

Neutral Citation Number: [2019] EWHC 1783 (Admin)

Case No: CO/3930/2018

IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION ADMINISTRATIVE COURT

Royal Courts of Justice Strand, London, WC2A 2LL

Date: 9 July 2019

Before:

THE HONOURABLE MR JUSTICE MURRAY

Between:

THE QUEEN ON THE APPLICATION OF HELEN JANE MACDONALD

<u>Claimant</u>

- and -

SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

Defendant

Ms Cathryn McGahey QC (instructed by Olephant Solicitors) for the Claimant Mr Ned Westaway (instructed by the Government Legal Department) for the Defendant

Hearing date: 6 March 2019

Approved Judgment

Mr Justice Murray:

- 1. This case concerns a male alpaca named Geronimo. The claimant, Ms Helen Jane Macdonald, Geronimo's owner, challenges the decision of the defendant, the Secretary of State for Environment, Food and Rural Affairs ("the Secretary of State") to slaughter Geronimo on the basis that he is infected with *Mycobacterium bovis* ("*M bovis*"), the main cause of bovine tuberculosis ("bTB"), which is contagious and therefore dangerous to other animals, including humans, that are susceptible to contracting bTB.
- 2. Ms Macdonald challenges the Secretary of State's decision ("the Decision") set out in a letter to her dated 15 July 2018 sent on the Secretary of State's behalf by Mr George Eustice MP, Minister of State for Agriculture, Fisheries and Food ("the Minister"), in which the Minister confirmed the earlier decision of the Secretary of State compulsorily to slaughter Geronimo, set out in a Notice of Intended Slaughter (Form TN03) ("a TN03 Notice") issued on 21 December 2017 on behalf of the Secretary of State by the Animal and Plant Health Agency ("APHA"). APHA is an executive agency of the Department for Environment, Food and Rural Affairs ("Defra").
- 3. In the Decision, the Secretary of State relies on the fact that Geronimo has twice tested positive for bTB on serology (blood) tests, the first test having been performed on Geronimo on 21 August 2017 and the second test having been performed on Geronimo on 11 December 2017. Ms Macdonald maintains that there is a substantial risk that these test results are false positives and by her challenge is seeking an order quashing the Decision and the TN03 Notice issued on 21 December 2017. As far as Ms Macdonald is concerned, if she is successful on this claim, it is a matter for the Secretary of State whether further testing is required and, if so, in what form. She is willing to co-operate in respect of further testing. Geronimo is currently in isolation, and it is common ground that he therefore currently poses no risk to human or animal health.

Legal framework

4. The Animal Health Act 1981 ("AHA 1981") is a consolidating act that gives widespread powers to the Government to control prescribed diseases in animals. The power on which the Secretary of State relied in making the Decision is set out in section 32(1) of the AHA 1981:

"The Minister *may*, *if he thinks fit*, cause to be slaughtered any animal which -

- (a) is affected or *suspected of being affected* with any disease to which this section applies; *or*
- (b) has been exposed to the infection of any such disease." (emphasis added)
- 5. Section 32(2) of the 1981 Act provides that the power under section 32(1) to cause an animal to be slaughtered applies to such diseases of animals as may from time to time be directed by order made by the Secretary of State.

- 6. The relevant order in this case is the Tuberculosis (Non-bovine animals) Slaughter and Compensation (England) Order 2017 ("the 2017 Order"), which applies to South American camelids as well as other non-bovine animals, namely, deer, goats, pigs and sheep. Article 3 of the 2017 Order directs that section 32(2) of the 1981 Act applies to tuberculosis, which is defined as "infection with *Mycobacterium bovis* (*M. bovis*)".
- 7. Section 34 of the 1981 Act sets out provisions relating to the Secretary of State's power to slaughter an animal that is diseased or suspected of being diseased or affected by exposure to disease and relating to compensation payable to the owner of a slaughtered animal. Article 4 of the 2017 Order makes specific provision for the Secretary of State to pay compensation in accordance with the Schedule to the 2017 Order to the owner of a non-bovine animal, such as a South American camelid, slaughtered under section 32(1) of the 1981 Act. The compensation payable for the slaughter of a stud male South American camelid over 18 months old is £1,500.
- 8. Various powers under the 1981 Act relating to the control of disease are implemented and given further effect in relation to tuberculosis or suspected tuberculosis in deer and in South American camelids by the Tuberculosis (Deer and Camelid) (England) Order 2014 ("the 2014 Order") made by the Secretary of State. Part 3 of the 2014 Order applies specifically to South American camelids. It sets out rules relating to mandatory notification of suspected bTB (article 11), rules relating to the testing of South American camelids for bTB (article 12), rules relating to vaccination and therapeutic treatment of South American camelids affected or potentially affected by bTB (article 13), rules dealing with measures to prevent the spread of bTB and empowering the Secretary of State to impose by notice various restrictions for that purpose (article 14) and rules dealing with the slaughter of South American camelids to prevent the spread of bTB (article 15).

Testing of South American camelids for bTB

9. Article 12 of the 2014 Order includes the following provision at paragraph (5):

"A person must not perform a test for tuberculosis on a camelid except with the written consent of the Secretary of State, and a person to whom such consent is given must, as soon as any positive tuberculosis result of such a test is known, report such result to the Secretary of State."

- 10. In contrast to cattle, South American camelids are not subject to mandatory surveillance for bTB at prescribed intervals. The APHA, together with the British Alpaca Society and other interested parties, developed protocols for the testing of South American camelids for bTB in 2012, which continue to be used and are periodically reviewed and updated. The protocols are set out in the following documents published by the APHA:
 - i) Camelid bTB Testing Scenarios Guidance (TN191) ("the Guidance"), of which the version dated July 2018 was included in the hearing bundle; and
 - ii) Operations Manual: Ancillary Testing in Camelids ("the Operations Manual"), of which the version dated 28 August 2018 was included in the hearing bundle.

- 11. It is common ground that there are no significant differences between these versions of the Guidance and the Operations Manual, respectively, and the versions in effect at the time of the Decision or the TN03 Notice dated 21 December 2017.
- 12. Under the Protocols, different testing procedures apply in different scenarios. In 2014 a voluntary scheme for testing for bTB in South American camelids was established ("the Voluntary Camelid Testing Scheme"), which reflects the appropriate protocols set out in the Guidance and the Operations Manual. The Voluntary Camelid Testing Scheme is administered by a private company, SureFarm Ltd ("SureFarm") and was developed by the British Alpaca Society and other South American camelid industry groups in consultation with Defra and APHA.
- 13. In this case, it is common ground that the first serology test was conducted on Geronimo on 21 August 2017 in accordance with the Voluntary Camelid Testing Scheme, in compliance with the relevant protocol for a test under that scheme. Despite that, Ms Macdonald asserts that the positive test result in respect of Geronimo must be (or is highly likely to be) false for reasons I will elaborate in a moment.

Background

- 14. Ms Macdonald imports and breeds alpacas, most of which remain on her property and which she farms for wool. She is a Registered Veterinary Nurse and a member of the British Alpaca Society.
- 15. Ms Macdonald has invested heavily in biosecurity. Her property is surrounded by badger-proof fencing, badgers being a known vector (that is, carrier) of bTB.
- 16. Alpacas are members of the camelid family of animals (*Camelidae*), which family includes camels and South American camelids. There are four types of South American camelid, namely, alpacas, llamas, vicuñas and guanacos. Camelids are not bovine, but they are nonetheless susceptible to infection by *M bovis*, resulting in bTB, along with many other bovine and non-bovine mammals, including badgers and even humans.
- 17. On or about 11 August 2017 Ms Macdonald imported Geronimo into the United Kingdom from New Zealand. She intended to use him for stud. Before leaving New Zealand, on 9 September 2016 he had been tested for bTB, using a skin test. He tested negative. Prior to his export from New Zealand, Geronimo was held in quarantine, a condition of import to the United Kingdom. On 31 July 2017, while still in New Zealand, Geronimo underwent a further skin test for bTB. He again tested negative.
- 18. On his arrival at Ms Macdonald's farm, Geronimo was placed in quarantine with a companion animal. It is considered that, for welfare reasons, alpacas, which are herd animals, should not be kept alone.
- 19. On 21 August 2017 Ms Macdonald arranged for Geronimo to have a voluntary test for bTB under the Voluntary Camelid Testing Scheme. Geronimo was tested using a serology test known as the Enferplex test on a "4-antigen" or "4-spot" interpretation.

- 20. The Enferplex test was developed by SureFarm, in partnership with Defra and the APHA, and is manufactured by Enfer Scientific, a division of an Irish company, Enfer Group.
- 21. An "antigen" is any substance that causes the immune system to produce antibodies against it. A serology test, such as the Enferplex test, attempts to measure the antibody response to one or more antigens, depending on the purpose and design of the test. An Enferplex test on the "4-antigen" or "4-spot" interpretation is a test that is considered positive if there is a blood reaction in a test animal to at least four out of the seven antigens administered to the animal by the test. Similarly, an Enferplex test on a "2-antigen" or "2-spot" interpretation is a test that is considered positive if there is a blood reaction to at least two out of the seven antigens administered to the animal by the test.
- 22. The Enferplex 4-antigen test administered to Geronimo on 21 August 2017 showed him as positive for bTB. The results were considered under the "high specificity" interpretation of the Enferplex test, which is applied in private tests of camelids not subject to restrictions relating to bTB (in other words, where the animal has not previously tested positive and there are no other circumstances giving rise to suspicion that the animal might have been exposed to the risk of contracting bTB).
- 23. It is common ground that no test for bTB is infallible. As will be seen, there are different possible tests for bTB. Each has its own mechanism and relative advantages and disadvantages. The "specificity" of a test is a measure of the probability of the test's producing a false positive (in other words, identifying an animal as infected when the animal is not infected). The higher the specificity of a test, the lower the risk that the test will produce a false positive. The Enferplex 4-antigen test is said to be "highly specific", meaning that there is a very low risk of its producing a false positive.
- 24. Another important aspect of a bTB test is its "sensitivity". The "sensitivity" of a test is a measure of the probability of the test's producing a false negative (in other words, identifying an animal as not infected when the animal is infected). The higher the sensitivity of a test, the lower the risk that the test will produce a false negative.
- 25. Skin tests for bTB, such as the one that was administered to Geronimo on 31 July 2017 shortly before he arrived in the United Kingdom, involve injecting tuberculin into the skin of an animal to see whether there is a detectable reaction on the surface of the skin. Skin tests have a low sensitivity, meaning that there is a comparatively high risk that a skin test for bTB will produce a false negative. In other words, there is a comparatively high risk that there will be no detectable reaction on the surface of the animal's skin even where the disease is already present in the animal.
- 26. Tuberculin is an extract of *M bovis*, *Mycobacterium microti* (which most commonly causes tuberculosis in small rodents such as voles but can also affect other animals such as cats and even humans) or *Mycobacterium tuberculosis* (which is the human tuberculosis bacterium) used in skin testing of animals and humans to identify a tuberculosis infection. There are several types of tuberculin, but the most important type is PPD or "purified protein derivative", which is a complex mixture of antigens.

- 27. The Voluntary Camelid Testing Scheme under which Geronimo was tested on 21 August 2017 set out a protocol for the testing of a camelid, such as Geronimo, where there was no prior suspicion that he might be affected by bTB. The protocol was satisfied by the use of an Enferplex 4-antigen test, preceded by at least 10 to 30 days by "priming" in the form of injection of tuberculin via a skin test. This is intended to give rise to what is known as the "anamnestic boost effect", the meaning of which will hopefully become clear in a moment.
- 28. The reason for the requirement of priming is set out in a paper entitled "The anamnestic boost effect of the skin test on antibody responses to *M bovis* in camelids summary of evidence", the principal author of which was Dr Ricardo de la Rua-Domenech, APHA Veterinary Advisor to Defra TB Programme ("the Priming Paper"). The Priming Paper was first prepared in November 2013 and subsequently updated, most recently in October 2018. The latest update prior to the Decision was in May 2017.
- 29. In light of the importance to this claim of the issue of priming and the Secretary of State's approach to it, I briefly summarise key points made in the May 2017 version of the Priming Paper:
 - i) The Priming Paper noted that the administration of tuberculin to a camelid via a skin test "boosts" the antibody response in a camelid that has been infected with bTB, increasing the sensitivity of a subsequent blood test and thus increasing the chance of identifying an infected camelid.
 - ii) The Priming Paper surveyed available evidence regarding the effect of priming in connection with blood tests performed on camelids and notes that "[t]he anamnestic boost effect can be observed from 1-2 weeks to several months after tuberculin injection, depending on the type and dose of tuberculin, the host species, stage of infection, format of the antibody test used and other factors".
 - iii) The Priming Paper recommended a period of 10 to 30 days prior to the blood test for the priming to occur to allow time for the anamnestic boost effect to become established and to ensure that blood samples are taken while the effect is at its peak.
 - iv) The Priming Paper included the following note of caution, which is relied on by Ms Macdonald:

"The negative impact of the administration of tuberculin on the *specificity* of antibody tests in TB-free animals (i.e. the likelihood of false positive results) is a potential concern when antibody tests [are] used outside TB breakdown situations, such as private routine surveillance or pre-post-movement testing. It has not been possible to assess this effect directly in camelids yet, due to lack of samples from skin-tested animals in unrestricted, TB-free herds." (emphasis in original)

v) The Priming Paper qualified that note of caution as follows:

"Even so, analysis of data generated with sera from alpacas on premises with confirmed *M. bovis* infection in GB (under the conservative assumption/worst-case scenario that all the non-visible-lesion seropositive animals in those herds were false positives) did not suggest that the specificity of the StatPak antibody test was substantially different between animals that undergo prior skin testing and those that do not."

vi) The conclusion of the Priming Paper was:

"In herds with confirmed or with a strong suspicion of M. bovis infection, priming of the antibody TB tests with a tuberculin skin test conducted 10-30 days before blood sampling is essential for optimal performance of those tests, i.e. to maximise the overall sensitivity (probability that an infected animal is classified as positive by the test). For private routine screening or pre-movement testing presumed TB-free herds, skin test priming of the antibody tests is recommended. Although this increases the cost and complexity of testing, it helps identify any undetected infected animals present in those herds without impacting negatively on the test specificity." (emphasis added)

- 30. On or about 1 September 2017 SureFarm notified Ms Macdonald of the results of the Enferplex 4-antigen test that had been performed on Geronimo on 21 August 2017. On 1 September 2017 SureFarm also notified APHA of the results, as required by article 12(5) of the 2014 Order. On the same day, APHA on behalf of the Secretary of State served on Ms Macdonald a Notice Prohibiting Movement of Specified Animals (Form TN02) ("a TN02 Notice"), which was a whole herd movement restriction notice that also required isolation of Geronimo ahead of movement to slaughter. On 5 September 2017, APHA on behalf of the Secretary of State issued a TN03 Notice dated 4 September 2017 in respect of Geronimo.
- 31. Bearing in mind Geronimo's history, quarantine and earlier negative bTB skin tests, Ms Macdonald considered the result from the Enferplex test to be surprising. Her solicitors, Olephant Solicitors ("Olephant"), in a letter to the Secretary of State dated 7 September 2017, explained that Ms Macdonald considered the result likely to be a false positive. She asked the Secretary of State to agree to defer slaughter and to re-test Geronimo.
- 32. In a letter dated 8 September 2017 the Secretary of State agreed to take no further action in respect of Geronimo's slaughter without giving seven days' notice to Ms Macdonald.

The veterinary risk assessment

33. On 13 September 2017 a veterinary risk assessment, running to 28 pages including two appendices, of the likelihood of Geronimo having been affected by bTB following the positive result on the Enferplex 4-antigen test carried out in August 2017 ("the Veterinary Risk Assessment") was completed by Dr de la Rua-Domenech. In the Veterinary Risk Assessment, on which various colleagues had provided comments, Dr de la Rua-Domenech concluded that given the very high specificity of the Enferplex 4-antigen test, the likelihood of Geronimo being infected with *M bovis* was assessed as high, even if the prior probability of his having contracted bTB in New Zealand was assumed to be very low. In part 5 of the Veterinary Risk Assessment, he said:

"The key conclusion from the probability calculations is that, because of the very high Sp [diagnostic specificity of the test] of the post-import TB test that was applied on the imported alpaca, the PPV [positive predictive value] of the test is also high, i.e. there is a high probability that this animal is truly infected with *M. bovis*. That is the case even where the assumed (prior) probability of infection with *M. bovis* in the tested alpaca is considered to be as low as 1% (PPV=74%) or 5% (PPV=94%). The PPV then very quickly reaches 100% once that probability exceeds 5%"

- 34. In part 6 of the Veterinary Risk Assessment, Dr de la Rua-Domenech noted that a number of hypotheses, which he considered "questionable", had been put forward in correspondence by "the owner of the positive alpaca, the private laboratory [at SureFarm] and representatives of the camelid industry ... to argue that this was a false positive test result", in support of their (by implication, collective) request for the animal to be tested again rather than slaughtered.
- 35. Dr de la Rua-Domenech set out in a table in part 6 of the Veterinary Risk Assessment the arguments that had been raised and his counter-arguments, which are broadly consistent with the position that the Secretary of State subsequently adopted and maintained in correspondence. The table gives a good summary, albeit not exhaustive, of most of the principal arguments and counter-arguments that the parties have made during the course of this dispute and shows that quite early on their respective positions on the key issues were well marked out. I set out the table in Appendix 1 to this judgment for reference.
- 36. Dr de la Rua-Domenech set out his conclusions in part 7 of the Veterinary Risk Assessment:
 - "a) Summary of the veterinary impact / consequences

The negative consequences of the imported Enferplex TB-positive alpaca being truly infected with *M. bovis* and remaining alive in the UK would be the eventual development of clinical TB and potential death of the animal after a period that can range from a few weeks to years depending on the rate of progression of infection. In the meantime, the animal could

infect other alpacas in the same herd and in other herds. The potential for spread of infection would be increased by the alleged high breeding value of the alpaca and its use as a stud male. Potential spread to other species, including badgers, cannot be excluded, although this risk may be mitigated by certain biosecurity (badger exclusion) measures adopted on this farm.

b) Summary of likelihood

The likelihood of the imported Enferplex TB-positive alpaca being infected with *M. bovis* (tuberculosis) is high, as demonstrated by the PPV [positive predictive value] calculations [set out in part 5 (risk assessment) of the Veterinary Risk Assessment]." (emphasis added)

- 37. I have highlighted Dr de la Rua-Domenech's comment on the possible length of time that it would take for clinical signs of bTB to manifest, which responds to another argument, not set out in the table that I have reproduced in Appendix 1, on which Ms Macdonald has relied, namely, that Geronimo has not yet manifested any clinical signs of bTB. At the time of trial, Geronimo had been in the United Kingdom over 18 months. Ms Macdonald's farm has strict biosecurity measures, and Geronimo has been kept in isolation for virtually all of that period, meaning, in her view, that there is virtually no risk of his having been exposed to *M bovis* since his arrival in the United Kingdom. Ms Macdonald's expert witness, Ms Karin Mueller, expressed the view that if Geronimo was exposed to *M bovis* in New Zealand, then it is likely that he would be showing advanced clinical signs of bTB by now.
- 38. In part 8 of the Veterinary Risk Assessment, Dr de la Rua-Domenech set out three options for consideration by the Secretary of State, namely:
 - i) to proceed with the slaughter of Geronimo without re-testing "as per existing procedures in the APHA Operations Manual and the terms of the voluntary testing scheme developed by Defra, APHA and the camelid industry";
 - ii) isolate and defer slaughter pending a re-test at the owner's expense, the fate of the animal then to be determined by the result of re-test undertaken "in-house" by APHA; or
 - iii) isolate and keep the animal under lifetime movement restrictions (if the owner refuses to re-test according to the required APHA protocol).

He set out the advantages and disadvantages of each option, with an accompanying comment, in a further table.

39. The final recommendation in the Veterinary Risk Assessment was:

"In light of this, APHA experts recommend that the Enferplex TB positive alpaca imported from NZ should be retested using the higher-sensitivity protocol routinely applied in all government-funded tests of camelid herds in England with confirmed M. bovis infection (and any tracings thereof). This is in order to minimise the risk of false negative results arising from the moderate sensitivity of the available tests:

- 1. A skin test with PPDB injection 90 days after the pre-export skin test that was conducted in NZ on 31 July. However, if this interval is considered impractical, it could be shortened to between 60 and 90 days (i.e. skin testing could take place from 29 September 2017);
- 2. If the suspect animal is deemed a reactor to the skin test, it will be removed straight away as a reactor with compensation;
- 3. If this skin test is negative, APHA will carry out a serology test at the Starcross Laboratory between 10 and 30 days after the tuberculin injection with the owners' [sic] choice of two tests from: two-antigen Enferplex TB, DPP VetTB and IDEXX ELISA. A positive to either (or both) component test(s) will result in the animal being designated as infected with TB and removed with the payment of compensation." (emphasis in original)

40. In the above extract:

- i) "PPDB" means PPD produced from M bovis;
- ii) "DPP" stands for Dual Path Platform, a quantitative lateral flow antibody test, supplied by a company called Chembio Diagnostic Systems, Inc. under the brand name "VetTB";
- iii) "ELISA" stands for enzyme-linked immunosorbent assay, in this case in the form of a test supplied by IDEXX Laboratories, Inc.

The decision to re-test Geronimo

- 41. In a letter dated 22 September 2017 to Ms Macdonald, the Secretary of State set out his decision agreeing to Geronimo being re-tested. He noted that a veterinary risk assessment of Geronimo had been carried out, and he required that any further testing must be carried out by an APHA employed veterinary inspector, with the sample being tested in an APHA laboratory on the basis that Geronimo was now to be treated as an animal suspected of being affected with bTB.
- 42. The Secretary of State required the further tests to be carried out in accordance with the protocol that was set out in the Veterinary Risk Assessment, with Ms Macdonald to select two out of the three serology test options specified in the protocol. If Geronimo tested positive for bTB on one or both of the serology tests, he would be slaughtered. He noted that Ms Macdonald had already been provided assurance that at

- least seven days' written notice of his intention to remove and slaughter Geronimo would be given.
- 43. Although the Secretary of State was, in practical terms, consenting to a request for further testing, he stated in his letter dated 22 September 2017 that, as a matter of law, he was requiring these further tests pursuant to his powers under article 12 of the 2014 Order and that his letter constituted the necessary notice under the 2014 Order.
- 44. There then followed an exchange of letters in which the parties set out, in some detail, their views on the reliability of the original test in August 2017, the role of priming in relation to serology tests for bTB in camelids and other issues, expanding on and supplementing the arguments summarised in the table set out in Appendix 1 to this judgment. I do not attempt to summarise each argument, but simply to highlight some of the key points raised in order to indicate the contours of the debate.
- 45. By letter dated 16 October 2017 from Olephant to the APHA, Ms Macdonald objected to the use of the protocol proposed in the Secretary of State's letter of 17 September 2017, which had been recommended in the Veterinary Risk Assessment.
 - i) The principal basis of her objection was that the protocol was intended for use when there was a herd breakdown, namely, when there were acknowledged incidences of bTB within the herd. In the letter, Ms Macdonald explained that, in her view, it was highly likely that the Enferplex test was a false positive, in that it had measured Geronimo's antibody response to the skin test injection that he had had in New Zealand 21 days earlier.
 - ii) The skin test involves the injection of tuberculin. The use of the protocol, which required a further skin test injection, would simply replicate the circumstances in which the first suspect Enferplex result had been obtained. She noted that there was no evidence to determine the safety or consequences of repeated injections of tuberculin in healthy camelids. She referred to the policy of the Swedish government since 2015 that, before an alpaca is exported to Sweden, there must be a serological test of the animal carried out before skin testing in order "to avoid possible interactions". She also referred to (and enclosed a copy of) a "Camelid Industry" presentation dated 4 September 2015 in which it had been said that the anamnestic response has not been confirmed in alpacas.
 - iii) Ms Macdonald referred in her letter to an extract from the March 2017 version of the Priming Paper that was substantially the same as the first sentence of the extract that I quoted at [29(iv)] above, raising a "potential concern" about the administration of tuberculin to TB-free animals outside "TB breakdown situations", in other words, "the potential induction of false positive results".
 - iv) Ms Macdonald made some criticism of ELISA serology testing (of which the Enferplex test is an example), saying that it was "not an exact science". She referred to recent examples of "unexpected results at the 3-antigen level" and gave two examples.
 - v) Ms Macdonald concluded that a proportionate and balanced approach required that the re-test should take the form of an Enferplex test only, without priming.

- 46. By letter dated 23 October 2017 from the Government Legal Department to Olephant, the Secretary of State replied to the letter of 16 October 2017, making a number of points, including the following:
 - i) The Secretary of State first noted that in accordance with the protocol agreed by Defra with the British camelid industry bodies, Geronimo should have been removed and slaughtered after he failed the Enferplex 4-antigen test in August 2017. He considered that he was acting in a proportionate and reasonable manner by agreeing to re-test Geronimo, as a matter of exception from the agreed protocol. He reiterated his belief that the Enferplex 4-antigen test has a high degree of specificity, near 100 per cent, so the likelihood of a false positive test was extremely small.
 - ii) He did not accept that it was likely that the pre-export skin test three weeks prior to the Enferplex 4-antigen test was the most likely reason for the positive Enferplex test result. He defended the use of priming 10 to 30 days before a serology test by reference to the May 2017 version of the Priming Paper.
 - iii) The Secretary of State set out his views on the risk of Geronimo having been exposed to bTB in New Zealand, noting that although the bTB situation in New Zealand is "far better" than it is in the United Kingdom, New Zealand was "by no means free from that disease". He added:

"There are still large areas of the country with endemic *M. bovis* infection in possums (the main wildlife maintenance host), known as 'vector risk' areas, including the North Island [where the farm from which Geronimo was imported is located]. Sporadic bTB breakdowns continue to be recorded even in the low bTB risk ('vector free') areas of NZ in which cattle herds are subjected to routine biennial or less frequent testing."

- iv) He noted that he was aware of the policy of the Swedish government, which had a different risk assessment from that of the United Kingdom, and he referred to the position in Norway, which followed the United Kingdom approach.
- v) The Secretary of State rebutted the points made by Ms Macdonald about "unexpected results" from Enferplex 3-antigen tests, rejecting the examples given as not relevant.
- vi) The Secretary of State considered that Ms Macdonald had not raised any new arguments in her letter of 16 October 2017 that had not been considered by APHA's bTB test and veterinary experts in formulating the protocol set out in the Veterinary Risk Assessment, as communicated to Ms Macdonald on 22 September 2017.
- vii) The Secretary of State noted that:

"[I]t is paramount for the credibility of the private TB testing scheme that APHA is seen to apply government disease control policy consistently and fairly to all camelid keepers."

- viii) The Secretary of State therefore maintained his position that the re-test protocol, which was intended to stress sensitivity over specificity in order to be confident that a negative test result was truly indicative of Geronimo's being free from *M bovis* infection before restrictions could be lifted on Geronimo.
- 47. On 2 November 2017 Olephant wrote to the Government Legal Department to confirm that Ms Macdonald chose the Enferplex 2-antigen and DPP VetTB serology tests, to be performed as part of the protocol stipulated by the Secretary of State. She also requested that a blood test be taken from Geronimo immediately prior to the skin test with a view to its being analysed using the Enferplex test, which would "provide further useful data and information to assist further understanding of this issue in relation to camelids". From context, I take Olephant to be referring on her behalf to the issue of priming.
- 48. On 10 November 2017, the Secretary of State agreed that a blood sample could be taken from Geronimo before the skin test so that a sample unaffected by the skin test was available, if required, for further analysis. A blood sample was taken from Geronimo on 13 November 2017, followed by a skin test. Geronimo tested negative for bTB on the skin test.
- 49. Further blood was taken from Geronimo on 11 December 2017 for serology testing. The serology tests undertaken were the Enferplex 2-antigen test and the DPP VetTB test. Of these, the DPP VetTB test was negative for bTB. The Enferplex 2-antigen test was positive for bTB, with Geronimo testing positive in relation to three antigens.
- 50. The Secretary of State received the test results on 14 December 2017. Ms Lidia Guevara, the veterinary officer at APHA responsible for the case, attempted to contact Ms Macdonald on that day to advise her of the results. After Ms Guevara had exchanged messages with Ms Macdonald, the APHA laboratory that had conducted the test issued the results to Ms Macdonald. She received them on 20 December 2017 and forwarded them that same day to Mr Alastair Hayton, a Director at Synergy Farm Health Ltd ("Synergy Farm Health"), who had been involved in the development of the Enferplex test. I understand that SureFarm is a subsidiary of Synergy Farm Health.
- 51. At 23:44 on 20 December 2017, Mr Hayton sent to Ms Macdonald an email with the following text:

"Thank you for sending the data from Geronimo's re-test. I have discussed these with the Enfer team and Neil Watt at SureTest. We note that:-

• There is a response to three antigens, albeit just above cutoff for two of them (Mpb70pep and PPDb) – at this level we expect specificity to be about 97% based on the data held so far.

- The antibody levels and/or numbers of positive antigens have declined, even in the presence of a PPDb boost, which is not suggestive of a progressive disease state
- There has been no response to ESAT6 which is thought to be the most specific antigen for M. bovis.

Given these observations, and that there is very reasonable doubt from a clinical and epidemiological perspective as to whether the animal is a true M. bovis positive, then we would continue to highly recommend caution in interpretation of the results."

- 52. At 10:10 on 21 December 2017 Ms Macdonald sent an email to Ms Guevara confirming that she had received the test results and forwarding a copy of Mr Hayton's email. At 13:09 that day Ms Guevara sent an email to Ms Macdonald saying that, following the receipt of the positive results from the tests administered to Geronimo on 11 December 2017, she had been advised to notify Ms Macdonald of the Secretary of State's intention to slaughter Geronimo, as had been previously agreed with Ms Macdonald and her solicitors. She also advised her that she had issued a new TN03 Notice dated that day and that APHA would arrange for the removal of Geronimo from Ms Macdonald's farm and for his slaughter.
- 53. Further correspondence between the parties ensued over the next few months, one stream between Olephant and the Government Legal Department and one between Ms Macdonald and APHA, the latter principally concerning APHA's efforts to make practical arrangements for the removal and slaughter of Geronimo. It is not necessary to summarise it all, but I note some important exchanges.
- 54. On 16 January 2018 Olephant wrote to the Government Legal Department complaining about the timing of the TN03 Notice on 21 December 2017, reaffirming Ms Macdonald's objections to the re-test protocol (which she maintained was "simply not reliable" as a basis for the decision to cull Geronimo) and commenting and expanding on the comments of Mr Hayton in his message of 20 December 2017, which Ms Macdonald had forwarded to Ms Guevara at APHA on 21 December 2017 by email.
- 55. On 18 January 2018 the Government Legal Department responded to Olephant setting out the Secretary of State's reasons for refuting Ms Macdonald's criticism of the retest protocol, noting that by letter dated 2 November 2017 Ms Macdonald had agreed to the protocol and that now, given that Geronimo had re-tested positive for infection with *M bovis* under the Enferplex 2-antigen test, the Secretary of State considered that he had more than sufficient reason to suspect that Geronimo is diseased and to require him to be slaughtered, exercising his power to do so under section 32 of the 1981 Act.
- 56. In the letter, the Secretary of State responded to the three numbered points in Mr Hayton's email of 20 December 2017. He continued to reject the relevance of Geronimo's not yet exhibiting clinical signs of bTB on the basis that the progress of the illness was often slow and progressive with no outward signs of illness even when the animal is infectious. Ms Macdonald was asked to accept the Secretary of State's reasons and to arrange for release and removal of Geronimo in accordance with the

- TN03 Notice, to avoid compromising "the high health status of her own valuable breeding flock ... [and the] risk [of] spreading the disease on to other alpaca keepers".
- 57. On 26 January 2018 Olephant responded to the letter of 18 January 2018, reiterating some of the arguments previously raised by Ms Macdonald regarding the testing process and stating that, in the absence of an acceptable response from the Secretary of State, Ms Macdonald would be instructing Olephant to prepare an application for judicial review.
- 58. The Government Legal Department replied in detail by letter dated 30 January 2018 to Olephant. The Secretary of State sought to refute Ms Macdonald's criticisms of the testing process, the use of priming and so on, covering much of the same ground as in earlier correspondence. The Secretary of State rejected the suggestion that the re-test had been ordered because he accepted that the Enferplex test performed on Geronimo in August 2017 was flawed or a likely false positive. The agreement to re-test, which created an exception the normal protocol under which Geronimo should have been slaughtered following the initial positive test, was to reassure Ms Macdonald that the initial positive test was accurate. The Secretary of State noted that Ms Macdonald had agreed in advance to accept the result of the re-test in December 2017.
- 59. At para 5 of the letter of 30 January 2018, the Secretary of State set out his view as to why ordering a third test would be a "completely futile exercise":

"If the tests were repeated a third time, and then in the highly unlikely scenario that there was no positive result, our Minister would still not have certainty that the alpaca in question was truly TB-free in light of the two previous positive results."

- 60. The letter gave notice that the Secretary of State intended to apply for a warrant under section 62B of the 1981 Act to authorise entry to Ms Macdonald's farm in order to remove Geronimo and offered Ms Macdonald a telephone discussion with a senior Defra veterinarian later that week to discuss her concerns. Finally, the letter acknowledged that the Secretary of State was aware that Ms Macdonald was contemplating seeking judicial review.
- 61. To address and dispose of a side issue raised during the hearing by the letter of 30 January 2018, I note that at para 13 the letter stated:

"Defra is very disappointed to see that Mr Hayton and SureFarm are now casting doubts about the reliability of their own diagnostic test. The upshot of this change of position might well leave Defra with seriously considering withdrawing use of their product as a validated test for camelids because it will become very difficult [to] enforce a positive result in the future whenever a camelid keeper does not like the outcome."

62. While there appears to have been no objection to this paragraph in the subsequent correspondence, Ms Cathryn McGahey QC, counsel for Ms Macdonald, characterised it during her submissions at the hearing before me as intended to deter the supplier of the Enferplex test from raising legitimate science-based concerns, by threatening dire

- commercial consequences if it did so. Obviously, any such threat, if intended, would be highly improper.
- 63. Mr Ned Westaway, counsel for the Secretary of State, said that the paragraph should be viewed as no more than an expression of frustration by the Defra legal adviser who had prepared the letter, made in passing, during the course of a detailed three-page response to the latest letter from Ms Macdonald's solicitors in the context of a by then protracted dispute.
- 64. I can see that the wording of the paragraph is unfortunate and capable of bearing the construction that Ms McGahey put on it, but in context it seems to me that Mr Westaway's characterisation is likely to be the correct one. It would have been better, of course, had the Defra legal adviser not made that point in that way. I say no more about it.
- 65. As to the Secretary of State's offer to arrange a telephone discussion between Ms Macdonald and a senior Defra veterinarian, Olephant responded by saying that Ms Macdonald would prefer a face-to-face meeting. That was arranged. The meeting took place on Friday, 16 February 2018 between Ms Macdonald and the Deputy Chief Veterinary Officer at Defra, with others in attendance. Further correspondence took place following the meeting, but neither the meeting nor the subsequent correspondence resulted in any significant shift in the positions of Ms Macdonald or the Secretary of State on the key points.
- 66. At some time around the end of January or in early February 2018, Ms Macdonald wrote directly to the Secretary of State (the copy of the letter in the bundle is undated). On 3 April 2018, Ms Macdonald wrote directly to the Minister, setting out her principal concerns and asking him to intervene and to meet with her.
- 67. On 11 April 2018 the Secretary of State notified Ms Macdonald of his intention to seek a warrant to enter her farm and remove Geronimo for slaughter. On the same day Ms Macdonald wrote again to the Minister requesting that he authorise the testing of the blood sample taken from Geronimo prior to the skin test in November 2017. She followed this with a short email dated 20 April 2018 noting that the latest routine annual test for bTB conducted that week at the farm in New Zealand from which Geronimo had been imported confirmed that the farm's herd of 88 cattle had tested completely negative for bTB and hoping that the Minister would take this into account.
- 68. The Decision was the Minister's response to those letters, in particular her letter of 11 April 2018. He apologised for the delay in reverting to her and said that after a number of discussions with his officials, he had reluctantly concluded that the decision to slaughter Geronimo must stand. He then set out responses dealing with a number of technical points Ms Macdonald had raised as objections to the Enferplex tests, as well as related issues. It appeared to be common ground at the hearing that no new arguments were raised by the Minister at this stage. He concluded by acknowledging the difficulty and distress caused by the decision to slaughter Geronimo and agreed that Geronimo could be euthanised on Ms Macdonald's farm, as per a request she had previously made, if that was still her wish.

- 69. Further correspondence ensued during the course of the next few months. On 28 September 2018, the Government Legal Department wrote to Olephant notifying that it had begun preparing an application for a warrant under section 62B of the 1981 Act and giving a deadline of 5 October 2018 for representations on the application.
- 70. On 5 October 2018 Olephant notified the Government Legal Department that they intended to file a judicial review claim on 8 October 2018.

Procedural history

- 71. On 8 October 2018, Ms Macdonald made an urgent application to the court seeking an order to restrain the Secretary of State from seeking or executing a warrant from the magistrates' court under section 62B of the Animal Health Act 1981, permitting him to enter Ms Macdonald's premises and to seize Geronimo. On 16 October 2018 Mr Justice Swift granted the injunction sought and also ordered that Ms Macdonald keep the animal in isolation (together with any companion animal also kept in isolation) at her property in accordance with the TN02 Notice that had been issued on 1 September 2017 and the TN03 Notice that had been issued on 21 December 2017.
- 72. On 6 November 2018, Mrs Justice Lang, on a review of the papers, granted permission for Ms Macdonald to seek judicial review of the Decision, given her view that it was a fully considered decision that could form the basis of a claim for judicial review. However, out of caution, she also extended time for Ms Macdonald to bring a claim for judicial review of the TN03 Notice that had been issued on 21 December 2017.
- 73. On 24 January 2019 Roger ter Haar QC, sitting as a Deputy High Court Judge, granted an application by Ms Macdonald, made by Application Notice dated 21 December 2018, for permission to rely on her second witness statement, dated 21 December 2018, including, by way of exhibit, the second and third expert reports of Ms Karin Mueller dated 8 November 2018 and 14 December 2018 and the witness statement of Dr Catherine Rees of PBD Biotech Limited dated 2 October 2018. Admission of this evidence was said to be necessary to address matters raised in the evidence and documentation submitted by the Secretary of State in response to her application for permission to apply for judicial review, including further evidence in the form of the second witness statement of Dr Shelley Rhodes dated 6 December 2018.
- 74. On 7 February 2019 Neil Cameron QC, sitting as a Deputy High Court Judge, granted an application by Ms Macdonald for permission to rely on further evidence, namely the witness statement of Ms Leonie Walker dated 24 January 2019, together with exhibits to that statement. Ms Walker is the owner of Nevalea Alpacas, the alpaca breeding farm in New Zealand from which Geronimo was imported into the United Kingdom in August 2017. Admission of this evidence was said to be necessary to address the Secretary of State's contention that it is reasonable to conclude that Geronimo could have been exposed to infection with bTB whilst in New Zealand.
- 75. On 11 February 2019 Jeremy Johnson QC, sitting as a Deputy High Court Judge, granted Ms Macdonald permission to rely on her third witness statement and also a witness statement by Mr Robert Broadbent, both dated 1 February 2019. Admission of this evidence was said to be necessary to update the court on developments since

Ms Macdonald's last witness statement. Mr Broadbent is the veterinarian who examined Geronimo in December 2018.

The evidence

- 76. I have referred already to much of the evidence that I have reviewed for the purposes of this claim, including the Priming Paper, the Veterinary Risk Assessment and the correspondence both prior to and following the Decision. There were a number of witness statements, including from the Secretary of State's scientific adviser, Dr Rhodes, and reports from Ms Mueller, Ms Macdonald's independent expert.
- 77. Ms Mueller is a veterinary surgeon, based in Llanrhydd, who works as a Consultant in Camelid & Bovine Medicine and is a Senior Lecturer at the University of Liverpool. She has been involved with South American camelid medicine since 1999 and was one of the advisers to the British Alpaca Society and the British Llama Society in their negotiations with Defra to establish the Voluntary Camelid Testing Scheme and in the development of the protocols reflected in the Guidance and the Operations Manual. She provides first opinion and referral services and training for owners, undergraduate students and veterinary colleagues. She has also published in the field of camelid medicine. She provided expert reports dated 21 September 2018, 8 November 2018 and 14 December 2018, together with supporting documentation.
- 78. Dr Rhodes is an official of APHA, where she works as a senior research scientist in the TB Research Group. She has been actively involved in bovine tuberculosis immunology since 1998. She has been the test consultant for the bovine TB blood interferon-gamma test since 2009 and for the camelid TB serology test since 2014, in which role she provides scientific oversight of the tests as well as data analysis and advice to Defra and Welsh and Scottish TB Policy Advice colleagues. She has also published in her areas of research. She provided witness statements dated 29 October 2018 and 6 December 2018, together with supporting documentation.
- 79. As should be clear from the procedural history, some of the additional evidence adduced was not available to the Minister at the time of the Decision, for example, the evidence of Ms Walker. Most, if not all, of the post-Decision evidence goes to points already raised by the evidence prior to the Decision and some of it simply updates the position. None of the post-Decision scientific evidence appears to have moved either party to change their position on any of the key points.
- 80. Ms Walker, in her witness statement dated 24 January 2019, said the following:
 - i) No animal (bovine or non-bovine) has ever, since her farm, Nevalea, was established in 1994, tested positive for bTB, despite regular skin testing since 1994, including as part of New Zealand's voluntary bTB testing scheme for camelids, or ever shown to have clinical signs of bTB or, on slaughter, to have been reported as having visible bTB lesions.
 - ii) Geronimo was bred at Nevalea and kept there until June 2017 when he was removed and placed into quarantine prior to export to the United Kingdom.
 - iii) Geronimo was used at stud, where he was partnered before export with three female alpacas, all of whom remain at Nevalea, where all tested negative for

bTB in August 2018 (along with the rest of the herd). Neither they nor any of their cria (young alpacas) have shown any clinical sign of disease.

81. The evidence included emails disclosed by the Secretary of State that range in date from 1 May 2018 to 14 June 2018, relating to this case. The exchanges involved one or more employees in the Defra TB Programme (the names of some of the senders are redacted), the Minister's private secretary and Dr Rhodes. An internal memorandum prepared for the Minister dated 1 May 2018, advising the Minister "on options for dealing with a TB test positive alpaca", was also disclosed. The correspondence refers to and, in some cases, summarises points made during or arising from internal meetings and/or conference calls within Defra.

Grounds

- 82. Ms Macdonald's grounds, briefly summarised, are that:
 - i) the Decision is irrational in that the Secretary of State has refused to recognise the scientific and factual evidence to the effect that the test results, in which Geronimo tested positive for bTB, are unreliable; and
 - ii) in reaching the Decision the Secretary of State has failed to take into account relevant evidence, in particular:
 - a) the warning from the manufacturer of the Enferplex tests to which Geronimo was subjected that the results are not consistent with the presence of a progressive disease and "should be treated with great caution";
 - b) the fact that Geronimo, after first testing positive for bTB on 21 August 2017, is still showing no clinical signs of the disease; and
 - c) the scientific evidence that the "priming" to which Geronimo was subjected could cause false positive results.

Claimant's submissions

- 83. Ms Cathryn McGahey QC for Ms Macdonald began her submissions by referring to the power of the Secretary of State under section 32(1)(a) of the 1981 Act, "if he thinks fit", to cause to be slaughtered any animal which is "affected or suspected of being affected with any disease to which this section applies" or "has been exposed to infection of any such disease". She acknowledged that the provision confers a wide power, but she stressed that where the power is being exercised on the basis of a suspicion that an animal is affected by a disease, as in this case, the suspicion must be a reasonable one. She submitted that, in this case, there is no basis for the Secretary of State reasonably to suspect Geronimo of being infected with bTB. The evidence, she submitted, is, in fact, "overwhelmingly" against such a suspicion.
- 84. Ms McGahey's principal submissions were as follows:
 - i) The Secretary of State is relying on the results of two blood tests, the Enferplex tests conducted on 21 August 2017 and 11 December 2017, each of which was preceded by priming by administration of a skin test using bovine

tuberculin. In addition, Geronimo had been tested for bTB using a skin test on 9 September 2016. Accordingly, in the 14 months prior to the second Enferplex test, Geronimo had been primed three times. The repeated priming either caused, or is highly likely to have caused, each of the Enferplex tests to have produced a false positive.

- ii) The Secretary of State has irrationally "closed his mind" to the increasing body of evidence that demonstrates compellingly that Geronimo is not infected with bTB and that the Enferplex test results are not reliable due to the repeated priming over a 14-month period. As early as 12 April 2016 at a meeting to discuss tuberculosis in camelids between Defra, APHA, the British Alpaca Society and other camelid industry bodies, together with Synergy Farm Health, camelid industry representatives had raised a concern about whether the administration of two or more skin tests during a six month period was causing a build-up of tuberculin in animals that could cause false positives to further blood tests.
- iii) The increasing body of evidence includes the following:
 - a) The evidence of Ms Walker (which I summarised at [80] above) excludes any realistic possibility that Geronimo contracted bTB in New Zealand, given that there has not been a confirmed or even suspected case of bTB in any animal on the farm since it was established in1994.
 - b) Geronimo tested negative for bTB on the skin test conducted in New Zealand on 31 July 2017 prior to his importation, on the skin test in the United Kingdom on 13 November 2017 prior to the second Enferplex test and on the DPP blood test on 11 December 2017.
 - c) Ms Macdonald has never had any other suspected or confirmed case of bTB on her farm and has excellent biosecurity measures (a fact not disputed by the Secretary of State), including badger-proof fencing.
 - d) Geronimo has been kept in isolation with four (subsequently five) other alpacas since his arrival in the United Kingdom in August 2017. He has been examined twice by a veterinary surgeon who is an expert in camelids, Mr Robert Broadbent, his most recent examination having been on 31 January 2019. Mr Broadbent's evidence confirms that neither Geronimo nor any of his companion animals is showing any clinical signs of bTB.
 - e) Seven other alpacas imported into the United Kingdom in the same consignment as Geronimo and owned by another alpaca farmer, Mr K Freivokh, were tested for bTB, using skin and serology tests on 21-24 August 2018 and 6 September 2018, respectively, and found to be negative for bTB.
 - f) Ms Macdonald's expert witness, Ms Mueller, who is independent, has given evidence to the effect that, if Geronimo had been infected with bTB in New Zealand, it is highly likely that he would by now be in the advanced stages of the disease and would be showing clinical signs of

- it. Ms Mueller also states that it is not possible to say, on the current state of scientific knowledge, that priming by injection with bovine tuberculin does not cause false positive results, and there is some evidence that it may do so. The Secretary of State's scientific adviser, Dr Shelley Rhodes, who is employed by the Secretary of State and therefore not independent, has acknowledged that evidence on the effect of priming in camelids is "sparse".
- g) Mr Hayton of Synergy Farm Health, which developed the Enferplex test, advised Ms Macdonald in his email of 20 December 2017, following the second Enferplex test administered on 11 December 2017, that there is "very reasonable doubt from a clinical and epidemiological perspective as to whether the animal is a true *M. bovis* positive" and would "highly recommend caution in interpretation of the results".
- iv) The Secretary of State is irrationally refusing to permit or order a further retest of Geronimo and/or other alpacas (for example, Geronimo's companion animals), when that testing would strengthen further the case that Geronimo is not infected with bTB.
- 85. Ms McGahey directed me to various places in the correspondence where the Secretary of State is alleged to have shown his "unlawfully closed-minded approach" and/or where he is alleged to have shifted his arguments when faced with evidence that he is wrong. She gave as an example the evidence of Dr Rhodes in her second witness statement at para 32 where she stated that in conducting the second Enferplex test in December 2017 it was necessary to apply a protocol that maximised sensitivity over specificity "given that Geronimo was highly likely to be infected based on the result of the highly specific Enferplex (four spot) test of August 2017". Ms McGahey asserted that this approach is logically flawed, given that the reason for the second test was the suspicion that the first test had returned an incorrect result. There was therefore no justification for applying a second test with a stricter sensitivity than the first test.
- 86. Ms McGahey also submitted that it was "entirely perverse" for the Secretary of State to insist that Geronimo be primed before the second test when the reason for the first test being suspect was Geronimo had been primed before the test.
- 87. Ms McGahey submitted that the Secretary of State had refused to obtain further evidence. For example, the Secretary of State has refused to allow the blood sample taken from Geronimo before he was primed in November 2017 to be tested until after he is slaughtered. She notes that the Secretary of State argued in his Summary Grounds of Resistance (at para 65) that any test result would fall outside the APHA testing protocol and would therefore not be a reliable guide as to whether Geronimo is infected with bTB, but allowing the test post-slaughter would be interesting for research purposes if Geronimo's corpse shows visible legions. Ms McGahey submitted, however, that a test result, whether positive or negative, before slaughter would be equally informative and would contribute to the Secretary of State's knowledge and overall picture of Geronimo's bTB status; the Secretary of State is narrow-mindedly and irrationally sticking to a protocol agreed with camelid industry

- bodies several years ago and refusing to take account of or to obtain evidence that would or might shown him to be wrong.
- 88. In support of her submission that the Secretary of State has irrationally refused to obtain relevant evidence, Ms McGahey referred to his refusal to test Geronimo's companion animals until after a post-mortem examination of Geronimo. Ms Macdonald is prevented from obtaining this evidence herself due to article 12(5) of the 2014 Order.
- 89. Ms McGahey submitted that the Secretary of State also had regard to irrelevant factors in reaching the Decision. To illustrate this, Ms McGahey referred to a letter dated 23 October 2017 from the Government Legal Department to Olephant in which it was noted at para 16 that:
 - "APHA and Defra emphasise that it is also paramount for the credibility of the private TB testing scheme that APHA is seen to apply government disease control policy consistently and fairly to all camelid keepers."
- 90. Ms McGahey then referred to a submission made by a Defra adviser to the Minister dated 1 May 2018, in which he wrote:
 - "Allowing a repeat TB positive animal to remain on farm would set a very unhelpful precedent not just for other camelid keepers, but also for cattle keepers wanting to challenge their positive TB test results. The private camelid TB test scheme will become more difficult to manage and APHA will encounter more resistance when attempting to remove test positive animals in the future on other farms, thus increasing the costs of delivering the policy."
- 91. Ms McGahey submitted that the perceived need to maintain public confidence in, and be seen to take a robust approach to, Defra's bTB eradication programme should not have played any part in the Secretary of State's thinking in relation to this case.
- 92. Finally, Ms McGahey submitted that the evidence demonstrates "to a high degree of probability" that Geronimo is not infected with bTB. Therefore, the Secretary of State has no proper basis reasonably to suspect that Geronimo is so infected. By concluding that Geronimo is infected and refusing to change his mind when faced with increasing evidence to the opposite effect, the Secretary of State has acted irrationally and unlawfully. The Decision and the TN03 Notice should therefore be quashed, and a new reliable serology test conducted without any "priming" before the test.

Defendant's submissions

93. Mr Westaway for the Secretary of State summarised the Secretary of State's position as follows: having regard to all relevant factors and informed by expert veterinary advice, Geronimo is highly suspected of being infected with bTB and should therefore be slaughtered. The basis for that suspicion is that he has tested positive twice on reliable tests that leave little room for doubt. The Secretary of State has taken into account that Geronimo is not showing clinical signs of disease, but bTB is a slow,

- progressive disease that can take years to manifest physically. While it is impossible to know with certainty how Geronimo came to be infected, it is not unrealistic to conclude that it could have occurred due to exposure to bTB in New Zealand.
- 94. Mr Westaway emphasised that section 32(1) of the 1981 Act gives the Secretary of State a broad discretion in any case where "he thinks fit" to cause an animal to be slaughtered if it "is affected or suspected of being affected with" a specified disease, such as bTB. He also noted that the Secretary of State must bear in mind the wider policy imperative of controlling bTB in England. The bTB testing protocols reflected in the Guidance and Operations Manual, developed by APHA in collaboration with the camelid industry, show that the Enferplex test is recognised as one of the best methods of detecting bTB in camelids. No test is perfect. False positives are possible, but the priority is to avoid false negatives.
- 95. Mr Westaway submitted that it is not for the court to resolve the disagreements between the parties on the scientific evidence. The court can only intervene if the Decision and/or the issuing of the TN03 Notice of 21 December 2017 was irrational or otherwise unlawful in public law terms. In this case, the Secretary of State has given careful consideration to all of the arguments raised by Ms Macdonald but nonetheless maintains his suspicion that Geronimo is infected with bTB. There are no public law grounds on which the Decision or the TN03 Notice can be quashed.
- 96. Mr Westaway submitted that it is clear from the Veterinary Risk Assessment, which was prepared before the TN03 Notice of 21 December 2017 was issued, as well as all of the Decisions and all of the other correspondence between the parties, both before and after the Decision, that Geronimo's case has been given extensive and exceptional consideration and reconsideration by the Secretary of State.
- 97. Mr Westaway also submitted that this is not a case where substantial new issues and evidence have emerged over time. The principal issues, such as the effect of priming on the reliability of Enferplex tests, emerged early in discussions between the parties. It is not fair to say that the Secretary of State has "doggedly" maintained his position, as Ms McGahey said in her skeleton argument. The Secretary of State has been broadly consistent throughout in his position, just as Ms Macdonald has been broadly consistent in hers.
- 98. Mr Westaway gave as an example the assertion that the reason that the Secretary of State had exceptionally ordered a re-test of Geronimo, despite its being the case that under the protocol normally a positive result to an Enferplex 4-antigen test administered as part of the Voluntary Camelid Testing Scheme, as happened in this case on 21 August 2017, would result in the animal being slaughtered. Ms Macdonald has maintained that the reason that the Secretary of State had ordered the re-test was that the August 2017 test had returned an incorrect (false positive) result. Mr Westaway noted, however, that the conclusion of Dr de la Rua-Domenech in the Veterinary Risk Assessment was that, following the August 2017 test, "[t]he likelihood of the imported Enferplex TB-positive alpaca being infected with M. bovis (tuberculosis) is high, as demonstrated by the [positive predictive value] calculations [set out in part 5 of the Veterinary Risk Assessment]". The Secretary of State had ordered the re-test, not because he accepted that the initial test was flawed, but to provide reassurance to Ms Macdonald, as noted at paragraph 9 of the letter of 30 January 2018 from the Government Legal Department to Olephant.

- 99. In relation to the dispute regarding the reliability of the Enferplex tests, which is at the heart of this case, Mr Westaway rejected Ms Macdonald's contention that the positive test results are "flawed science", as stated by Ms McGahey in her skeleton argument. The Secretary of State maintains that there is solid scientific evidence that priming ahead of an Enferplex test increases the specificity of the test, that is, it decreases the risk of a false positive. Dr Rhodes in her evidence gave the risk of a false positive on an Enferplex 4-antigen test after priming 10 to 30 days previously as 0.34 per cent (or 1 in 291 animals). The risk of a false positive on an Enferplex 2-antigen test after priming 10 to 30 days previously is 0.7 per cent (or 2 in 291 animals). The accuracy and reliability of the tests was confirmed and updated in an internal paper entitled "APHA Camelid TB Serology Test: re-assessment", produced by APHA in March 2018 ("the Camelid TB Serology Test Paper"), the principal author of which was Dr Rhodes.
- 100. The scientific basis for the Secretary of State's position that priming should occur before an Enferplex test, as set out in the testing protocols, is evidence-based, the reasons for priming explained in the Priming Paper.
- 101. Mr Westaway noted that Ms Macdonald's expert witness, Ms Mueller, in para 12 of her third expert report dated 14 December 2018 does not dispute the low probability of a false positive on either interpretation (4-antigen or 2-antigen) of the Enferplex test. At para 8 of that report, she says:
 - "I maintain my opinion that we lack the evidence base to categorically say that there is no potential for priming to cause artificially elevated antibody levels which may result in a false-positive reaction to serological tests like Enferplex, whether after single or multiple priming."
- 102. Mr Westaway submitted that that conclusion is far from a conclusion that the science underlying the use of priming in connection with serological tests is "flawed".
- 103. As to Mr Hayton's e-mail message of 20 December 2017 in which he recommended "caution in interpretation of the results" of the Enferplex tests, Mr Westaway submitted that the Secretary of State had adopted such caution. Mr Hayton's comments were carefully addressed, he submitted, in the Secretary of State's response dated 18 January 2018 to the letter dated 16 January 2018 sent by Olephant on behalf of Ms Macdonald. Mr Westaway noted that this deals with the point made by Ms McGahey that the Secretary of State failed to have regard to this evidence from Mr Hayton.
- 104. In her email of 12 May 2018 to the Minister, Dr Rhodes said that "[p]ublished research on the potential for repeat skin testing to boost detectable specific antibody responses is sparse", a point reiterated by the Minister in the Decision. The March 2018 Paper, which is referred to in Dr Rhodes's email of 12 May 2018 and in the Decision, validates the use of priming in connection with serological tests for bTB in camelids. Mr Westaway noted that, in addition to this unpublished data, both Ms Mueller and Dr Rhodes referred to a number of independent published studies, constituting sufficient material from both published and unpublished sources to provide a clear and rational basis for the Secretary of State's conclusion as to the

- validity and robustness of priming to achieve an anamnestic boost in camelids being tested for bTB.
- 105. Mr Westaway submitted that the many references in the correspondence, as well as in the internal Defra communications in respect of this case disclosed by the Secretary of State to Ms Macdonald (which are described at [81] above), to the issue of whether priming increases the risk of false positives or otherwise undermines the reliability of the Enferplex test dispose of Ms McGahey's submission that the Secretary of State irrationally closed his mind to the issue. It is clear from those sources that the Secretary of State considered the issue in detail and set out his views on the issue in correspondence with Ms Macdonald with some care.
- 106. As to "the increasing body of evidence" that was said by Ms McGahey to demonstrate that Geronimo is not infected with bTB and that the Enferplex test results are not reliable due to repeated priming over a 14 month period (which I have attempted to summarise at [84(iii)] above), Mr Westaway submitted that none of the points raised are determinative. They are, at best, circumstantial factors to be taken into account in considering whether Geronimo may be infected with bTB.
- 107. In relation to some specific points raised by Ms McGahey, Mr Westaway submitted that:
 - Notwithstanding the evidence of Ms Walker, the possibility that Geronimo was exposed to bTB in New Zealand cannot be excluded. Nevalea is large farm where alpacas are mixed with cattle and other livestock. The Secretary of State has had regard to the evidence of Ms Walker, as can be seen from the correspondence and as reflected in the Decision. But the Secretary of State is not in a position to interrogate the evidence. As noted in correspondence (for example, the letter dated 23 October 2017 from the Government Legal Department to Olephant), the Secretary of State is concerned that in New Zealand bTB surveillance in relation to alpacas is not as rigorous or systematic as it is in relation to cattle, testing is voluntary and based solely on a skin test with a low sensitivity for camelids (meaning a comparatively high risk of false negatives results). Also "vector risk" (that is, the risk of an alpaca being exposed to bTB through contact with a wild animal) cannot be excluded. Accordingly, the evidence of Ms Walker does not take matters much further.
 - ii) In relation to the evidence from Mr Broadbent that Geronimo is not yet showing clinical signs of the disease and the evidence of Ms Mueller that if he had been exposed to bTB in New Zealand, then it is highly likely that he would by now be in the advanced stages of the disease, the Secretary of State has had regard to this evidence. He accepts Mr Broadbent's evidence, but he relies on his own scientific advisers for the view that clinical signs of bTB may not manifest themselves in a camelid for years after exposure to the disease. He is not bound to accept Ms Mueller's view, which, in any event, Ms Mueller qualified in her original expert report dated 21 September 2018 by saying:

"There are reports of animals without overt clinical signs having visible TB lesions at post-mortem examination. Therefore, the picture is not as clear-cut as one would like."

iii) The Secretary of State has taken a consistent position in relation to this point regarding Geronimo not yet showing clinical signs of the disease. For example, in the Minister's letter of 13 August 2018 to Ms Macdonald, the Minister said:

"Properly validated serological tests, such as the Enferplex test for camelids, are potentially valuable in that they are able to detect disease in the early stages, before clinical signs appear. Given this, it is possible that Geronimo could live for many months or years without signs of ill health"

- 108. In relation to Ms McGahey's submission that the Secretary of State has improperly "shifted his arguments" in the face of Ms Macdonald's arguments and evidence, Mr Westaway submitted that that is unfair and wrong. There has been a lengthy correspondence regarding this case, during which numerous arguments and counterarguments have been raised. The Secretary of State has responded to Ms Macdonald's points as they have developed. Reading the correspondence fairly and as a whole, Mr Westaway submitted, that the Secretary of State has been remained consistent on the key points. In any event, a change of position would not, in itself, be unlawful.
- 109. In relation to the point made by Ms McGahey, relying on internal Defra communications, that the Secretary of State took into account irrelevant factors by having regard to the need to maintain public confidence in Defra's bTB eradication programme, Mr Westaway submitted that the advice relied on was sound and unremarkable. There is nothing improper about the Secretary of State bearing in mind broader policy considerations. The Secretary of State's approach to this case has not been blindly dictated by the protocols set out in the Guidance and the Operations Manual.
- 110. Finally, Mr Westaway submitted that, ultimately, the question is simply whether the Secretary of State had, on the available evidence, reasonable grounds to suspect that Geronimo is affected by bTB, justifying his decision to order that he be slaughtered. He submitted that the Secretary of State had justified his reliance on the Enferplex tests by reference to the available evidence, reaching lawful reasoned conclusions. It cannot be said that there is "no proper basis" for the Decision or the TN03 Notice. Accordingly, there is no public law ground on which they can be quashed. The claim should therefore be dismissed.

Discussion and decision

- 111. I have set out the submissions made by each side in some detail because I am aware that there is considerable interest in this case from a variety of parties beyond those directly involved. It has not, however, been possible to set out each argument and counter-argument made throughout months of correspondence. Nor, in my view, is it necessary to do so.
- 112. The Secretary of State's power under section 32(1) of the 1981 Act is to be exercised as he "thinks fit". This is clearly intended to confer a broad discretion. The Secretary of State is charged by Parliament with the onerous and important public duty of

exercising the functions of expert decision-maker in relation to the control of disease in animals in the United Kingdom.

113. The authorities make it clear that this court must not seek to usurp that function. In *R* (*Mott*) *v Environment Agency* [2016] EWCA Civ 564, [2016] 1 WLR 4338, a decision of the Court of Appeal in relation to a judicial review claim concerning restrictions imposed by the statutory regulator on salmon fishing rights, Beatson LJ referred at [74] with approval to the following proposition of Lightman J in *R v Director General of Telecommunications, ex parte Cellcom* [1999] ECC 314 (which concerned the regulator's assessment of whether to release two new network services providers in the mobile telephone market from certain restrictions) at [26]:

"The court must be astute to avoid the danger of substituting its views for the decision-maker and of contradicting ... a conscientious decision-maker acting in good faith with knowledge of all the facts."

114. Beatson LJ made the following observation in *Mott* at [77]:

"A reviewing court should be very slow to conclude that the expert and experienced decision-maker assigned the task by statute has reached a perverse scientific conclusion."

- 115. Finally, in *Mott* at [69], Beatson LJ approved the proposition, which he noted was common ground between the parties, that:
 - "... in principle the court should afford a decision-maker an enhanced margin of appreciation in cases, such as the present, involving scientific, technical and predictive assessments."
- 116. I do not understand either of the parties to disagree with any of these general statements of principle. In this case, where there is a conflict of expert scientific evidence, on which there has been an extended and detailed correspondence, I also bear in mind the observation of Mitting J in *R* (*High Burrow Organic Farming Partnership*) *v Secretary of State for Environment, Food and Rural Affairs* [2008] EWHC 953 (Admin) (a case involving a challenge to positive blood and skin test results for bTB in relation to a herd of cattle on an organic dairy farm) at [19]:

"Judicial review is not ... an appropriate set of proceedings in which to determine ... complex scientific questions."

117. In that same paragraph of his judgment, Mitting J referred to the following observation of Lord Bingham in *R v Secretary of State for Health*, *ex parte Eastside Cheese Company* [1999] EuLR 968 at 987G:

"[On] public health issues which require the evaluation of complex scientific evidence, the national court may and should be slow to interfere with a decision which a responsible decision-maker has reached after consultation with its expert advisors."

- 118. Against that background, I note that the hurdle that Ms Macdonald has to surmount in order to establish that the Decision and the TN03 Notice are unlawful is high. There needs to be compelling evidence that the Secretary of State has acted perversely or unfairly or reached a decision that no reasonable decision-maker, faced with the evidence in this case, could reach. Ms McGahey did not shy away from attempting to surmount this high hurdle on behalf of Ms Macdonald, but despite her thorough and forceful submissions, I do not find that she has succeeded.
- 119. At the heart of this case is a conflict of view as to the level of risk associated with the fact that Geronimo was primed three times over a 14-month period. There is a conflict of evidence on this point. Neither Ms Mueller's evidence nor any other evidence adduced by Ms Macdonald comes close to establishing that the Secretary of State's assessment of the risks raised by priming is irrational or perverse. I agree with Mr Westaway's submission that Ms Mueller's conclusion at para 8 of her third expert report, which I have quoted at [101] above, is far from a conclusion that the science underlying the use of priming in connection with serological tests is flawed. The Priming Paper shows that the issue has been considered.
- 120. The Secretary of State has made an assessment of risk in relation to priming that differs markedly from that of Ms Macdonald, who considers that priming makes it "highly likely" that both of the positive Enferplex tests in respect of Geronimo are flawed. While having acknowledged in the Priming Paper a possible "negative impact" from priming on the specificity of serology tests performed on healthy animals, the Priming Paper nonetheless notes the lack of evidence on this point. It concludes that priming is essential for serology tests conducted where there is a confirmed or strong suspicion of *M bovis* infection and recommended for private routine screening of presumed bTB-free herds. Dr Rhodes noted in her evidence that evidence on the effect of priming is sparse. In my judgment, it is not possible to say that the position taken by the Secretary of State on this point is so unreasonable that no rational decision-maker could have taken it.
- 121. As far as the suggestion that the Secretary of State ignored Mr Hayton's recommendation of caution in the interpretation of the Enferplex tests, it is my view that the correspondence shows that Mr Hayton's recommendation was not ignored. It was taken seriously and specifically addressed in the letter dated 18 January 2018 from the Government Legal Department to Olephant to which I refer at [55-56].
- 122. More generally, it is clear from the correspondence, as well as the internal communications within Defra that I have referred to at [81], that every substantive point raised by Ms Macdonald, either directly with the Secretary of State or the Minister, or by Olephant was considered and addressed by the Secretary of State. The fact that the Secretary of State did not change his views on the reliability of the Enferplex tests as a result of that correspondence does not demonstrate that he had "closed his mind" to Ms Macdonald's submissions or that he was "doggedly" persisting in his views in the teeth of the evidence.
- 123. Ms McGahey submitted that the internal communications within Defra that were disclosed during this trial show that Secretary of State had taken into account irrelevant factors, as I have noted at [89-91]. I agree, however, with Mr Westaway's submission that the advice given is "sound and unremarkable" and that there was

- nothing improper in the Secretary of State's having regard, as part of an overall consideration of the relevant factors, to broader policy considerations.
- 124. Ms McGahey's submission that it was "entirely perverse" of the Secretary of State to require priming before the second Enferplex test in December 2017 rests on the premise, not accepted by the Secretary of State, that the August 2017 Enferplex test meant that the earlier test result was a likely false positive or otherwise flawed due to the effect of priming. It is common ground that the re-test ordered by the Secretary of State in December 2017 was an exception to the protocol agreed with the camelid industry that applies under the Voluntary Camelid Testing Scheme, under which Geronimo, having failed the Enferplex test on a 4-antigen interpretation would ordinarily have been removed and slaughtered without a further ante-mortem test.
- 125. The rationale for the protocol that the Secretary of State insisted should apply to the re-test in December 2017 was set out in the Veterinary Risk Assessment and further explained in correspondence between the parties. The requirement of priming and the use of an Enferplex 2-antigen test (chosen by Ms Macdonald as one of two out of three possible serology tests) deliberately enhanced the sensitivity of the protocol at the expense of specificity in order further to reduce the risk of a false negative, given the strong suspicion of *M bovis* infection aroused by the first positive Enferplex test in August 2017. In other words, the Secretary of State decided to require a protocol for the re-test that lowered the risk that Geronimo (if, in fact, infected) might nonetheless give a false negative, even though this raised slightly the chance that he would (if not, in fact, infected) give a false positive. This decision cannot, in my view, be said to be irrational or perverse.
- 126. As I understand it, the Secretary of State does not deny that it is possible, despite the evidence of two positive Enferplex tests, that Geronimo is not infected with *M bovis*. In other words, it is possible that Ms Macdonald is correct that the Enferplex test results are false positives. Nonetheless, the two positive results provide strong evidence, to a high degree of certainty, that he is so infected. Given the contagious nature of bTB and the devastating effect it can have on other animals, bovine and non-bovine, including the risk to humans, the Secretary of States deems it fit to exercise his power to have Geronimo slaughtered and to pay compensation to Ms Macdonald.
- 127. The Secretary of State's response to Ms Macdonald's request that there be a third test, without priming, is that a third test, if negative, would not resolve the situation. First, without priming, there would be a higher risk of a false negative, which would decrease the Secretary of State's confidence in the test result. Secondly, there would still have been two positive results, meaning that the Secretary of State would continue to have strong reasons to believe that Geronimo is infected with *M bovis*. Accordingly, ordering a third test would be a "futile exercise". In my view, that is a judgment for the Secretary of State rather than this court. It is not a judgment that is clearly irrational, perverse or unfair, even if it is not the judgment that a different decision-maker might come to.
- 128. The Secretary of State has had regard to the scientific and factual evidence put forward by Ms Macdonald, has considered it and has given his reasons for not accepting Ms Macdonald's key criticisms of the scientific basis relied on by the Secretary of State for the Decision and the TN03 Notice. The Secretary of State has clearly taken into account (i) the recommendation from Mr Hayton that the two

Enferplex test results in respect of Geronimo be treated with caution, (ii) the fact that Geronimo is still not showing clinical signs of the disease, (iii) the scientific evidence put forward by Ms Macdonald that priming before a serology test, such as the Enferplex test, could cause a false positive result and (iv) the other issues, such as the evidence of the absence of bTB among the animals on Nevalea farm, Geronimo's history, the biosecurity measures at Ms Macdonald's farm and so on. The Secretary has given adequate reasons for his views on each of those issues and why he nonetheless maintains his decision that Geronimo should be slaughtered.

- 129. I fully understand that the Secretary of State's decision that Geronimo should be slaughtered as an animal strongly suspected of being affected with bTB is highly distressing for Ms Macdonald and her supporters, as the Secretary of State has himself acknowledged in correspondence, including in the Decision. The claim, however, does not disclose any public law error made by the Secretary of State in the exercise of his discretion under section 32 if the 1981 Act, on the basis of which the court would have the power to intervene and quash the Decision and the TN03 Notice dated 21 December 2017.
- 130. The Secretary of State is the expert decision-maker, entrusted by Parliament to control diseases in animals, such as bTB in camelids. In the absence of the establishment by Ms Macdonald of a public law error made by the Secretary of State in reaching the Decision and in deciding to issue the TN03 Notice, the Secretary's decisions must be respected by the court.
- 131. Accordingly, the claim must be dismissed.
- 132. When I circulated my judgment in draft to the parties' legal representatives in accordance with Practice Direction 40E, I had included in the draft the word "highly" before the word "contagious" in paragraphs 1 and 126 of the draft judgment (which are the same paragraphs in this final judgment). It is a qualifier that I picked up from one of the many documents that I reviewed during the preparation of the judgment. In his suggested corrections to the judgment, Mr Westaway suggested that I remove the word. Ms McGahey objects to my removing it on the basis that my apparent belief that bTB is highly contagious forms a ground of appeal. I have removed the word on the basis that it makes no difference to my conclusions whether bTB is "contagious" or "highly contagious". I have recorded the submissions of counsel on this point so that Ms McGahey may refer to it in her grounds of appeal to the Court of Appeal to the extent that she continues to consider it relevant.

Appendix 1

Extract from Part 6 of the Veterinary Risk Assessment, referred to at [35] of this judgment (footnote added)

| | Argument | Counter-argument |
|---|---|--|
| 1 | The alpaca has originated from a farm in NZ that is asserted to have been free from TB continuously for 22 years | This animal comes from a very large mixed alpaca and cattle farm in NZ. Although the bTB situation in NZ is better than in the UK, it is by no means a country officially free from TB and there are still high bTB risk areas with endemic <i>M. bovis</i> infection in possums (wildlife maintenance hose), including the North Island of NZ. Sporadic TB breakdowns in cattle herds continue to occur in low risk areas of NZ subjected to biennial or less frequent testing. Additionally, TB surveillance in NZ alpaca herds is not as systematic and rigorous as it is in cattle or farmed herds because camelids are not included in the national bTB eradication strategy and TB testing is voluntary. |
| 2 | The animal was skin tested with negative results shortly before export date | The tuberculin skin test is difficult to perform and has a low sensitivity in camelids. Used on its own, it has a very low negative predictive value (i.e. negative skin tests are unreliable). |
| 3 | Possible interference of the pre- export skin test with the subsequent post-movement antibody test carried out three weeks after tuberculin injection ('priming' effect) | There is no evidence that the anamnestic antibody response observed in TB-infected camelids injected or tested with tuberculin also occurs in TB-free animals. The current scientific evidence and the results of field antibody testing carried out in GB in camelids from unrestricted herds adjoining or co-located with infected cattle herds strongly indicates that a prior injection of bovine tuberculin into the skin does not affect the specificity of the antibody tests. See reference no. 3. |
| 4 | The animal suffered a degree of stress from flights all the way from NZ and the pre-export quarantine | The stress of travel and quarantine would, if anything, have caused immunosuppression and thus a false negative result would have been more likely than a false positive. |
| 5 | Other countries, like Sweden, advise against skin testing camelids in the 30 days before the collection of samples for serological TB testing | The veterinary authorities in different countries have different risk appetites. The Swedish authorities are willing to sacrifice sensitivity for specificity. by contrast, the veterinary authorities in other countries like Norway do require serological testing to be completed 10—30 days after skin testing, either in the herd of origin or the herd of destination. |

[Reference no 3 is the May 2017 version of the Priming Paper.]

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| | Argument | Counter-argument |
|---|--|---|
| 6 | Re-testing of Enferplex positives is allowed by APHA | That is only the case for camelids that give positive results on the more sensitive (but less specific) interpretation of the test, i.e. the two-antigen Enferplex test. However, this is a different situation, in that we are dealing with an alpaca that has given positive antibody responses to four different <i>M. bovis</i> antigens on the highly specific format of the Enferplex TB test. The animal was declared positive by the private lab, which has not acknowledged any errors in the performance of the test. |