Q Fever Risk Management Plan for proposed intensive dairy goat farms, 715 Geelong-Ballan Road, Moorabool, VIC 3221 and 240 Forest Road South, Lara, VIC 3212

Prepared for:

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Summary:

This risk assessment and management plan was prepared for Nuchev Pty Ltd to address the risks of *Coxiella burnetii* infection on the proposed dairy goat farm on Ballan Road, Moorabool and the proposed farm and milk processing plant on Forest Road South, Lara and potential for spread to the surrounding area.

The review considered the information contained in the detailed EPA Works Approval and EPA Works Approval Pathways Applications, other information provided in meetings with Nuchev representatives and related to the planned operation and infrastructure of the proposed properties, papers in the peer-reviewed scientific literature, an unpublished PhD thesis, fact sheets and recommendations from government health and agricultural agencies internationally, and the experiences of the reviewer and his colleagues with this infection on other properties and establishments in Victoria.

It is accepted as a starting point that at least a small proportion of the goats entering these properties will already be infected with *C. burnetii*. It is also accepted that a small proportion of the domestic animals, wildlife and feral animals in the state are already infected with *C. burnetii.* This is regarded as reflective of the prevailing situation in the state and is considered the background risk for human infection.

The risk management plan is designed from the perspective that reduction of risks on the properties will reduce the risk at the boundaries of the properties to no higher than that already existing in the state so that buffer zones are not required. For the movement of vehicles containing potentially contaminated material off the property, the risk is managed to ensure that it is contained within the vehicle.

The assessment of risk and the risk management recommendations for the proposed goat farms are considered in three categories:

- The risk of infection entering the properties with the introduced goats and by intrusion of wildlife or feral animals onto the farm sites,
- The risk of human infections occurring on the properties and the risk of a build up of infection in the goat flocks and the environment of the proposed properties, and
- The risk of infection spreading off the properties to the surrounding areas.

In addition to implementation and auditing of the risk management measures proposed in this report, the level of infection on the properties will be monitored by regular, frequent testing of bulk milk for the presence of *C. burnetii* DNA and by investigating any abortions that occur. This will provide early warning and permit prompt identification of any increase in infection above baseline levels so that appropriate action to mitigate can be formulated by the Review Panel and implemented by Nuchev in advance of any increased risk developing to the community.

If adopted, the risk management measures proposed are expected to ensure that the risk of operating on these sites presents at worst, no higher risk of human infection in the surrounding area than the current background level within the state. The additional safeguard of regular monitoring of infection level will permit early detection and response to any variation from this background level.

Introduction:

This risk management plan was prepared to address the potential risks of the proposed goat dairy enterprises acting as a source of *Coxiella burnetii* for human infections leading to Q fever in humans either within or outside the farms.

Q fever is a zoonotic disease of humans. Infection with the causative agent, *C. burnetii*, occurs in a wide range of animal species and is widespread throughout the world with the exception of New Zealand. Although many animal species are susceptible to infection with *C. burnetii,* human infection is most often associated with direct or indirect contact with goats, sheep and cattle. Other animal species including dogs, cats, horses, rabbits and native Australian wildlife may also be infected and recent surveys of feral animals and native wildlife in Queensland and Western Australia indicate serological evidence of recent infection ranging from about 7 to 40% (e.g. 43.8 % foxes and 38.7% feral cats in Queensland, 30.4% macropods in northern Queensland but 13% in southern Queensland; in the south west of Western Australia 22.8% of macropods were serologically positive).

Q fever was first recognized as a novel infectious entity in abattoir workers in Queensland in the 1930s and most human infections in Australia are recorded in Queensland and northern New South Wales. Victoria accounts for only about 7% of human infections recorded each year. Human infections typically occur in recognized at-risk occupational groups with animal contact such as abattoir workers, shearers, veterinarians and farm workers. The accepted route of human infection is by inhalation of infected aerosols containing *C. burnetii* when unvaccinated people are working in close proximity to infected ruminants or handling their contaminated bedding, especially after the ruminants have been giving birth or aborting and discharging infected tissues and fluids into the environment. However, some infections occur outside these recognized higher risk occupations and are associated with airborne spread of the agent over some distance, or with contaminated inanimate objects ('fomites') such as farm workers' clothing. Direct human-to-human spread is not usually considered significant although a couple of reports of human infection have been attributed to spread in infected semen.

Infection of domestic ruminants is often sub-clinical although infertility and abortions may be observed. Infected ruminants shed *C. burnetii* in faeces, urine, milk and semen but most shedding of the infectious agent is associated with the placental tissues and birth fluids at the time of parturition and more particularly if abortion occurs. Abortions in *C. burnetii* infected ruminants, which typically occur in the last month of gestation, are regarded as the most important situation for shedding of infectious organisms. The level of excretion is believed to be less for birth of healthy kids, calves and lambs. In the case of abortions, the concentration of *C. burnetii* in placental tissues may be up to 10^9 infectious organisms per gram of tissue. In this context it is important to note that the infectious dose for humans via the respiratory route is only 1 to 10 organisms.

C. burnetii is an obligate intracellular bacterium. That is, it can only replicate within the living cells of an animal host. Once shed from an infected animal into the environment it can no longer replicate but it can persist in an infectious form for many months particularly in dry, dusty conditions.

It is several decades since a survey of Victoria cattle found a very low prevalence of serological evidence of infection (less than 1%) and it has been assumed that most instances of human infection in Victoria in the intervening years have resulted from contact with ruminants imported into the state from northern states. This assumption is supported by recorded outbreaks in Victorian abattoir workers in association with slaughter and dressing of ruminants that have been brought into Victoria from the northern states. However, some more recent instances of Q fever in Victoria have had no such association and appear to have been acquired from on-farm contact with ruminants that have spent all their lives in Victoria. There is presently no published information on serological prevalence of infection in native or feral animals in Victoria.

Whereas the available evidence suggests that the prevalence of infection in Victorian domestic and free ranging animals is lower than in equivalent animals in the northern states, it is reasonable to assume that infection is present in Victorian animals and, under appropriate ecological conditions that favour transmission between infected and susceptible animals, the prevalence of infection could significantly increase. One such situation would be intensive farming of ruminants with several reproductive cycles in a year. For example, an outbreak of Q fever cases in farm workers occurred on a sheep and goat property in Victoria that had four reproductive cycles per year and was not at the time implementing a risk management plan. This ensured almost a continuous supply of susceptible goat kids that were being exposed to *C. burnetii* and led to an increase in the proportion of the herd that was infected. Although the Nuchev properties will only have two reproductive cycles per year and any increase in the prevalence of infected goats in the herd would be expected to be less or at least much slower, a 'worst case' approach is taken in this risk assessment and the management plan is designed to mitigate against any increase in proportion of infected goats and also to provide early warning of any such increase. It would be expected that the risk of transmission of infection to humans would increase in line with any increase in the proportion of the herd that is infected because of the presence of a more highly infected source of infected animals in a concentrated area, unless appropriate risk management procedures are implemented.

Although an intensive farming system would be expected to provide the ecological conditions to favour an increase in the proportion of infected animals on the enterprise, such a relatively contained farming system also provides opportunities to take actions to manage the risk of transmission of infection to humans working on the farm and to those in the surrounding area.

Risk assessment and management:

In conducting this risk assessment and risk management plan, the terminology and approach recommended by the World Organisation for Animal Health (OIE) is adopted. This requires hazard identification, risk assessment, risk management and communication of risk.

In addition to the above four components, the implementation of the plan will be audited and data collected during the herd establishment phase relating to the infection status of the goat herd (regular bulk milk testing plus abortion investigation). The results of the audits and the ongoing testing will be considered by a Review Panel, who will determine any changes that are required to maintain risk at the desired level in advance of any increased risk to the community.

In this risk management plan the following terminology is used to qualitatively categorise risks into likelihood categories.

Negligible	So rare that it does not merit to be considered
Very low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs often
Very high	Event occurs almost certainly

A. Hazard identification

The hazard is *C. burnetii* and the possibility of its presence in goats on the Nuchev properties (Ballan Road, Moorabool and Forest Road South, Lara) and subsequent transmission to humans on the properties or in the surrounding areas.

B. Risk Assessment and Management Plan

Since there is direct evidence that infection with *C. burnetii* is present in goats and cattle in Victoria and highly likely to be present in a range of wildlife species, there is always a background risk that humans may become infected. Even excluding the human infections that have occurred in recent years in persons working on a large goat and sheep dairy property in Victoria, there are still a number of cases that occur each year; about 7% of the total for Australia. It is therefore not reasonable to expect that a managed risk on this property should result in a level of risk to the surrounding community that is lower than background for people living in a rural area. In Victoria, the background risk of developing Q fever would be ranked as 'low' (i.e. rare but does occur).

The risk management plan recommended in this document therefore is designed to realistically reduce any identified risk of Q fever to no higher than 'low' and, where possible, to 'very low' (i.e. very rare but cannot be excluded). The risk management plan is designed from the perspective that

reduction of risks on the properties will reduce the risk at the boundaries of the properties to no higher than that already existing in the state so that buffer zones are not required. For the movement of vehicles containing potentially contaminated material off the property, the risk is managed to ensure that it is contained within the vehicle.

Additionally, the plan includes regular monitoring of the infection level in the goats on the properties to promptly detect any change from background level and to facilitate early response to mitigate any such change.

The risk assessments and risk management plans are considered in three categories.

1. Infection entering the properties: risk of the goats entering the properties already being infected or infected wildlife and feral animals coming onto the properties.
2. Infections occurring on the properties: risk of human infections amongst staff and visitors to the property and risk of increase in proportion of goats on the properties being infected, and
3. Risk of infection from the properties spreading to the surrounding neighborhood.

1. Risk of infection entering the properties in goats or in wildlife and feral animals.

Some serological testing has already been conducted on a portion of the embryo donor flock off-site and shown that about 2.15% were sero-positive. The embryo recipient goats are derived from feral populations and, although not tested, are highly likely to have at least the same rate of sero-positivity, possibly higher. Although not all goats that have serological evidence of past exposure will be shedding *C. burnetii*, the evidence is that infection is present in the population of goats that will, either themselves or their progeny, come onto the Nuchev properties.

A large number of goats (about 5000) have already kidded off-site, with only two observed abortions, both of which have been tested by the highly sensitive polymerase chain reaction (PCR) and the presence of *C. burnetii* has not been detected in either case.

It is almost certain that there will be some infected goats entering the properties, even though the proportion of infected goats entering the properties is not expected to be very high. However, the risk that some of the goats entering the properties are already infected and shedding *C. burnetii* is considered to be 'very high'.

A number of tick species have been shown to carry infection in Australia and they may play a role in transmission between animals but are not regarded as significant in spread to humans.

A number of risk management actions have been considered to see whether only non-infected goats could be selected to enter the properties as detailed following.

- Serologically test all goats and cull those positive. This is not a feasible option because not all infected goats will be detected by the serological tests available; some infected goats will give negative reactions in the serological tests.
- An alternative approach of PCR or cultural testing is not reliable because infected goats do not always shed organisms in detectable amounts all the time.
- A number of repeated cycles of serological testing would be required to detect those goats that become infected just before or after the previous test.
- Even if a serologically negative flock could be produced there is still the possibility of infection entering the flock e.g. by contact with wildlife or pasture contaminated with faeces, urine and birth products of native or feral animals.
- Vaccination of whole flock. At present there is no vaccine available for goats in Australia (However see recommendation regarding monitoring vaccine availability at the end of this section). The vaccine available in Europe is believed to have little effect on reducing shedding if administered to goats that are already infected but to significantly reduce shedding if administered before challenge.

It is concluded that it is not presently feasible to source only proven uninfected goats for the properties. Even if this were possible there remains the possibility of infection entering the flocks from other animals (e.g. infected wildlife or feral animals that may enter the site). Therefore a number of risk management actions are proposed, as follows below, to monitor the reproductive health of the flock and to reduce transmission from infected to uninfected does in the flock thus keeping the proportion of the flock infected no higher than background level.

<u>Recommended risk management actions for goats being prepared to enter the properties:</u>

- Continue to investigate abortions as they occur and test for presence of *C. burnetii* in fetus and placenta by PCR.
- Remove products of abortion in sealed containers (e.g. sealed, leak-proof plastic bags) and dispose of as potentially infective waste (e.g. by burial, incineration, thermophilic composting).
- If *C. burnetii* detected or if the percentage of abortions rises above 5% of pregnant does, then convene the Review Panel to decide on response.
- Regularly inspect goats for presence of ticks and, in the unlikely event that they are detected, seek off label approval for use of a suitable acaricide.

A further possibility for infection entering the properties on Ballan Road and Forest Road South is with wildlife or feral animals entering the sites. Surveys in Queensland, NSW and Western Australia indicate up to about 30% of kangaroos may be sero-positive for *C. burnetii*. No data is currently available for Victoria.

Recommended risk management for wildlife and feral animal intrusion:

Although no measure can guarantee to keep all wildlife and feral animals off the site the following will reduce the risk of entry.

- Erect secure fencing (diamond mesh or similar) around the boundary of the properties. Review for presence of wildlife on properties and consider adding a top electrified wire if needed.

Recommended monitoring of vaccine availability and usage

Although a goat vaccine is not currently available in Australia, there are two future possibilities that may change this situation. The Review Panel will consider and recommend on vaccine use if approval is given by the responsible authorities for importation and use of the European goat vaccine for *C. burnetii* infection. An application to import and use the European vaccine has been considered and rejected by the responsible authorities. No further application is currently in train.

When an isolate of *C. burnetii* is obtained in the laboratory from a goat on a Nuchev property, the isolate will be used to develop an autogenous vaccine and application made to the responsible authorities to use this vaccine in goats on the Nuchev sites. Note that an autogenous vaccine cannot be developed until an isolate is obtained from an animal in the herd in which the vaccine is intended to be used. See Appendix 1 for more details on development and approval of an autogenous vaccine. When an autogenous vaccine is developed it will be used to vaccinate all goats in the herd as soon as possible.

2. Risk of human infections amongst staff and visitors to the properties and risk of increase in proportion of goats on properties being infected.

The physical location of the properties and details of the construction of the goat farm units (GFUs) and milking parlour, milk processing plant, layout of infrastructure and the waste management systems are detailed in "EPA Works Approval Application: Goat Farm, 715 Geelong-Ballan Road, Moorabool, 3221 August 2015 and in "EPA works approval pathways application: Supporting documentation for goat milk drying plant, 240 Forest Road South, Lara, 3212. August 2015".

Risk assessment and management plan for human infection on the properties

Since a small proportion of the goat flock being established on the properties is expected to be infected with *C. burnetii* and two kidding periods will take place each year with the potential for shedding infectious organisms, there is considered to be a 'very high' risk, in the absence of appropriate risk

management procedures (specifically, appropriate testing and vaccination), for anyone working on the properties either as employees or regular visitors becoming infected. Risk may vary by the type of work done by the employees and visitors, particularly the amount of direct contact they have with goats and their excreta in the months around the kidding period. However, in a recent outbreak in Victoria, amongst unvaccinated staff, similarly high rates of infection were observed in office workers as in those in regular close contact with dairy goats.

The risk management plan to reduce the risk of human infection to 'negligible' does not need to differentiate between levels of risk based on activity on the property. A requirement for testing followed by vaccination at least 14 days before commencing work of all those employees and regular visitors that do not exhibit a pre-existing immune response will reduce risk of infection to 'negligible'.

Vaccination will not be mandatory for occasional visitors (no more than once per year), who will be advised of the risks and their options regarding vaccination before entering the property. Unvaccinated persons with specified pre-existing medical conditions should not visit the property. Those unvaccinated occasional visitors that decide to proceed and enter the property, will be signed in through the single entry way, accompanied by an employee, will not have direct contact with goats and will be required to wear coveralls, footwear covers and wear a N95 face mask. They will leave the protective clothing behind and wash hands and face before exiting the site, and be advised to contact their GP immediately if they experience an illness consistent with Q fever in the month following their visit.

<u>Risk assessment and management plan to avoid increase in proportion of infected goats on the properties and environmental contamination</u>

Since a small proportion of the goats entering the properties have a 'very high' risk of being infected, there is the possibility that, without appropriate risk management procedures, the proportion will increase over time and there will be concomitant increased contamination of the farm environment. Infected goats can shed the organism in faeces, urine, milk and semen. However, by far the greatest shedding occurs in placental tissues and fetal fluids during kidding and, to an even greater extent, in the event of a *C. burnetii* induced abortion (typically in the last month of gestation). Of particular importance in considering risk of human infection, it has been noted that investigations of human infections during the epidemics in the Netherlands found that the human infections were preceded by 'waves of abortions' in the associated goat herds. Although detailed records are not available for the large outbreak of Q fever on the dairy goat farm in Victoria, the recollection of the farm manager is that an increase in goat abortions started several years before the first human cases were diagnosed.

C. burnetii survives for months in an infectious form in the environment after being shed from an infected animal. However, it does not replicate outside the infected animal. Increase in the amount of infectious *C. burnetii* in the

environment therefore depends on continued shedding and build up from the infected animals. In the absence of appropriate management, it is expected that build up would occur, in decreasing order of risk, in the bedding in the kidding areas, in the bedding in the general housing areas, along the laneways leading from the housing to the milking parlour, in the milking parlour, and in the waste water from the goat housing and washing of other areas.

Risk management measures are therefore directed at restricting the areas of the farm where kidding will occur, removal and clean up/disinfection of potentially infectious material, and ongoing monitoring of infection status of the goat flock.

It is considered that without any appropriate management that the risk of environmental build-up of infection is 'very high' and the risk of increasing the proportion of infected goats in the flock is 'very high'. However, with the following risk management measures, it is considered that the risk of such build up is low and will be detected and addressed well before it reaches a critical level.

Risk management measures:

- Pregnant goats will be managed in discrete groups during the last 30 days of pregnancy. Kidding will occur in segregated areas within each Goat Farming Unit. The specific area to be utilized will be determined by onsite personnel prior to each kidding period, and may vary between kidding periods. These areas will be clearly designated and delineated with temporary fencing or the equivalent.
- Any abortions will be investigated (including PCR testing for *C. burnetii*) and goats will be moved to a restricted designated area for kidding. Drop down blinds will be fitted to the kidding area to enable greater confinement in the case of windy conditions. Mitigation of dust generation from the kidding area will be achieved by dampening down the bedding as determined by the prevailing weather conditions.
- After collection of samples for investigation from placentas and fetuses from any abortion, the remaining tissues and contaminated bedding will be removed in sealable containers (e.g. sealed, leak-proof plastic bags) for safe disposal of potentially infectious waste and the immediate area sprayed with disinfectant (such as 0.1 mM NaOCl or Virkon S). Does that have aborted will be removed promptly from the kidding area to a restricted quarantine area while awaiting results of PCR testing.
- During kidding, placentas will be collected in leak-proof containers and stored in a cool room until such time as they can be buried on site. Burial will be in accordance with relevant EPA Guidelines.
- At the completion of the kidding periods, all bedding where kidding occurred will be dampened down with disinfectant and the bedding removed from the kidding area. The floor area (compacted soil) will be cleaned and sprayed down with disinfectant.
- Laneways will be kept clean of faecal material (dry removal). They will be washed with fresh water (not recycled) and sprayed with disinfectant as required.

- At the Ballan road site wastewater from sheds, milking parlour, general cleaning and disinfection is collected to a series of treatment ponds after solids removal. Solids will be removed from the site along with used bedding (see later for removal conditions). Aeration of ponds and use of treated waste water for irrigation will be restricted to low wind days and managed to avoid aerosol generation.
- At the Forest Road South site, all wastewater is discharged directly to sewer under a trade Waste Agreement with the local water authority. There is a maximum 20,000 L sump from which the wastewater is pumped. (Note: A study conducted in the Netherlands during the decline period of the recent epidemic of Q fever reported detection of *C. burnetii* DNA in influent water and active sludge at a sewage water treatment plant receiving water from an area where there were highly infected goat farms. However they did not test effluent water and they considered the health risk to workers and residents to be low. They also noted that since they only tested for the presence of *C. burnetii* DNA, they were not able to conclude whether this was from infectious or non-infectious organisms.)

3. Manage the risk of any infection on the properties spreading to the surrounding area

There are three potential risk categories for spread of any infection on the properties to the surrounding areas: windborne spread of contaminated dust/aerosols; contaminated workers (clothing etc) leaving the site after contacting infected animals (fomite spread); and infected bedding material being trucked to a managed off-farm site or wastewater leaving the site (fomite spread and potential aerosols en route).

Although each of these categories must be regarded as possible risks, the size of the risk will depend on whether the level of infection (i.e. the proportion of the herd infected and the extent of the farm environment contaminated) is similar to background level for rural Victoria or whether, at the other extreme, an outbreak situation with frequent abortions is prevailing. For example, in the Netherlands epidemic it was found that, without risk mitigating measures and when abortions were occurring frequently on an intensive dairy goat farm, there was an increased risk of persons living within 2 km of the farm becoming infected. This is not the initial situation on these properties (i.e. the proportion of goats and environmental contamination is no higher than the norm for other areas of the state) and risk management measures are in place to minimize the chance of such a higher risk situation developing. Additionally, regular systematic monitoring of the level of infection in the goats will enable any increase in infection rate to be detected early and an appropriate response mounted as determined by the Review Panel.

However, even if the proportion of goats infected on the sites is similar to that in the general population, the large number of goats eventually to be housed on the sites means that, for example, there will be up to about 300 infected goats in the herd of 14,000. For example, if we consider the sero-prevalence already found in

the donor goats of 2.15% and assume a worst case scenario that all of these sero-positive animals are in fact infected and shedding some organisms, then that would mean that around 300 infected goats would be present when the population builds up to 14,000 at the Ballan Road site. However the number of goats on the sites at start up will be much less, about 3000, meaning that only about 60 infected goats will be present. The build up to the total population on the sites will occur over several years, allowing time to implement, audit and monitor all components of the risk management plan to ensure compliance and effectiveness. It will also provide time to develop an autogenous vaccine or obtain an approved commercial vaccine. During this period of build up of the herd the total herd size at the Ballan site will be capped at 10,000 until vaccine is available.

As described in the previous section of this report, risk management measures will be in place to minimize the chance of the proportion of infected goats rising above this background level. When this farm is established, the initial risk of spread off the site to the surrounding area is regarded as 'low' (rare but may occur). On this basis, the following risk management measures will be in place to reduce that 'low' risk to 'very low' (very rare but cannot be excluded).

- Goats are to be housed in sheds with open sides (i.e. not at pasture and not completely indoors), and, on windy days the drop down blinds will be lowered to prevent wind-borne dispersal of any dust from within the sheds.
- Any farm activities that could potentially generate aerosols (e.g. loading used bedding materials, irrigation) will be avoided on windy days.
- Windbreaks will be strategically established on the properties taking account of prevailing wind information.
- All-weather roadways in the at-risk areas of the properties (e.g. laneways used by goats, around the milking parlour, around the goat housing areas, loading areas where used bedding is collected) will be dampened down when windy days are predicted.
- Open paddock areas will be sown down and irrigated with treated water (avoiding activities on windy days).
- All staff working directly with goats, including milk harvesting and processing, will leave outer work clothes on site for laundering, change footwear and wash hands and face before leaving the site. In case of gross contamination of a staff member (e.g. cleaning up after an abortion), showering and complete change of clothing required before leaving site.
- Staff vehicles and feed delivery vehicles entering site will be confined to restricted areas away from potentially high-risk areas (e.g. goat kidding areas). Trucks transporting waste materials and animals will be inspected before leaving the sites and cleaned as and when needed to remove any visible contamination (e.g. physical removal of contamination or washing with gurney – note the need to limit pressure washing to avoid potentially infected aerosols). All waste water will go through the treatment ponds or to the sewer as appropriate to each site.
- Milk collection trucks and fittings will be constructed and operated to prevent milk spillage or aerosol generation. Milk will be transferred to

tanker trucks in a designated area so constructed that any inadvertent spillage is easily cleaned up with disinfectant and waste going to waste water treatment ponds or to sewer as appropriate to each site.

- Tanker trucks delivering milk to the processing plant will be similarly managed to avoid spillage, which can be readily cleaned up with disinfectant. Milk will be contained within the processing plant to avoid spillage and aerosol generation and, after pasteurisation, will present a negligible risk.
- Used bedding from sheds will be dampened down before loading on trucks for removal from site, avoiding windy days. Trucks will be so fitted out to enable the load to be completely covered to avoid any dust or solid material escaping during transport off site and will be externally cleaned to remove any visible contamination before leaving the site. Route of travel to the receiving facility for the used bedding material and potentially infectious waste will be advised to local council and will avoid potential risk areas. Arrangements will be made to ensure that the receiving facility is apprised of the nature of the bedding and other material and the potential risks involved and has an approved protocol for safely treating and handling of the material to avoid spread of infection (e.g. thermophilic composting for 4 – 6 weeks).
- At the Ballan Road site wastewater treatment ponds and winter storage ponds will be regularly monitored to ensure that no wastewater leaves the site. At the Forest Road South site all wastewater is discharged directly to sewer.

C. Auditing, monitoring, review and response

Continuing from the current development of the goat flock off-site, a regular process of monitoring and review is implemented to detect promptly any changes in the infection status of the flock, audit of the implementation and effectiveness of risk management procedures and to develop appropriate responses in consultation with experts in the field should any changes of concern be detected.

For the initial 6 months of the establishment of the milking flock, fortnightly bulk milk samples will be collected from each of the bulk milk tanks and tested by qPCR for the presence of *C. burnetii* DNA. Once the baseline measurements are completed, bulk milk tank testing will be conducted monthly.

All abortions will be investigated to determine cause where possible and tested for the presence of *C. burnetii*.

For the first two years of operation as the herd builds up to full strength at each site, Review Panel meetings will be scheduled six monthly, particularly to assess implementation of risk management procedures and to review results of laboratory testing of bulk milk samples and any abortions. In addition, an extraordinary Review Panel meeting will be triggered if *C. burnetii* DNA detected in bulk milk samples rises above background levels or from increasing abortions,

to review current risk management measures and to determine the response. The approach to reviewing and responding to the results of the monitoring is provided in more detail in Appendix 2.

The potential for untoward events that may affect the operation of the Nuchev properties include such events as power failures ('blackouts') or industrial action that could impact on feed deliveries, milk transport and other aspects of the operation. It is not considered that in the short term any of these would lead to a rapid change in the assessed and managed risk relating to Q fever. If any of the untoward events were likely to continue for more than a few days then this would trigger an extraordinary Review Panel meeting to examine the situation and determine what, if any, actions were needed to respond.

D. Communication

The risk management plan will be explained to all staff as part of their induction and training sessions at commencement of employment, at the same time that vaccination will be discussed and appropriately conducted.

Standard operating procedures will incorporate the appropriate elements of the risk management plan for each area of the farm operations and will be audited.

Some key resources consulted:

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European Food Safety Authority Committee. Scientific opinion on risk assessment terminology. (2012) *EFSA Journal* 10(5), 2664. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2664.pdf

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Public Health Agency of Canada. *Coxiella b*urnetii. Pathogen safety data sheet – Infectious substances. http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/coxiella-burnetii-eng.php

State of Washington, Department of Agriculture. Best practices to control Q fever. http://agr.wa.gov/foodanimal/animalhealth/diseases/qfevermanagementpractices.pdf

US National Response Team. NRT Quick Reference Guide: *Coxiella burnetii*. http://www.nrt.org/production/nrt/nrtweb.nsf/AllAttachmentsByTitle/A-1009WMDQRGCoxiellaburnetii/$File/120502_Q_Fever_QRG_Final.pdf?OpenElement

Banazis M. Development of tools for surveillance of *Coxiella burnetii* in domestic animals and Australian marsupials and their waste. PhD thesis. Murdoch University, School of Veterinary and Biomedical Sciences, Division of Health Sciences. 12 June 2009.

Appendix 1

Development of autogenous vaccine for *C. burnetii*

Approval to use any autogenous vaccine needs to be obtained from the Australian Pesticides and Veterinary Medicines Authority (APVMA) and from the state veterinary authority in which use of the vaccine is proposed. Key components to the approval process for developing and using an autogenous vaccine are that the organism used to develop the vaccine has been derived from the herd in which the vaccine is to be used and that there is currently no available vaccine already registered for use for this purpose.

Workers at the Australian Rickettsial Reference Laboratory (ARRL, Geelong) and at the Faculty of Veterinary and Agricultural Sciences at The University of Melbourne are already at an advanced stage in the development of an autogenous *C. burnetii* vaccine for use on another goat property in Victoria. Specifically, an isolate has been obtained from an aborted fetus, propagated in the laboratory under PC3 level secure laboratory conditions, chemically inactivated and adjusted to a suitable vaccine concentration similar to commercial vaccines available for human use in Australia and for animal use in Europe (no approved vaccines are available in Australia for use in goats). A vaccine trial has been conducted in goats and excellent serological responses have been induced by the vaccine. Continuing work will evaluate the vaccine in field trials and laboratory studies will refine methods to enable production of the large number of doses required to vaccinate the herd once APVMA approval is obtained.

Experience gained with the above work means that, even though it would not be permissible to use this autogenous vaccine in the Nuchev goat herd, the methods have been developed and experience gained to repeat the process with an isolate from the Nuchev herd should one be obtained. The following is the approach that will be taken to develop an autogenous vaccine for use in the Nuchev herd. When a vaccine is developed it will be used to vaccinate all the goats in the herd.

The steps and approximate time lines are:

1. Obtain an isolate (2 months). As part of the normal monitoring of reproductive health in the herd, if an abortion occurs, tissues will be collected including fetus and placenta and submitted to the laboratory. The tissues will be tested by qPCR for the presence of *C. burnetii* DNA and stored appropriately until the results are available. Tissues testing positive by qPCR will be subjected to isolation attempts in eggs and tissue culture. The qPCR and the methods for isolation in eggs and tissue culture are standardized and already used successfully at the ARRL.
2. Preparation of vaccine (3 months). An isolate will be selected and propagated in eggs to obtain growth to a high titre while remaining as Phase 1 organisms. The isolate will be adjusted to the required concentration, chemically inactivated (confirmed inactivated by failure to grow in culture) and dispensed for use as trial vaccine.

3. Evaluation of vaccine (3 months). In pen trials, 20 seronegative kids will be allocated randomly to test and control groups. Prevaccination blood samples will be collected from each goat, injections will be given (test group receives vaccine, control group receives preparation from uninfected eggs) and blood samples collected for serology over the following weeks. Goats are monitored daily for adverse reactions to the injections (local and systemic reactions). A booster vaccine is given at 4 weeks after the primary vaccine and blood samples collected for a further 2 weeks.
   Efficacy of the vaccine is tested in laboratory studies under PC3 containment facilities in vaccinated and control guinea pigs that are then challenged with the live organism and febrile response monitored.
4. Field trial (2 months). Following successful vaccination in the pen trials, larger groups of goats will be vaccinated in the source flock and serological responses and adverse reactions evaluated.
5. Production of vaccine (2 months and ongoing). Following successful results from the pen, laboratory and field trials, the vaccine production will be scaled up to produce enough doses for the ongoing needs of the herd.

Note that all vaccine development and evaluation studies will be conducted under GLP and GMP guidelines to meet the requirements of the APVMA, who must approve any autogenous vaccine, along with the state veterinary authorities, before it can be used.

The approximate time line (totaling 12 months) for vaccine development is based on our current experience but can only be approximate and assumes isolation of an organism that grows well under laboratory conditions is successful within a reasonable time. Application for APVMA approval will be initially lodged at the successful completion of Step 3 and the approval process will continue in parallel with the additional production steps.

On the basis of knowledge of Q fever infections arising in people associated with highly infected herds overseas as reported in the scientific literature and that gained from local experience, there is a time lag of several years, even in the absence of any risk management plan, between increased abortions in the goat herd and the first human cases occurring. We therefore expect that, with the enhanced monitoring of abortions proposed with the Nuchev herd and implementation of the risk management plan, there will be ample time to develop an autogenous vaccine and implement herd vaccination after the first abortions are observed and well before there is a heightened risk of human infections.

Appendix 2

Toolkit for response to any indication of increase in infection rate in the herd

Two tools will be used to monitor the herd for any increase in infection rate:

1. Monthly bulk milk testing (BMT) by qPCR to detect DNA of *Coxiella burnetii*
2. Monitoring reproductive health by recording abortions and testing abortion products (fetus, placenta and fluids as available) by qPCR for the presence of *C. burnetii.*

The reasoning behind this approach is consistent with our view that infection will already be present at a low level in the herd when established on the properties. The risk management plan is designed and implemented to ensure that the level of infection does not rise.

Records are already being kept of any abortions in the source herd (two recorded abortions, both negative by qPCR, from about 5000 births). The background qPCR results for the BMT will be established as the milking herd moves onto the farm and the dairy begins operating.

The important point to note with BMT is that monitoring is to detect any increase or upward trend in detection of *C. burnetii* DNA in the milk (i.e. it does not depend on attempting to define acceptable and unacceptable levels but on determining whether the level is rising, indicating that level of herd infection is rising). Any rise in BMT triggers a response as detailed below.

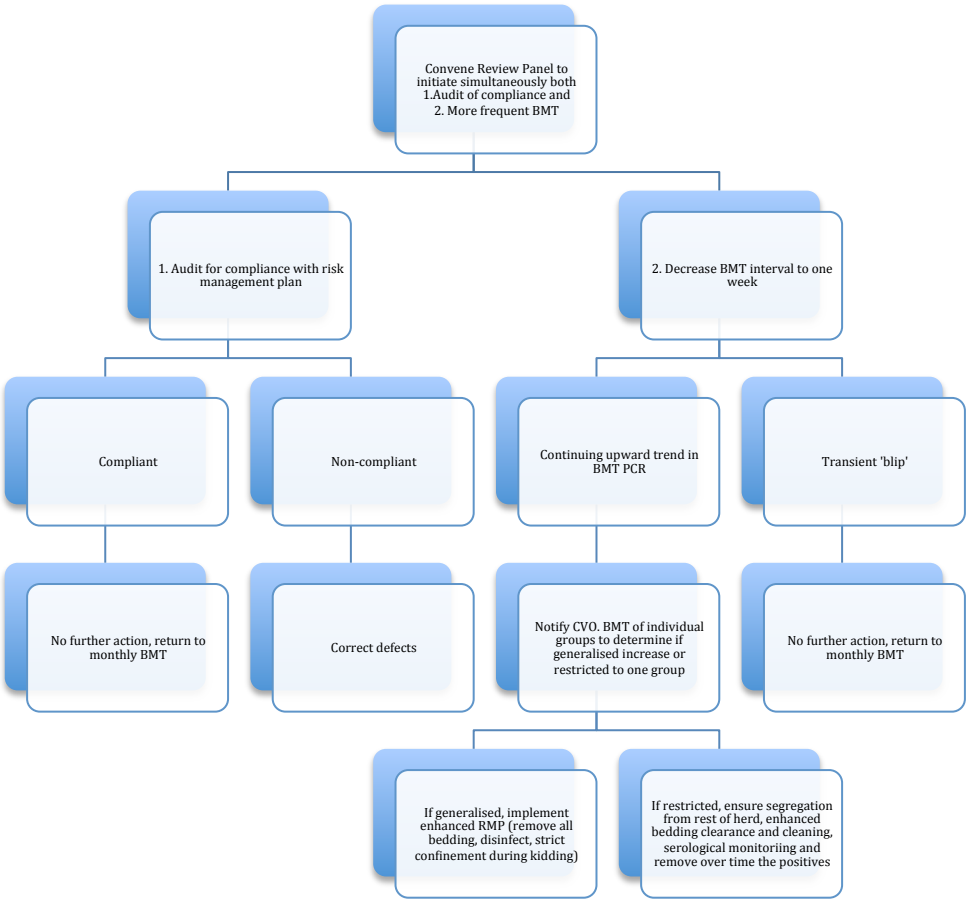
As indicated in the Risk Management Plan, the intention is to commence operations on the Ballan site with about 3000 milking goats and build up over several years to the full complement. The baseline data on BMT results will be accumulated during this time when the number of goats on the property is gradually increasing.

There is not sufficient hard information available to clearly state how long it would be expected to take from first detection of rising infection level for that rise to reach a level where it could be considered a potential risk to people in the surrounding area. However some information, albeit largely retrospective and anecdotal, from an outbreak on a large dairy sheep and goat farm in Victoria provides some indication that a rise in infection level in the herd to present a risk to human infection is not a rapid process (Bond et al 2015). On that farm, which had no risk management plan in place to deal with Q fever, 17 human cases were detected among approximately 100 staff over a 28-month period in people working or living on the farm. The only case off-farm was the wife of a farm worker and fomite spread via contaminated clothing is the most likely route of spread. The first confirmed human case was in 2013, although serological testing suggests that undiagnosed infections may have occurred earlier. No detailed records are available but the owner/manager states that an increased abortion rate in the goat herd, cause undetermined, commenced several years before the

earliest confirmed human cases (first abortion increase possibly as early as 2004). This strongly suggests that, even in a farm without a risk management plan to control infection, it would take several years for there to be a major risk of human infection on the farm from the start of an increase in goat abortions, and even longer for it to reach a potential risk for people in the surrounding area.

With the risk management plan in place and the regular monitoring, as indicated on the Nuchev properties, it is expected that there would be ample time to detect and deal with any trend of increasing infection level in the herd before there is a heightened risk of human infection in the surrounding area.

Response to increase in BMT for *C. burnetii*



Response to an abortion diagnosed as due to *C. burnetii* infection

The response to any abortion, including testing for *C. burnetii* and disinfection of the immediate area, has been described in the RMP. Unlike any indication from BMT that there may be an increase in infection in the herd, the event of an abortion immediately indicates which Goat Farm Unit the infection is associated with. Further investigation of that GFU can then be undertaken to determine if this is just an occasional event or if the infection level is increasing in that GFU. If the evidence from further investigation is that infection level is increasing then the actions that will be taken are as described above when infection is confined to one GFU.

Autogenous vaccine

In addition to the above actions, any indication that the level of infection is rising in the herd (e.g. by increasing BMT detections) will prompt increased surveillance of reproductive health so that, if an abortion due to *C. burnetii* occurs, an isolate will be obtained to develop an autogenous vaccine. As soon as an autogenous vaccine is produced and approved by the appropriate authorities, the whole herd will be vaccinated.