewed by Kaupapa Kura Taiao (KKT) at the EPA and the following advice was provided dated 8th December 2016.

4.2. The application was broadly consistent with the principles of Manaakitanga (due care and protection), and in the context of the application, caring for and protecting the health and well-being of chickens, people and the environment because:

- releasing Poulvac Bron Vic S will enable poultry farmers to protect their flocks against IBV
Poulvac Bron Vic S shares close whakapapa and whanaungatanga (familial origins and relatedness) with the currently used Pacificvet IBNZ ‘A’ strain i.e. they are closely related.

- no adverse impact on taha hauora (human health and well-being) are anticipated as a result of releasing the Poulvac Bron Vic S vaccine
- no culturally significant species are likely to be adversely affected by the release of the Poulvac Bron Vic S vaccine, in particular native birds
- the Poulvac Bron Vic S vaccine is an effective replacement as the Pacificvet IBNZ ‘A’ strain vaccine is no longer available and another IBV vaccine is required to maintain health of poultry flocks,
- the risk of not vaccinating is significant, potentially resulting in a substantial reduction in productivity and animal welfare
- potential losses from not vaccinating chickens against IBV are likely to be economically and socially detrimental for those working in the poultry industry, some of whom are Māori.

4.3. The KKT advice also recognised that:

- the risk of creating a more virulent or resistant strain is low
- risk can be further addressed by reducing the number of chickens persistently affected by IBV
- the original vaccine strain will remain effective even where mutation might produce a more virulent strain.

4.4. An overall assessment of the application information provided by KKT concludes that risks to Māori culture or traditional relationships with the environment should be negligible. Furthermore, the release of the Poulvac Bron Vic S vaccine is unlikely to breach the principles of the Treaty of Waitangi, including the principle of active protection.

5. Supporting Information from the Poultry Industry

5.1. Comment was received in support of this application from the Egg Producers Federation (EPF) and the Poultry Industry Association of New Zealand (PIANZ). These two organisations collectively represent 99% of poultry producers in New Zealand.

5.2. In a letter to Pacificvet Limited dated 6th Dec 2016, PIANZ highlighted that PIANZ veterinary members supported the request to import the live Poulvac Bron Vic S Infectious Bronchitis (IB) attenuated vaccine.

5.3. It also noted that:

- the inability to source a constant reliable supply of the existing live IBNZ strain A vaccine places meat chicken breeders, layers and layer breeders at risk of IBV infections
- the poultry veterinarians have considered the risk of importing live vaccine strains that are not identified in New Zealand, and balanced this against the inability to vaccinate New Zealand poultry. In their view, the risks to the poultry industry (welfare and production) from having no vaccination available for IBV outweigh those of having a not-identified strain of IBV present in New Zealand for use as a vaccine.
after extensive use of the vaccine (many millions of doses), the vaccine has not reverted to virulence or recombined to produce a more virulent strain of IBV, from the Australian experience with Poulvac Bron Vic S

- there is a close phylogenetic relationship between the Australian 'Vic S' and the New Zealand 'A' strains.

6. **Information from other Agencies**

6.1. The Department of Conservation (DOC) and the Ministry for Primary Industries (MPI) were given the opportunity to comment on the application.

6.2. DOC noted that feedback would be provided by their veterinarian if there were specific concerns. No response was received within the assessment timeframe.

6.3. No response from MPI was received during the assessment timeframe for this application. MPI has previously noted on a similar application (APP202377), that Ignjatović and Sapats (2000) recommended “strong considerations should be given to measures to restrict the introduction of exotic IBV variants” as an incursion of unrelated IBV strains would impact on the vaccines needed to control the disease. Introduction of new IBV variants would also increase the pool of genetically different viruses that circulate on a site, increasing “the likelihood of generating new and more variable strains through processes such as recombination” (Ignjatović and Sapats, 2000).

6.4. MPI is also reviewing the vaccine as required by its responsibilities under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, and the Biosecurity Act 1993.

7. **Legislative criteria for consideration**

The HSNO Act (1996) Section 38I

7.1. Section 38I of the Act provides for a rapid assessment of applications seeking the release of qualifying organisms, where a qualifying organism is a new organism that is or is contained in a veterinary medicine1.

7.2. In order to be approved for release as a qualifying organism, section 38I(3) of the Act requires that the decision maker be satisfied that, taking into account all the controls that will be imposed (if any), it is highly improbable that:

(a) the dose and routes of administration of the veterinary medicine would have significant adverse effects on-

(i) the health of the public; or

(ii) any valued species; and

(b) the qualifying organism could form an undesirable self-sustaining population and would have significant adverse effects on-

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1 As defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997.
(i) the health and safety of the public; or
(ii) any valued species; or
(iii) natural habitats; or
(iv) the environment.

7.3. In the first instance we have assessed the organism against these criteria. This assessment is set out in the following sections of this report.

7.4. If the organism does not meet these criteria, the applicant may request that the application be considered under section 38, or section 38A.

Other approvals required

7.5. Section 38I(5) of the Act specifies that an approval granted under section 38I is not an approval to use a qualifying veterinary medicine until the veterinary medicine has been approved for use under the Agricultural Compounds and Veterinary Medicines Act 1997. As noted by the applicant, the vaccine is yet to be approved by ACVM as it is waiting for EPA approval. The vaccine will also be subject to controls imposed by ACVM for a vaccine, initially on an emergency release regime (Special Use Authorisation) and then full registration (refer to section 6.1 of the application).

7.6. We also note that the vaccine may trigger requirements under the hazardous substance provisions of the HSNO Act, and the Biosecurity Act.

8. Is the organism a veterinary medicine?

Agricultural Compounds and Veterinary Medicines Act 1997

8.1. The organism is the main constituent part of a vaccine called Poulvac Bron Vic S, produced by Zoetis Animal Health USA. This product is a veterinary medicine as defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997, as it is a biological compound intended for use in the direct management of poultry.

8.2. The organism Avian IBV, a live attenuated virus, is the active ingredient in a vaccine known as Poulvac Bron Vic S made by Zoetis Animal Health USA. ACVM has indicated that this product is a veterinary medicine as defined in section 2(1) of the ACVM Act. Veterinary medicine means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal. A previous application (APP202377) for release as a qualifying organism of an avian IBV vaccine known as Poulvac IBMM or Zoetis Bron-Mass, has been approved. As such, the Poulvac Bron Vic S is a qualifying organism and may be assessed under section 38I of the Act.

Dose and routes of administration

8.3. The vaccine can be administered to birds from one day in age by intranasal (inhaled into nasal cavity), intraocular (drops into eye) or by spray (directly above the birds) methods. It can also be administered in drinking water for birds from two weeks of age.
8.4. It is recommended that a control be imposed requiring that the vaccine only be administered at the dose rate recommended by the manufacturer, and that all chicks in a flock, or on a farm, be vaccinated simultaneously/concurrently (mass application). This will reduce the potential for the vaccine strain to spread to unvaccinated chickens, and reduce potential for mutation or recombination with wild-type strains of IBV (OIE, 2013), and will cement current best practice in New Zealand.

9. Potential adverse effects of the vaccine

Adverse effects on the health and safety of the public

9.1. Avian infectious bronchitis has no known human health significance (Jackwood and de Wit, 2013) and IBV is not known to pose any human health risk, and there have been no reports of human infection with IBV (OIE, 2013). Ignjatović and Sapats (2000) report that no evidence exists to suggest that humans act as a reservoir for active replication of IBV and no evidence has been found of transmission from human to human or human to animal.

9.2. The manufacturer’s Safety Data Sheet (Zoetis Australia Pty Ltd, Australia), indicates that the vaccine is classified as non-hazardous and outline AS/NZS standards for use of safety equipment and personal protective equipment during application.

9.3. It is highly improbable that the dose and routes of administration of the vaccine would have significant adverse effects on the health and safety of the public.

9.4. It is highly improbable that the vaccine could form an undesirable self-sustaining population and would have significant adverse effects on the health and safety of the public.

Adverse effects on any valued species

Through the intended dose and routes of administration

9.5. IBV-associated disease has only been recorded in chickens, and no adverse effects have been reported from the intended use of this vaccine.

9.6. The vaccine is intended to be administered to poultry in the form of a vaccine to protect against IBV-associated disease. This vaccine is widely in use in Australia.

9.7. Vaccination of commercial poultry for IBV using a combination of live attenuated and inactivated vaccines is standard practice in New Zealand (Bernardi, 2008). The applicant has noted (see section 5 of the application) that the vaccination programme will reduce the likelihood of an undesirable mutation or recombination by reducing the number of chickens that harbour persistent infections of IBV.

9.8. It is highly improbable that the dose and routes of administration of this vaccine will have significant adverse effects on any valued species.
Through establishment of an undesirable self-sustaining population

9.9. Chickens are a valued species in New Zealand; they are reared commercially for meat and egg production, and non-commercially in ‘backyard flocks’. As noted above, chickens are the only known natural, susceptible host of IBV, and it is highly improbable that the intended use of the vaccine will result in adverse effects to those chickens treated with the vaccine.

9.10. There is potential for the vaccine strain of IBV to mutate, or recombine with circulating field strains of IBV. Mutation of the vaccine strain, similarly with mutation of wild-type field strains, could result in a more virulent variant of IBV. There is also potential for the vaccine strain to spread to non-vaccinated birds, providing an environment where mutation or recombination is more likely to occur.

9.11. A more virulent IBV strain could cause adverse effects on commercial and domestic chicken, such as clinical disease which has animal welfare consequences. Sub-standard hygiene, reutilisation of old litter and improper use of vaccines can create an environment that promotes mutations and recombination. These conditions do not occur in the New Zealand poultry industry (see Section 5 of application).

9.12. Proposed control 2 requires that the vaccine only be used in accordance with OIE best practice including concurrently vaccinating all animals on site at the dosage recommended by the manufacturer. These precautions reduce the potential for back-passaging of the virus, and the subsequent potential for mutation or recombination.

9.13. There is also potential for the vaccine to spread to wild birds, who could act as vectors or reservoirs for the virus, or as a source of genetic material for recombination. There is no evidence to indicate that acting as a reservoir results in significant adverse effects on wild birds. In addition, proposed control 2 reduces the potential for spread to wild birds.

9.14. Given that IBV-associated disease is not known in non-avian species, we have not identified any potential adverse effects on valued non-avian species.

9.15. Taking into account the proposed controls, it is highly improbable that the vaccine could form an undesirable self-sustaining population and would have significant adverse effects on valued species.

Adverse effects on natural habitats and the environment

9.16. IBV has only been recorded as causing disease in chickens; there is no known potential impact from these diseases on natural habitats or the wider environment.

9.17. It is highly improbable that the vaccine could form a undesirable self-sustaining population and would have significant adverse effects on natural habitats or the environment.

10. Recommendation

10.1. We recommend that this application to release from containment and/or import for release Avian infectious bronchitis virus (Vic S strain) be approved subject to the following controls:
Control 1  The organism may only be released in the form of the vaccine known as Poulvac Bron Vic S vaccine.

Control 2  The vaccine must be used in accordance with OIE best practice including concurrent vaccination of all animals on site, at the dosage recommended by the manufacturer.

10.2. We have consulted with the applicant on the proposed controls, and they indicated that the controls are consistent with current practice.
11. References


Zoetis Australia Pty Ltd. Safety Data Sheet: Poulvac Bron Vic S
