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[redacted]

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Dear [redacted]

EXPORT OF PIGS FROM THE UNITED KINGDOM TO THE PEOPLE'S REPUBLIC OF CHINA: DEALING WITH NON-NEGATIVE TEST RESULTS

I hope you are well. I am writing further to my letter of 9 August 2011 (copy enclosed) to [redacted] regarding non-negative test results in pigs selected for export to China. I have discussed this in some detail with [redacted] and she has asked me to write to you about this.

[redacted] has informed me that it has been decided that if a blood sample from a pig gives a non-negative serological test result, the pig will have to be removed from the consignment and that there is no option to retest the blood sample, or the pig itself, to identify if the non-negative test result is false.

Due to the nature of the tests and the number of different tests involved, the consequence of this decision is that a significant number of pigs in all consignments will now be ineligible for export. A number of pigs were removed from the last consignment of pigs for export to China due to non-negative test results for *Brucella*, transmissible gastroenteritis (TGE) and *Actinobacillus pleuropneumoniae (APP)* and the result was that the exporter (JSR) was unable to provide the number of pigs required in the contract.

As I mentioned in my letter to [redacted] with certain tests, due to incomplete test specificity, non-negative test results are not uncommon even in uninfected pigs especially when large numbers of pigs are tested. In other circumstances, when non-negative test results occur, it is normal practice to take further action to confirm or negate the original test results. Options are to repeat the original test, to re-test the original sample using different tests (if available) and to re-sample the animal(s) with the non-negative test result(s) and then to repeat the original test(s) and different tests if available. Clearly all testing must be

carried out in laboratories that are competent to do the work. In the UK, pre-export testing of samples from pigs for export to China is carried out in UK Government laboratories where the tests are accredited according to ISO17025.

For these reasons, I would be grateful if the decision to remove a pig simply on the basis that a non-negative serological test result has been obtained could be reconsidered and I request that the final decision should instead be taken once further testing has been carried out to resolve each case. Indeed my recollection is that we discussed and agreed this principle in 2009 when for example we considered changing the serological testing requirement for porcine reproductive and respiratory syndrome (PRRS) from immunoperoxidase monolayer assay (IPMA) to enzyme-linked immunosorbent assay (ELISA). In those discussions we discussed that about one sample in a hundred gives a non-negative result in the PRRS ELISA and that such a result has to be resolved by re-testing by IPMA. This is standard practise.

If the principle of retesting is agreed for *Brucella*, TGE and APP the approach must vary according to the tests involved. For TGE and APP as there are no available confirmatory tests, the best option is that the pig should be re-sampled and then re-tested. For *Brucella*, the initial sample should be re-tested by ELISA and if that test is non-negative the pig should be re-sampled and then retested using the SAT and other tests available (ELISA, Rose Bengal test (RBT) and complement fixation test (CFT).

As sample quality can also affect results, if samples of poor quality (eg haemolysed samples) are received at the laboratory, I propose that the pigs should be re-sampled. This point is particularly important when using the Brucella SAT and APP CFT.

If a pig fails a re-test it should be removed but if a pig passes the re-test I request that it should then be allowed to proceed to the next stage. These approaches are practical and will enable more pigs to be exported. Assurance that the pigs exported are not infected with these (and other) specified infectious agents will be provided by the fact that the pigs exported will be re-tested in pre-export quarantine and again after import into China in post-import quarantine and this will be supported by the assurances provided in the Export Health Certificate.

I mentioned problems related to laboratory testing in my letter to [redacted] of 18 May 2011 (copy enclosed) and I discussed this with him when I visited China in June 2011. While I appreciate that the revised protocol for the export of pigs from the UK to China was signed only last year, it would be useful in due course to agree changes to the protocol to address these issues.

However, in the meantime it would be very helpful if we could agree on a way to help resolve this immediate problem and I suggest this can be achieved by agreeing on the interpretation of the import protocol. The requirement for the pig to be removed from the consignment in the event of a non-negative screening test result has occurred following strict interpretation of the protocol and I do not think this was the intention indeed as I have mentioned, we discussed a different interpretation when we met in 2009.

Unless we can agree this, at present the only option will be for exporters to select a large number of additional pigs for each export to allow for test failures. This is very expensive and wasteful and also raises the risk that certain lines of pigs may not be exported.

For the longer term, for *Brucella* there is a further option that I have discussed with [redacted] and I have said that I would mention to you, and that is to consider a possible change to the test for *Brucella* from SAT to an ELISA. I expect though that this will require a change to the protocol. The SAT is not a prescribed test for international trade purposes (according to the OIE manual prescribed tests are the indirect and competitive ELISAs, the Rose Bengal

test (RBT), the complement fixation test (CFT) and the fluorescence polarisation assay (FPA)).

My colleagues at the Animal Health and Veterinary Laboratories Agency laboratory at Weybridge in the UK have advised me that their competitive ELISA (cELISA) 'Compelisa' is their preferred test for screening pigs for serological evidence of antibodies to *Brucella*.

This preference is supported by other laboratory workers around the world. Indeed in September 2011 a paper was presented on this by workers including some from the EU/OIE/FAO Brucellosis Reference Laboratory in France at a conference in Argentina. This study[1] recorded that the AHVLA 'Compelisa' gave the best sensitivity (96.4%) and specificity (99.6%) compared to another commercial cELISA, an indirect ELISA, the RBT and FPA. I have enclosed a copy of this paper for your information.
I also understand from our laboratory experts that other experts in EU member states (France, Germany and Denmark in particular) no longer rely on the SAT and that they all recommend using cELISA for porcine blood samples. Accordingly while the SAT is relatively cheap & simple to use, it is no longer the test of preference for Brucella serology in pigs. A further consideration is that while the Brucella SAT is affected by reduced sample quality, the cELISA is still usable when testing samples of reduced quality[2]

Even so the Brucella cELISA is not 100% specific and accordingly it would be of great assistance if we can still be permitted to carry out retesting even if a change from SAT to cELISA is agreed.

I would therefore be grateful if we could agree some changes to the current procedures very soon as this ruling regarding non-negative test results is significantly affecting the ability of UK pig breeding companies to export pigs to China.

I would like to take this opportunity to thank you and your colleagues for your continuing cooperation with the export of pigs from the UK to China. The procedures involved are very complicated and we know very well that the export of pigs to China would not be possible without the considerable assistance which you and your colleagues very kindly give us.

I look forward to hearing from you.

Best regards.

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[1] A. Praud, L. Meyer, B. Garin-Bastuji. Estimation of sensitivity and specificity of five serological tests for the diagnosis of porcine brucellosis. (2011). Paper presented at Brucellosis 2011, International Research Conference including the 64th Brucellosis Research Conference at Buenos Aires, Argentina, September 21st to 23rd, 2011. The manuscript has been submitted to Preventive Veterinary Medicine.

[2] Stack, J.A., Perrett, L.L., Brew, S.D. and MacMillan, A.P. A Competitive ELISA for bovine brucellosis suitable for testing poor quality samples. (1999) *Veterinary Record*, 145(25):735-736.