
PUBLIC PROTECTOR
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Report on allegations of maladministration and undue delay by the Free State DARD and the DAFF

REPORT ON AN INVESTIGATION INTO ALLEGATIONS OF MALADMINISTRATION BY THE FREE STATE DEPARTMENT OF AGRICULTURE AND RURAL DEVELOPMENT (DARD), AND THE DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES (DAFF) RELATING TO ITS HANDLING OF AN OUTBREAK OF BRUCELLOSIS (CONTAGIOUS ABORTION) ON THE FARM OF MRS RONEL BEHRENS
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Executive Summary

(i) This is my report issued in terms of section 182(1)(b) of the Constitution of the Republic of South Africa, 1996, and section 8(1) of the Public Protector Act, 1994.

(ii) The report relates to an investigation into allegations of maladministration by the Free State Department of Agriculture and Rural Development (DARD), and the Department of Agriculture, Forestry and Fisheries (DAFF) relating to its handling of an outbreak of Brucellosis on the farm of Mrs Roné Behrens.

(iii) Brucellosis is a highly contagious disease caused by a bacterium called Brucella abortus. Clinically, the disease is characterised by abortions in the later stages of pregnancy, retained placenta and decreased fertility. Humans are also susceptible, by drinking unpasteurised, unboiled milk, or eating undercooked meat of infected animals. The disease in humans is known as undulant fever.

(iv) The product RB51 is a vaccine registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, as a stock remedy to be used for the prevention and / or control of Brucellosis. The vaccine was registered in 2002. The original registration holder was Schering Plough and the registration was later transferred to Intervet South Africa (now called MSD Animal Health).

(v) The World Organisation for Animal Health (OIE) was established in 1924. It is an intergovernmental organisation concerned with the coordination, support and promotion of animal disease control. Standards of the OIE are adopted by consensus and serve as guidelines. South Africa became a permanent delegate of the OIE on 20 February 2006.
(vi) The Complainant, Mrs Ronél Behrens, and her husband, Cobus Behrens, are dairy farmers who farm with stud cattle on the farm Goedemoed in the district of Venterburg, Free State. The herd, known as Waterbron Jerseys, was inherited from the Complainant’s father, Mr J B Heyns, in the 1990’s. Since Mr Heyns took over the herd in 1987 and officially registered it, the herd itself has won numerous prizes, which included being voted, on numerous occasions, one of the top ten Jersey herds in South Africa. Some of the animals were also exhibited on various dairy shows where numerous bronze, silver and gold awards were won by them. Fifteen (15) Meester Suiwel Boer awards were won by the Complainant between 1994 and 2010. All the milk produced on the farm was sold to Bandini Cheese, where it was used to make Mozzarella cheese.

(vii) In the main, the complaint was that: 1) the Complainant’s animals were infected with Brucellosis despite the fact that they were vaccinated by the vaccine registered and prescribed by the DAFF; 2) the DAFF unduly delayed and / or failed to produce to the Complainant a report on its investigation into the suspected lack of efficiency of the RB51 vaccine and; 3) that the Free State DARD failed to implement control measures in terms of the Animal Diseases Act, 1984, on her farm after the outbreak was initially reported to it in 2010 and 4) that Brucellosis is a state-controlled disease in terms of the Animal Diseases Act, 1984, and that the State is therefore liable to compensate the Complainant for her damages.

(viii) The Department did not dispute the fact that control measures stipulated in the Animal Diseases Act were not implemented on the Complainant’s farm in 2010, when the outbreak of the disease was first reported to the State Veterinarian in the Free State. The Department however indicated that this was as a result of the State Veterinarian who did not report the outbreak to the Director: Animal Health as required by legislation. The Department further did not dispute the fact that there
was a delay to produce to the Complainant a copy of its report into her allegations, but claimed that the delay was caused by the complexity of the investigation.

(ix) The Department did however dispute the following:

a) The Complainant’s allegation that the vaccine, RB51, was registered in South Africa without following due process;

b) Whether there was enough evidence before the DAFF to cancel the registration of the vaccine;

c) That it is liable to compensate the Complainant for her damages in terms of section 19 of the Animal Diseases Act, as the Director: Animal Health did not give an instruction for the slaughtering of the animals as a control measure, as envisioned by the Act.

(x) On analysis of the complaint, the following issues were identified and investigated:

(a) Whether the Free State DARD failed to implement control measures stipulated in the Animal Diseases Act, 1984, when the outbreak of the disease was allegedly reported to it in 2010, and whether such failure to implement control measures stipulated by the Act constitutes maladministration;

(b) Whether the Director: Animal Health failed to intervene on the farm when the outbreak was brought to her attention by the Complainant, and whether such failure constitutes maladministration;
(c) Whether the Registrar followed due process in terms of the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947*, to register the RB51 vaccine;

(d) Whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so;

(e) Whether the complainant suffered any improper prejudice as a result of the alleged conduct of the Free State DARD and the DAFF.

(xd) The investigation process was conducted through meetings and interviews with the Complainant and relevant officials from the two departments, as well as an inspection of all relevant documents and analysis and application of all relevant laws, policies and related prescripts.

(xii) Key laws and policies taken into account to determine if there had been maladministration by the Department and prejudice to the Complainant were principally those imposing administrative standards that should have been upheld by the Department and / or its officials. Those are the following: -

a) The relevant provisions of the *Animal Diseases Act, 1983*, and its Regulations, which sets out the control measures which should immediately be implemented by the State when an outbreak of a notifiable disease is reported to it;

b) The relevant provisions of the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947*, which highlights the process that the Registrar should follow prior to the registration of a stock remedy and which further sets out under which circumstances the registration of a stock remedy may be revoked and / or cancelled by the Registrar.
Having considered the evidence uncovered during the investigation against the relevant regulatory framework, I now make the following findings:

(a) Regarding whether the Free State DARD failed to implement control measures stipulated by the Animal Diseases Act, 1984, when the outbreak of the disease was allegedly reported to it in 2010, and whether such failure to institute control measures constitutes maladministration:

The period May 2010 to June 2011

(aa) The allegation that the Free State DARD, specifically Dr Louis van Rooyen failed to implement control measures stipulated by the Animal Diseases Act, 1984 in 2010 when the outbreak was reported, is substantiated;

(bb) Dr Van Rooyen failed to report the outbreak to the Director: Animal Health. He failed to follow due process to quarantine the farm and failed to issue Red-Cross permits for the movement of the Complainant’s animals to the abattoir.

(cc) In doing so, Dr Van Rooyen failed to adhere to the requirements of the Animal Diseases Act, its Regulations and the requirements set in terms of the Bovine Brucellosis Scheme;

(dd) His conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act;
(ee) In addition, the Free State DARD failed to ensure proper record keeping by the attending State Veterinarian and that proper records are kept pertaining to the actions taken on the Complainant’s farm and the instructions that were given to her;

(ff) The Free State DARD failed to adhere to section 24 of the Animal Diseases Act;

(gg) Its conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

The period June 2011 onwards

(aa) The allegation that the Free State DARD, specifically Dr Petra Kitshoff failed to implement control measures stipulated by the Animal Diseases Act, 1984 from June 2011 onwards, is substantiated;

(bb) Dr Kitshoff failed to report the outbreak to the Director: Animal Health. She failed to follow due process to quarantine the farm. She also failed to issue Red – Cross permits for the movement of the Complainant’s animals to the abattoir. Her conduct in respect of the Complainant’s use of an unregistered vaccine in her herd, knowing that it was not registered, also raises question marks;

(cc) In doing so, Dr Kitshoff failed to adhere to the requirements of the Animal Diseases Act, its Regulations and the requirements set in terms of the Bovine Brucellosis Scheme;
(dd) Her conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

(b) Regarding whether the Director: Animal Health failed to intervene on the farm when the outbreak was brought to her attention by the Complainant, and whether such failure constitutes maladministration:

(aa) The allegation that the Director: Animal Health failed to intervene on the Complainant’s farm when the outbreak was brought to her attention in December 2010, is substantiated;

(bb) The Director: Animal Health acknowledged that attention was drawn to the outbreak on the Complainant’s farm in an email to the PA of the then Director: Animal Health, but the Director took no action until, seemingly, September 2013;

(cc) The conduct of the Director: Animal Health falls short of the required standard of good governance and good public administration as envisaged in section 195 of the Constitution;

(dd) The conduct of the Director: Animal Health constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.
(c) Regarding whether the Registrar followed due process in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, to register the RB51 vaccine:

(aa) The allegation that the Registrar failed to follow due process in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, is substantiated;

(bb) South Africa became a permanent delegate of the OIE on 20 February 2006. When RB51 was registered in South Africa in 2002, the OIE’s principles and standards had no legal and binding status in South Africa. The Registrar used this non – binding international principle, with no legal status in South African law, to circumvent the requirements placed upon him by the Regulations issued in terms of the Animal Diseases Act. The Registrar failed to follow a proper process prior to granting an exemption to Intervet not to furnish proof of the efficacy of RB51 as determined under South African conditions. The Registrar could not provide justifiable reasons to justify the granting of the exemption to Intervet;

(cc) The application for the registration of RB51 was approved even though the application did not adhere to the requirements of Regulation 2(2)(c)(ii)(b) of the 1983 Regulations issued under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act;

(dd) The conduct of the Registrar constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.
(d) Regarding whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so: -

(aa) The allegation that the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so, is substantiated;

(bb) The Registrar did investigate the allegations with MSD and was provided with an explanation which could reasonably possibly be true. The Registrar however failed to complete the process as he neglected to investigate whether the advertisement of RB51 was in line with the registration requirements of the product;

(cc) In doing so, the Registrar improperly failed to apply his mind to whether there was a reason to consider the cancellation of RB51 under section 4(1)(f) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947;

(dd) The conduct of the Registrar constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

(e) Regarding whether the complainant suffered any improper prejudice as a result of the alleged conduct of the Free State DARD and the DAFF: -

(aa) The allegation that the Complainant suffered prejudice as a result of the maladministration of the Free State DARD and the Director: Animal Health, is substantiated;
(bb) The maladministration by the Free State DARD and the Director: Animal Health caused the Complainant pecuniary loss, frustration, inconvenience and distress;

(cc) Its conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and Improper prejudice as envisaged in section 6(4)(a)(v) of the Public Protector Act.

(xiv) The appropriate remedial action I am taking in pursuit of section 182(1)(c), with the view of placing the Complainant as close as possible to where she would have been had improper conduct or maladministration not occurred, is the following:

7.1 The Director - General to:

(aa) Within twenty – one (21) business days from date of this report issue a written apology to the Complainant, apologising for the manner in which the Free State DARD and the DAFF handled the outbreak of Brucellosis on her farm;

(bb) Within three (3) months from date of this report, and in consultation with the Minister and the Director: Animal Health, make an offer to the Complainant which she deems reasonable in the circumstances as an ex gratia payment for the inconvenience, distress and frustration suffered by the Complainant as a result of the maladministration.
Upon acceptance of the offer by the Complainant, the Director – General must pay the amount agreed upon by the parties to the Complainant within sixty (60) working days.

7.2 The Director: Animal Health to:

(a) Within one (1) month from date of this report, facilitate the process with the Department of Health to test the farmworkers working on the Complainant’s farm for Brucellosis infection, and to ensure that the infected workers get the necessary treatment;

(b) Within three (3) months from date of this report, put systems in place in all provincial offices to ensure proper record keeping of notifiable outbreaks and ensure that all instructions, steps, advise are properly recorded for future reference;

(c) To conduct annual audits on Provincial Veterinary Services to ensure compliance with statutory obligations;

(d) Within three (3) months from date of this report, address the conflict between the Brucellosis Manual and the Animal Diseases Act, specifically pertaining to the requirements for the setting of quarantine;

(e) Within three (3) months from date of this report, ensure that the DAFF adopts a policy which provide guidance on when and how intervention of the Director: Animal Health should be sought when there is an outbreak of Brucellosis.
7.3 The Director: Agricultural Inputs Control to:

(aa) Take urgent steps to investigate the selling of an unregistered vaccine by Mr Daan Goosen of Disease Control Africa and consider whether it is necessary to institute criminal proceedings against him. The Registrar is required to report back to the Public Protector on his investigation within sixty (60) days from date of this report;

(bb) To conduct and finalise an investigation into whether the advertisement of RB51 was / is contrary to the registration requirements of the product, and to submit to the Public Protector a report thereon within sixty (60) days from date of this report. This investigation should also include an investigation into the confusion that is or can be created by these off label uses of a product, especially when the off label uses are proposed by the registration holder itself. The Registrar should consider, within thirty (30) days from the date on which he concluded his investigation, whether or not it is necessary for MSD to issue a public retraction of the off label recommendations for RB51;

(cc) To, in consultation with MSD, liaise with Colorado Serum to satisfy himself of any further research that was conducted on RB51, and must, within sixty (60) days consider whether or not it may be necessary to amend the registration requirements of RB51 and / or the necessity to test the product in South Africa.
1. INTRODUCTION

1.1. This is my report as the Public Protector issued in terms of section 182(1)(b) of the Constitution of the Republic of South Africa, 1996 (the Constitution) and section 8(1) of the Public Protector Act, 1994 (the Public Protector Act).

1.2. The report is submitted in terms of section 8(3) of the Public Protector Act to the following people to note the outcome of my investigation:

1.1.1 The Minister of Agriculture, Forestry and Fisheries Mr S Zokwana, MP;

1.1.2 The Director – General of the Department of Agriculture, Forestry and Fisheries, Mr M M Miengana;

1.1.3 The Director: Agricultural Inputs Control, Mr J M Mudzunga;

1.1.4 The Director: Animal Health, Dr M Maja;

1.1.5 The Free State Acting Head of Department of Agriculture and Rural Dr. T J Masiteng.
1.1.6 The Director: Veterinary Services: Free State Department of Agriculture and Rural Development, Dr K Mojaapel;

1.1.7 The State Veterinarian: Laboratory Diagnostics & Epidemiology Services: Free State Department of Agriculture and Rural Development, Dr P Kitshoff;

1.1.8 The Managing Director of MSD Animal Health (Pty) Ltd, Mr Alan Kloek;

1.1.9 The Complainant, Mrs Ronél Behrens.

1.2 Section 7(9) Notices were previously sent to the following individuals to enable them to respond to my intended findings: -

1.2.1 The Minister of Agriculture, Forestry and Fisheries, Mr S Zokwana, MP;

1.2.2 The Director: Agricultural Inputs Control, Mr J M Mudzunga;

1.2.3 The Director: Animal Health, Dr M Maja;

1.2.4 The Acting Head of Department: Free State Department of Agriculture and Rural Development, Ms G Brown;

1.2.5 The State Veterinarian: Laboratory Diagnostics & Epidemiology Services: Free State Department of Agriculture and Rural Development, Dr P Kitshoff;

1.3 The report relates to an investigation into allegations of maladministration by the Free State Department of Agriculture and Rural Development (DARD), and the Department of Agriculture, Forestry and Fisheries (DAFF)
relating to its handling of an outbreak of *Brucellosis* (*contagious abortion*) on
the farm of Mrs Ronél Behrens.

2 THE COMPLAINT

2.1 The Complainant alleged that her animals were infected with *Brucellosis* despite
the fact that they were vaccinated by the vaccine registered and prescribed by
the DAFF;

2.2 That the DAFF unduly delayed and / or failed to produce to the Complainant a
report on its investigation into the suspected lack of efficiency of the RB51
vaccine and;

2.3 That the Free State DARD failed to implement control measures in terms of the
*Animal Diseases Act*, 1984, on her farm after the outbreak was initially reported
to it in 2010; and

2.4 That *Brucellosis* is a state-controlled disease and that the State is therefore
liable to compensate her for her damages.

3 POWERS AND JURISDICTION OF THE PUBLIC PROTECTOR

3.1 The Public Protector is an independent constitutional body established under
section 181(1)(a) of the Constitution to strengthen constitutional democracy
through investigating and redressing improper conduct in state affairs.

3.2 Section 182(1) of the Constitution provides that:

"The Public Protector has the power as regulated by national legislation –
(a) to investigate any conduct in state affairs, or in the public administration in any sphere of government, that is alleged or suspected to be improper or to result in any impropriety or prejudice;
(b) to report on that conduct; and
(c) to take appropriate remedial action.”

3.3 In the Economic Freedom Fighters v Speaker of the National Assembly and Others; Democratic Alliance v Speaker of the National Assembly and Others1 the Constitutional Court per Chief Justice Mogoeng stated the following when confirming the powers of the Public Protector:

3.3.1 Complaints are lodged with the Public Protector to cure incidents of impropriety, prejudice, unlawful enrichment or corruption in government circles;2

3.3.2 An appropriate remedy must mean an effective remedy, for without effective remedies for breach, the values underlying and the rights entrenched in the Constitution cannot properly be upheld or enhanced;3

3.3.3 Taking appropriate remedial action is much more significant than making a mere endeavor to address complaints which was the most the Public Protector could do in terms of the Interim Constitution. However sensitive, embarrassing and far – reaching the implications of her report and findings, she is constitutionally empowered to take action that has that effect, if it is the best attempt at curing the root cause of the complaint;4

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1 CCT 143/15; CCT171/15 [2016] ZACC 11, 2016 (5) BCLR 618 (CC); 2016 (3) SA 580 (CC); 31 March 2016.
2 Para [65].
3 Para [67].
4 Para [68].
3.3.4 The legal effect of these remedial measures may simply be that those to whom they are directed are to consider them properly, with due regard to their nature, context and language, to determine what course to follow;\(^6\)

3.3.5 Every complaint requires a practical or effective remedy that is in sync with its own peculiarities and merits. It is the nature of the issue under investigation, the findings made and the particular kind of remedial action taken, based on the demands of the time, that would determine the legal effect it has on the person, body or institution it is addressed to;\(^6\)

3.3.6 The Public Protector’s power to take appropriate remedial action is wide but certainly not unfettered. What remedial action to take in a particular case, will be informed by the subject-matter of the investigation and the type of findings made;\(^7\)

3.3.7 Implicit in the words “take action” is that the Public Protector is herself empowered to decide on and determine the appropriate remedial measure. And “action” presupposes, obviously where appropriate, concrete or meaningful steps. Nothing in these words suggests that she necessarily has to leave the exercise of the power to take remedial action to other institutions or that it is power that is by its nature of no consequence;\(^8\)

3.3.8 She has the power to determine the appropriate remedy and prescribe the manner of its implementation;\(^9\)

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\(^5\) Para [69].  
\(^6\) Para [70].  
\(^7\) Para [71].  
\(^8\) Para [71(a)].  
\(^9\) Para [71(d)].
3.3.9 "Appropriate" means nothing less than effective, suitable, proper or fitting to redress or undo the prejudice, impropriety, unlawful enrichment or corruption, in a particular case.\textsuperscript{10}

3.3.10 The remedial action taken by the Public Protector has a binding effect.\textsuperscript{11} The Constitutional Court further held that: “When remedial action is binding, compliance is not optional, whatever reservations the affected party might have about its fairness, appropriateness or lawfulness. For this reason, the remedial action taken against those under investigation cannot be ignored without any legal consequences.”\textsuperscript{12}

3.4 Section 182(2) directs that the Public Protector has additional powers and functions prescribed by legislation.

3.5 The Public Protector is further mandated by the Public Protector Act to investigate and redress maladministration and related improprieties in the conduct of state affairs. The Public Protector is also given power to resolve disputes through conciliation, mediation, negotiation or any other appropriate alternative dispute resolution mechanism.

3.6 Both the DAFF and the Free State DARD are organs of state and both Departments' conduct amount to conduct in state affairs, and as a result, the matter falls within the ambit of the Public Protector's mandate.

3.7 The Public Protector’s power and jurisdiction to investigate and take appropriate remedial action was not disputed by any of the parties.

\textsuperscript{10} Para [71(e)].
\textsuperscript{11} Para [76].
\textsuperscript{12} Ibid para [73].
4. THE INVESTIGATION

4.1 Methodology

4.1.1 The investigation was conducted in terms of section 182 of the Constitution and sections 6 and 7 of the Public Protector Act.

4.1.2 The Public Protector Act confers on the Public Protector the sole discretion to determine how to resolve a dispute of alleged improper conduct or maladministration. Section 6 of the Public Protector Act gives the Public Protector the authority to resolve a matter without conducting an investigation and resolve a complaint through appropriate dispute resolution (ADR) measures such as conciliation, mediation and negotiation.

4.1.3 The complaint was classified as an Administrative Justice and Service Delivery complaint for resolution by way of a formal investigation in line with sections 6(4) and (5) of the Public Protector Act, 1994.

4.2 Approach to the investigation

4.2.1 Like every Public Protector investigation, the investigation was approached using an enquiry process that seeks to find out:

4.2.1.1 What happened?
4.2.1.2 What should have happened?
4.2.1.3 Is there a discrepancy between what happened and what should have happened and does that deviation amount to maladministration?
4.2.1.4 In the event of maladministration what would it take to remedy the wrong or to place the Complainant as close as possible to where they would have been but for the maladministration or improper conduct?
4.2.2 The question regarding what happened is resolved through a factual enquiry relying on the evidence provided by the parties and independently sourced during the investigation. In this particular case, the factual enquiry principally focused on whether the Department followed proper processes when the outbreak of the disease was first reported to them and further whether the Department followed proper processes to register the vaccine for use in South Africa.

4.2.3 The enquiry regarding what should have happened, focuses on the law or rules that regulate the standard that should have been met by the Department or an organ of state to prevent maladministration and prejudice.

4.2.4 The enquiry regarding the remedy or remedial action seeks to explore options for redressing the consequences of maladministration. Where a Complainant has suffered prejudice the idea is to place him or her as close as possible to where they would have been had the Department or organ of state complied with the regulatory framework setting the applicable standards for good administration.

4.3 On analysis of the complaint, the following were issues considered and investigated:

4.3.1 Whether the Free State DARD failed to implement control measures stipulated in the Animal Diseases Act, 1984, when the outbreak of the disease was allegedly reported to it in 2010, and whether such failure to implement control measures stipulated by the Act constitutes maladministration;
4.3.2 Whether the Director: Animal Health failed to intervene on the farm when the outbreak was brought to her attention by the Complainant, and whether such failure constitutes maladministration;

4.3.3 Whether the Registrar followed due process in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, to register the RB51 vaccine;

4.3.4 Whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so;

4.3.5 Whether the complainant suffered any improper prejudice as a result of the alleged conduct of the Free State DARD and the DAFF.

4.4 The Key Sources of information

4.4.1 Documents

4.4.1.1 Copy of the package insert of the RB51 vaccine;

4.4.1.2 Brucellosis in cattle, Manual for the Veterinarian and Animal Health Technician, compiled by the Directorate of Animal Health of the Department of Agriculture in 1992, commonly referred to as the Brucellosis Scheme;

4.4.1.3 Copy of the report compiled by Prof Moritz van Vuuren on a review of scientific data presented by Schering-Plough Animal Health in support of its application to have the RB51 vaccine registered in South Africa, dated 12 September 2001;

4.4.1.4 Email from Ms S Hitzinger-Maas, Head of the Office of the Deputy Minister of Agriculture, Forestry and Fisheries to the Complainant dated 13 April 2013;
4.4.1.5 Original complaint emailed to our office by the Complainant on 10 January 2014; and annexures thereto;

4.4.1.6 Copy of a letter from Dr C M Wessels, the Complainant’s private veterinarian, addressed to the Complainant dated 17 April 2014;

4.4.1.7 Copy of letter from Prof Vries, the Director-General of DAFF to the Complainant dated 02 August 2014;

4.4.1.8 Copy of letter from the Director-General of DAFF to the Complainant dated 05 September 2014;

4.4.1.9 Copy of letter from the Director-General of DAFF, Prof Vries to Complainant dated 24 October 2014;

4.4.1.10 Report drafted by Mr Mooketsa Ramasodi, Chief Director: Inspection and Quarantine Services of DAFF, undated but hand delivered to our office on 04 November 2014, and annexures thereto;

4.4.1.11 Copy of email from Dr Petra Kitshoff to the Complainant dated 16 February 2015;

4.4.1.12 Written response of DAFF on questions posed during the meeting held on 18 February 2015, received on 31 March 2015;

4.4.1.13 Written response received from Mr Ramasodi of DAFF dated 07 May 2015 containing its response to discussions of the meeting held on 31 March 2015, and annexures thereto;

4.4.1.14 Documents received from the National Library of South Africa on 23 November 2015;

4.4.1.15 Beesbrusellose Monstervorm, containing the results of the Bovine Brucellosis tests conducted on 21 May 2009 on the Complainant’s herd, received from the Complainant on 20 September 2016;

4.4.1.16 Beesbrusellose Monstervorm, containing the results of the Bovine Brucellosis tests conducted on 18 May 2010 on the Complainant’s herd, received from the Complainant on 20 September 2016;
4.4.1.17 Bovine Brucellosis Sample Form, containing the results of the Bovine Brucellosis tests conducted on 18 April 2012 on the Complainant’s herd, received from the Complainant on 20 September 2016;
4.4.1.18 Letter received from the Institute for Disease Control Africa, confirming that on 09 September 2011, it provided the Complainant with a DNA vaccine to vaccinate her herd;
4.4.1.19 Documents received from the Director: Agricultural Inputs Control on 13 October 2016;
4.4.1.20 The South African Veterinary Strategy (2016 – 2026), received from the Director: Animal Health on 14 November 2016;
4.4.1.21 Subpoenas to Drs Kloeck and Schultheiss to appear before the Public Protector on 09 February 2017;
4.4.1.22 Technical Report on Vaccination of Cattle with *Brucella Abortus* Strain RB51;
4.4.1.23 Notes made during a LHPG Brucellosis Meeting at Harrismith on Wednesday 10 November 2010, provided to PPSA by Dr Kloeck of MSD during the meeting held on 09 February 2017;
4.4.1.24 Email received from Dr Alan Kloeck on 09 February 2017, containing communication between the Complainant and Mr Chema Blasco;
4.4.1.25 Email correspondence between Randy Berrier and Erik van Zyl dated 18 and 19 December 2014, given to PPSA by Dr Kitshoff during the meeting held with the Free State DARD on 13 March 2017.

### 4.4.2 Interviews conducted

4.4.2.1 Meeting held between officials from the Office of the Public Protector, delegates from the DAFF and the Complainant on 18 February 2015, attended by the following people:

- Adv J Raubenheimer (Chief Investigator: PPSA);
a) Mrs R Mdleleni (Senior Investigator: PPSA);

b) Ms C van Eeden (Investigator: PPSA);

c) Mr M Ramasodi (Chief Director: DAFF);

d) Mr J Mudzunga (Registrar: Act 36 of 1947);

e) Mr C Behrens (Complainant);

f) Mrs R Behrens (Complainant).

4.4.2.2 Follow-up meeting held between officials from the Office of the Public Protector, delegates from the DAFF and the Complainant on 31 March 2015, attended by the following people: -

a) Adv J Raubenheimer (Chief Investigator: PPSA);

b) Mr N Maoka (Senior Investigator: PPSA);

c) Ms C van Eeden (Investigator: PPSA);

d) Mr M Ramasodi (Chief Director: DAFF);

e) Mr J Mudzunga (Registrar: Act 36 of 1947);

f) Dr M Maja (Director: Animal Health: DAFF);

g) Mr C Behrens (Complainant);

h) Mrs R Behrens (Complainant);

4.4.2.3 An Interview conducted with Prof Moritz van Vuuren on 16 September 2016, during which interview the following people were in attendance:

a) Prof M van Vuuren (Professor Emeritus: Virology: UP)

b) Mrs P Mogaladi (Executive Manager: PPSA);

c) Adv PJ Smith (Senior Investigator: PPSA);

d) Ms C van Eeden (Investigator: PPSA).

4.4.2.4 An Interview conducted with Prof Darrell Abernethy on 03 November 2016, during which interview the following people were in attendance: -

a) Prof D Abernethy (Dean: Faculty of Veterinary Science: UP);
b) Mrs P Mogaladi (Executive Manager: PPSA);

c) Ms C van Eeden (Investigator: PPSA);

4.4.2.5 Inspection in loco on the Complainant’s farm on 08 November 2016, and interview with Dr Martin Wessels (private veterinarian of the Complainant) attended by the following people: -

a) Mrs P Mogaladi (Executive Manager: PPSA);

b) Adv PJ Smith (Senior Investigator: PPSA);

c) Ms C van Eeden (Investigator: PPSA);

d) Mrs R Behrens (Complainant);

e) Mr C Behrens (Complainant); and

f) Dr M Wessels (Private Veterinarian of the Behrens').

4.4.2.6 An interview with Dr K Govindasamy on 05 December 2016, attended by the following people: -

a) Dr K Govindasamy (CSV — Epidemiology, GDARD);

b) Mrs P Mogaladi (Executive Manager: PPSA);

c) Adv J Raubenheimer (Chief Investigator: PPSA);

d) Ms C van Eeden (Investigator: PPSA).

4.4.2.7 Meeting held with Drs Kloeck (Managing Director: MSD Animal Health) and Schutteiss (Ceva) during which meeting the following persons were in attendance: -

a) Adv K Malunga (Deputy Public Protector: PPSA);

b) Mrs P Mogaladi (Executive Manager: PPSA);

c) Adv J Raubenheimer (Chief Investigator: PPSA);

d) Adv PJ Smith (Chief Investigator: PPSA);

e) Ms C van Eeden (Investigator: PPSA);

f) Dr A Kloeck (General Manager: MSD Animal Health);
g) Dr W Schultheiss (BU Manager: Ceva);

h) Mrs K Wilson (Webber Wentzel Attorneys);

i) Mr P Crosland (Webber Wentzel Attorneys).

4.4.2.8 Meeting held with officials from the Free State DARD in Bloemfontein on 13 March 2017, during which meeting the following officials were present:

a) Mrs P Mogaladi (Executive Manager: PPSA);

b) Adv J Raubenheimer (Chief Investigator: PPSA);

c) Ms C van Eeden (Investigator: PPSA);

d) Dr K Mojapelo (Director: Veterinary Services, Free State DARD);

e) Dr K Mashishi (Deputy – Director: Veterinary Services, Free State DARD);

f) Dr P Kitshoff (State Veterinarian, Free State DARD);

g) Dr V Murenga (State Veterinarian, Free State DARD);

h) Mr T Letsoara (Legal Services: Free State DARD);

i) Mr R Sehong (Legal Services: Free State DARD);

j) Mr F Penn (Animal Health Technician: Free State DARD);

4.4.2.9 Telephonic interview with Mr Willie van Zyl (Animal Health Technician working with Dr Van Rooyen on the farm during the earlier stages of the outbreak) on 14 March 2017.

4.4.3 Correspondence sent and received

4.4.3.1 Email sent to the Director-General of DAFF by the PPSA Investigator dated 10 March 2014;

4.4.3.2 Email received by PPSA investigator from Mr M Ramasodi, Chief Director at DAFF dated 11 March 2014;

4.4.3.3 Letter received by PPSA investigator from Mr M Ramasodi titled Update on the Brucellosis case, dated 19 March 2014;
4.4.3.4 Email from PPSA investigator to the complainant dated 15 April 2014;
4.4.3.5 Email received from Mr M Ramasodi to PPSA investigator dated 16 April 2015;
4.4.3.6 Letter from PPSA investigator to Mr M Ramasodi dated 25 April 2014;
4.4.3.7 Email received by PPSA investigator from Complainant containing Information forwarded to Dr Petra Kitshoff, the State Veterinarian in the Free State, dated 07 May 2014;
4.4.3.8 Copy of email sent from the Complainant to Mr Ramasodi dated 12 May 2014;
4.4.3.9 Letter from PPSA investigator to Mr Ramasodi, undated and electronically transmitted on 16 May 2014;
4.4.3.10 Email received by PPSA investigator from Ms Linda Koekemoer, PA to Mr Ramasodi, dated 19 May 2014;
4.4.3.11 Response to the letter of 16 May 2014, received by PPSA investigator on 30 May 2014;
4.4.3.12 Email sent to PPSA investigator from Complainant dated 04 June 2014, which contains a copy of an email from Mr Ramasodi to the Complainant dated 16 July 2013, in which email Mr Ramasodi notes that the Registrar indicated that the report will be submitted to the Complainant by 23 July 2013;
4.4.3.13 Letter from the Executive Manager: Early Resolution of the PPSA, Mrs P Mogaladi, to the Director-General of DAFF, Prof E Vries, dated 04 June 2014;
4.4.3.14 Letter received from the Director-General of the DAFF, Prof Vries dated 03 July 2014, in response to the letter addressed to her dated 04 June 2014;
4.4.3.15 Email from PPSA investigator to Mr Ramasodi of DAFF dated 30 September 2014;
4.4.3.16 Email received by PPSA investigator from Mr Ramasodi dated 30 September 2014;

4.4.3.17 Email from PPSA investigator to Ms Koekemoer and Mr Ramasodi of DAFF dated 13 October 2014;

4.4.3.18 Email received by PPSA investigator from Mr Ramasodi dated 13 October 2014;

4.4.3.19 Email from Complainant to PPSA investigator dated 24 October 2014;

4.4.3.20 Letter from the Executive Manager: Early Resolution, Mrs P Mogaladi, to the Director-General of the DAFF, Prof Vries, dated 09 February 2015;

4.4.3.21 Letter from the Executive Manager: Early Resolution, Mrs P Mogaladi, to the Complainant, dated 09 February 2015;

4.4.3.22 Email from PPSA investigator to Ms Koekemoer of DAFF dated 19 February 2015, following discussions of the meeting held on 18 February;

4.4.3.23 Email received by PPSA Investigator from the Complainant dated 23 February 2015;

4.4.3.24 Email from PPSA investigator to Ms Koekemoer dated 12 March 2015;

4.4.3.25 Email received by PPSA investigator from Mr Mudzunga (Registrar of Act 36 of 1947) dated 23 March 2015;

4.4.3.26 Email from PPSA investigator to Mr Mudzunga dated 26 March 2015;

4.4.3.27 Letter from Executive Manager: Early Resolution, Mrs P Mogaladi, to Mr Mudzunga dated 26 March 2015 and electronically transmitted on 27 March 2015;

4.4.3.28 Email received by PPSA investigator from Mr Mudzunga dated 30 March 2015;

4.4.3.29 Email from PPSA investigator to Ms Koekemoer and Mr Ramasodi requesting further information pertaining to the discussions of the meeting of 31 March 2015, dated 01 April 2015;

4.4.3.30 Email from PPSA investigator to the Complainant dated 01 April 2015;
| 4.4.3.31 | Email received by PPSA Investigator from the Complainant dated 07 September 2015; |
| 4.4.3.32 | Email from PPSA investigator to Mr Ramasodi dated 07 September 2015; |
| 4.4.3.33 | Email received from Dr Maja (Director: Animal Health) by PPSA investigator dated 08 September 2015; |
| 4.4.3.34 | Letter to the National Library of South Africa dated 03 November 2015 and sent on 19 November 2015; |
| 4.4.3.35 | Letter from the PPSA Investigator to Prof M van Vuuren dated 13 September 2016; |
| 4.4.3.36 | Letter sent to the Director: Agricultural Inputs Control, Mr Mudzunga by the PPSA Investigator, on 21 September 2016; |
| 4.4.3.37 | Letter sent to the Director: Agricultural Inputs Control, Mr Mudzunga by the PPSA Investigator on 13 October 2016; |
| 4.4.3.38 | Letter to Dr Petra Kitshoff, dated and sent on 01 November 2016; |
| 4.4.3.39 | Letter to the Director: Animal Health, Dr Maja, dated 01 November 2016 and sent on 08 November 2016; |
| 4.4.3.40 | Subpoena to Dr Alan Kloeck (Managing Director of MSD) and Dr Willem Schultheiss (previously employed by MSD); |
| 4.4.3.41 | Response received from Director: Animal Health on 14 November 2016; |
| 4.4.3.42 | Email from the PPSA investigator to Dr Petra Kitshoff dated 14 November 2016; |
| 4.4.3.43 | Letter received from the Director: Animal Health, Dr Maja on 14 November 2016; |
| 4.4.3.44 | Email sent from the PPSA investigator to Dr Petra Kitshoff on 15 November 2016; |
| 4.4.3.45 | Response received to questions by Dr Petra Kitshoff on 28 November 2016; |
| 4.4.3.46 | Email and attachments received from Dr K Govindasamy on 05 December 2016; |
4.4.3.47 Letter received from Mrs Kerri Wilson of Webber Wentzel Attorneys dated 06 February 2017;

4.4.3.48 Letter from PPSA investigator to Dr K Mojapelo dated 06 February 2017 and electronically transmitted on 08 February 2017;

4.4.3.49 Letter from MSD Animal Health to Mr Mudzunga of DAFF dated 08 May 2014, titled Request for investigation into RB51 Vaccine;

4.4.3.50 Letter from MSD Animal Health to Mr Mudzunga of DAFF dated 06 September 2013, titled RB51 Adverse Reaction Reports: Preliminary Update;

4.4.3.51 Letter from Mr Mudzunga of DAFF to Mr Nkgapele of MSD dated 15 April 2014 and titled Request for Investigations on RB51 Vaccine;

4.4.3.52 Letter from MSD Animal Health to Mr Mudzunga of DAFF dated 08 May 2014, titled Request for investigation into RB51 Vaccine;

4.4.3.53 Letter from MSD Animal Health to Mr Mudzunga of DAFF dated 06 September 2013, titled RB51 Adverse Reaction Reports: Preliminary Update;

4.4.3.54 Letter from Mr Mudzunga of DAFF to Mr Nkgapele of MSD dated 15 April 2014 and titled Request for Investigations on RB51 Vaccine;

4.4.3.55 Email from PPSA investigator to Dr Mojapelo dated 27 February 2017;

4.4.3.56 Email from PPSA investigator to Dr Kitshoff dated 14 March 2017;

4.4.3.57 Email received from Dr Kitshoff by PPSA Investigator dated 14 March 2017;

4.4.3.58 Email sent to Mr Mudzunga from the PPSA investigator on 27 March 2017;

4.4.3.59 Response received from Mr Mudzunga by the PPSA investigator on 12 April 2017.
4.4.4 **Websites consulted / electronic sources**

4.4.4.1 www.daff.gov.za;
4.4.4.2 www.saflii.org;
4.4.4.3 www.oie.intl.

4.4.5 **Legislation and other prescripts**

4.4.5.1 *The Constitution of the Republic of South Africa, 1996;*

4.4.5.2 *The Public Protector Act, 23 of 1994;*

4.4.5.3 *The Animal Diseases Act, 35 of 1984;*

4.4.5.4 Regulations issued in terms of the *Animal Diseases Act, GG10469, 26 September 1986;*

4.4.5.5 *The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 36 of 1947;*

4.4.5.6 Regulations regarding the *Registration of Fertilizers, Farm Feeds, Agricultural Remedies, Stock Remedies, Sterilising Plants and Pest Control Operators, Appeals and Imports and Amendments to and Repeal of certain Regulations issued in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, GN R1449, 1 July 1983;*

4.4.5.7 *Bovine Brucellosis Scheme Regulations, GG11611, 9 December 1988;*

4.4.5.8 *The Law of Evidence Act, 45 of 1988.*

4.4.6 **Case Law**

4.4.6.1 *The Minister of Agriculture v Blueilliesbush Dairy Farming 270/07 [2008] ZASCA 60 (28 May 2008);*

4.4.6.2 *Manana v King Sabata Dalindyebo Municipality (345/09) [2010] ZASCA 144 (25 November 2010);*
4.4.6.3 Economic Freedom Fighters v Speaker of the National Assembly & Others; Democratic Alliance v Speaker of the National Assembly & Others [2016] ZACC 11, 31 March 2016.

4.4.7 Journal Articles


4.4.7.2 Caetano M C et al Control of Bovine Brucellosis from Persistently Infected Holdings Using RB51 Vaccination with Test –and – Slaughter: A Comparative Case Report from a High Incidence Area in Portugal 2016 (63) Transboundary and Emerging Diseases e39 – e47;

4.4.7.3 Abermethy D A et al Epidemiology and management of bovine brucellosis cluster in Northern Ireland 2011 (98) Preventative Veterinary Medicine 223 – 229;


4.4.8 Books


4.4.9 Public Protector Touchstones

4.4.9.1 Draft Technical Notes: Public Protector's Framework for Measures to ensure Remedial Action, undated.
THE DETERMINATION OF ISSUES IN RELATION TO THE EVIDENCE OBTAINED AND CONCLUSIONS MADE WITH REGARD TO THE APPLICABLE LAW AND PRESCRIPTS

5.1 **Issue 1:** Regarding whether the Free State DARD failed to implement control measures stipulated by the Animal Diseases Act, 1984, when the outbreak of the disease was allegedly reported to it in 2010, and whether such failure to institute control measures constitute maladministration:

*Common cause facts*

5.1.1 It was not disputed that the first reported case of *Brucellosis* on the Complainant’s farm confirmed by an accredited laboratory, was around May 2010. The Complainant’s private Veterinarian, Dr Martin Wessels reported the outbreak to the State Veterinarian, the late Dr Louis van Rooyen (Dr Van Rooyen).

5.1.2 Both the Complainant and the Department agreed that representatives of MSD (the registration holder of RB51) visited the farm thereafter. It was further agreed by the parties that, around June 2011, the newly appointed State Veterinarian, Dr Petra Kithoff, took over on the farm and started the implementation of some control measures prescribed by the Act. The first quarantine notice, however, was only served on the Complainant on 14 August 2012.

*Issues in dispute*

*Evidence adduced by Complainant*

5.1.3 The Complainant indicated that she did not have any idea what to do or how to deal with the outbreak, and she was not informed of any control measures which
should be implemented on her farm when the outbreak was first reported to the State Veterinarian, Dr Van Rooyen.

5.1.4 Dr Van Rooyen visited the farm with representatives of MSD and she was verbally informed of some of the control measures she should implement, such as calving in isolation. The MSD representatives suggested, however, that no action should be taken for a period of a year;

5.1.5 She alleged that, during the visit to her farm by Dr Van Rooyen and representatives of MSD, representatives from MSD informed her that no action should be taken on her herd for a period of one year. According to the Complainant Dr Van Rooyen accepted MSD's advice, that no action should be taken for a period of a year and did not implement or suggest any control measures, such as a prescription for an alternative vaccine for Brucellosis that was available on the market (low doses of S19 to vaccinate all contact animals);

5.1.6 According to the Complainant, there were one hundred and twenty four (124) infected animals in May 2010 when the Brucellosis outbreak was confirmed on her farm. According to the records provided, by April 2012, there were four hundred and forty three (443) infected animals;

5.1.7 Around June 2011 Dr Petra Kitshoff replaced Dr Van Rooyen as the State Veterinarian and took control of the farm. Oral instructions were given to the Complainant about the control measures she needed to implement on her farm, these included that bovines must calf separately and that all helpers must be vaccinated with S19. Arrangements were also made with the Ventersburg Abattoir for the positive animals to be slaughtered.

5.1.8 Around September 2011, the Complainant obtained an unregistered vaccine from a Dr Daan Goosen of the Institute for Disease Control Africa, which she
injected in the noses of the animals. She claimed she acted in desperation, and that her whole herd was already infected with Brucellosis when she used the unregistered vaccine. She acknowledged that she used the unregistered vaccine for about three months.

5.1.9 According to her, the vaccine was only used on cows which were already infected, and that the State Veterinarian, Dr Kitshoff, was aware of this, but did not instruct nor convince her not to use this unregistered vaccine. The Complainant further indicated that Dr Kitshoff took a sample of the vaccine, analysed it and confirmed that it was a dead Brucella Abortus Strain 19 vaccine (S19 vaccine). According to the Complainant, they did not really notice any results after the use of this product.

5.1.10 The Complainant further alleged that she only received a prescription for the low doses of the S19 vaccine to vaccinate all contact animals around August 2012.

5.1.11 The Complainant further states that apart from trying to control the spread of the outbreak by sourcing the vaccines referred to above, she also started to slaughter (on advice of Dr Van Rooyen) some of her herd. When the outbreak started she had 880 cows (including heifers) and lost 760 cows, which either died or were slaughtered.

5.1.12 The Complainant’s contention was that, if the Free State DARD intervened earlier and implemented control measures immediately, she could have saved the bulk of her herd. In this instance, she alleged that she had eight hundred and eighty (880) cows (including heifers), and only have one hundred and twenty (120) cows left from the original herd. Seven hundred and sixty (760) cows were either slaughtered or died. According to the records received from the Complainant, she slaughtered five hundred and thirty one (531) cows from June 2010 to July 2015;
5.1.13 When confronted about how the Complainant was able to start slaughtering some of her animals in June 2010 already (the Complainant’s farm was, at this stage, yet to be declared positive for Brucellosis and no records could be found indicating that a Red Cross Permit for the movement of animals were given to her), the Complainant indicated that Dr Van Rooyen orally instructed her to slaughter her whole herd;

5.1.14 Dr Wessels, the private Veterinarian of the Complainant indicated that the herd was negative for numerous years. He confirmed that there had never been an outbreak of any disease. When the first abortion occurred, tests confirmed that it was *Brucellosis*. The herd was bled (drawing blood sample for medical testing) and about 30% of the herd tested positive. The outbreak was reported and the State Veterinarian refused him permission to bleed the herd again. He was informed by Dr Van Rooyen that the State was taking control of the farm;

5.1.15 After about two months, the herd was bled again by Dr Van Rooyen. According to Dr Wessels, 80% of the Complainant’s herd tested positive within a couple of months after the outbreak;

5.1.16 According to his knowledge, the farm was quarantined. He knows that Dr Van Rooyen approached the milk buyers, Bandini Cheese, and informed them about the *Brucellosis* status of the herd.

5.1.17 MSD visited the farm twice, the second time they also brought a Consultant from an American company. According to him, they could not believe what had happened on the Behrens farm. He confirmed that the representatives from MSD who visited the farm, informed them to leave the herd, as he believed that RB51 will still become effective and the herd will test negative again. The resolution that
MSD proposed to the Complainant was to provide her with free vaccines for a period of a year;

5.1.18 Dr Wessels reiterated that nothing was done to the Complainant’s herd until Dr Kitshoff took over in June 2011;

**Evidence adduced by DAFF**

5.1.19 On the other hand the DAFF contended that the Complainant’s herd tested negative for *Brucellosis* until May 2009. The first abortion on the Complainant’s farm was noticed in December 2009, but the laboratory which conducted the tests was not accredited by the DAFF. In May 2010, the herd was bled again by an accredited laboratory, and there were many positive animals (125 positive animals according to the DAFF’s records);

5.1.20 DAFF alluded that, after consulting with the Free State DARD, at that stage, nobody believed that it was an outbreak of *Brucellosis*, as the herd was properly vaccinated and the reactors were not isolated;

5.1.21 When Dr Van Rooyen visited the farm with representatives of MSD, the complainant was verbally informed of some of the control measures she should implement, such as calving in isolation. The DAFF also confirmed that, during the said visit, instructions were given to the Complainant by representatives of MSD that no action should be taken for a period of a year;

5.1.22 The herd was bled again after two months and showed even more positive reactors. According to information received, on 19 July 2010, there were two hundred and fifty seven (257) positive animals. Dr Van Rooyen organised the
sampling of the foetuses and the field strain of Brucella (B. abortus biovar 1) was confirmed by different laboratories;

5.1.23 In October 2010 the farm was declared positive for Brucellosis by Dr Van Rooyen. He placed the farm under verbal quarantine;

5.1.24 In its written report to the Public Protector, received on 04 November 2014, DAFF advised as follows: -

"The DAFF and the Free State DARD had discussions on the matter in Kroonstad on 12 June 2014. The discussions were held to confirm the interview held with Dr Van Rooyen who had been involved with the farm since the outbreak of Brucellosis. At this meeting, the following were confirmed: -

- The farm was verbally put under quarantine by Dr Van Rooyen;
- The infected animals were not isolated and culled;
- Calving of animals were not in separate calving pens;
- Dr Van Rooyen was advised by MSD to leave the animals for a year without taking action;
- Notification of the disease by Dr Van Rooyen to the Director: Animal Health was not done."

5.1.25 DAFF advised that once there is a positive result to a Brucellosis test, the best way to eradicate the disease is to isolate and slaughter, and for negative animals to be vaccinated. The Brucellosis Scheme also requires separation and slaughtering of positive animals;

5.1.26 The DAFF confirmed that, by 2012 when the herd was bled again by the State Veterinarian, there were four hundred and forty three (443) positive animals.
5.1.27 Dr Mojapelo the Director: Veterinary Services in Free State DARD described the role of Veterinary Services in terms of the Animal Diseases Act as to prevent and control animal diseases. They implement the Act on behalf of the Director: Animal Health. Brucellosis is an endemic disease in South Africa and the first responsibility lies with the owner of the animals. He indicated that the State must quarantine the farm, test the entire herd, and if there are positive reactors, give an instruction for the infected animals to be slaughtered. He further indicated that the vaccination programme must continue and that control measures can be uplifted as soon as the herd shows negative results with further bleeds;

5.1.28 According to his evidence, issuing a written quarantine notice is not obligatory in terms of the Brucellosis Manual (1992), but advisable. He further explained that, if the slaughter of a herd would cause severe loss to the owner, the slaughtering of the animals can be delayed pending the implementation of other control measures;

5.1.29 The Free State DARD indicated that some of the initiatives taken by Dr Van Rooyen was to bring in Intervet (as MSD then was), and experts from the University of Pretoria, specifically Prof Fosgate. He conducted about two or three further bleeds on the herd. During the same time, there was also an outbreak of Rift Valley Fever, and Dr Van Rooyen thus requested studies on the aborted foetuses and different labs confirmed an outbreak of Brucellosis;

5.1.30 It was highlighted that the disease spread very fast on the herd of the Complainant, and within six (6) months, 80% of her herd was infected. The Free State DARD acknowledged that, by leaving the 125 animals initially infected in the herd, the source of the infection was not removed and further contaminated the environment;
5.1.31 It further acknowledged that it had no records from Dr Van Rooyen indicating what actions were taken on the Complainant’s farm and which instructions were given to the Complainant;

5.1.32 In June 2011, the Free State DARD allocated the farm to Dr Kitshoff. According to reports received from Dr Kitshoff, the Complainant was in denial about what was happening on her farm. She indicated that to slaughter out the Complainant’s whole herd would have bankrupted her. She further indicated that, by that time, most animals already aborted, and that there was no way in which to predict which animal will abort next;

5.1.33 Dr Mojapelo explained that they were confronted with a herd which was vaccinated, but where abortions occurred. Dr Kitshoff compiled a report and requested that a study be conducted on the efficiency of the RB51 vaccine. They met with the Registrar on the farm in 2013, where the report was handed over to him, and there was a subsequent meeting scheduled with the Director: Animal Health;\(^\text{13}\) and

5.1.34 In conclusion, the Free State DARD indicated that it was simply not true that it just left the Complainant. They committed resources, compiled a report and were still involved on the farm.

Evidence adduced by Dr Petra Kitshoff

5.1.35 Dr Kitshoff the State Veterinarian at Free State DARD reported that, on the last test date before June 2011, 239 of 302 animals tested, tested sero-positive;

\(^{13}\) See more in para 5.4 below.
5.1.36 She confirmed that the first quarantine notice was only served in August 2012. She indicated that according to her knowledge, Dr Van Rooyen verbally quarantined the farm in October 2010, but she could not find any evidence of a written quarantine notice;

5.1.37 The outbreak was formally reported to both the Registrar and the Director: Animal Health via her report on the suspected lack of efficiency of the RB51 vaccine;

5.1.38 She explained her delay to prescribe low doses of the Strain 19 vaccine (S19) as follows: "The delay to use LD S19 in my case was due to many factors which had to be taken into account. The factors are the Brucellosis control measures prescribed in the Brucellosis Scheme, the uncertainty how to handle a herd with so many positive animals on zero grazing and the proven success rate of LD S19 vaccination in such a herd and the percentage abortions which could occur due to vaccination. Normally positive animals are isolated and the owner decides when to slaughter the positive isolated animals OR the herd is slaughtered by instruction of the National Director which did not happen. The owner decided that she will not have the animals slaughtered. If all the animals in the herd would be slaughtered, the owners would be financially ruined and this also contributes to my final decision to prescribe LD S19 vaccination." (sic)

5.1.39 She further confirmed that she was aware of the use of the unregistered vaccine in the herd.

*Dr Kitshoff's response to my Notice in terms of section 7(9) of the Public Protector Act, 1994*

5.1.40 I received a response to my Notice in terms of section 7(9) of the Public Protector Act, 1994, from Dr Petra Kitshoff on 10 December 2018. In her response, she indicated that she quarantined the herd on 14 August 2012. In terms of the
Quarantine Notice, under the heading "Control Measures," she indicated that positive animals had to be isolated. She further indicated that the herd showed 90% sero-positive animals in April 2011, and which could lead to the conclusion that the entire herd was likely to be positive, and that the isolation of positive animals was therefore not feasible under the circumstances. The entire herd was isolated.

5.1.41 She further highlighted that it was the responsibility of the owner to request the State Veterinarian for a Red Cross Permit by submitting the cattle numbers intending for slaughter, in writing. In this respect, Dr Kitshoff presented documentary evidence of Red-Cross Permits issued by her at the request of the Complainant. These were issued on 01 April 2014; 27 June 2014; 20 April 2015; 30 March 2017 and 20 June 2017. This control measure was also outlined in her Quarantine Notice of August 2012, where she indicated "slag positiewe diere by 'n abattoir met 'n rool kruis permit."

5.1.42 Dr Kitshoff referred to the requirement that the responsible person must individually identify animals in isolation and must keep a register of isolated bovines. In this respect, she indicated that the Complainant is the owner of a stud herd, and that the Breeders’ Association requires that each animal be tattooed in the ear with its allocated registration number, and that each animal also has a name and an ear tag. In this regard, she again advised the Complainant, in the Quarantine Notice of August 2012, to keep records of animals. The Complainant did so, by keeping a cattle register in which she highlighted which animals died and which were slaughtered.

5.1.43 With these proper records in place, and with the animals tattooed in the ear with a unique ID for each bovine, and individual ear tags, the branding with a C on the right side of the neck was not enforced at the request of the owner. She indicated further that no animal could be sold other than to the abattoir due to records held
of each animal and mainly due to the unique tattoo marking in the ear of each animal at birth.

5.1.44 She then referred to the email which she sent to the Complainant in September 2015 and indicated that:

"I have issued a red cross permit to be used several times in the beginning. Every time when cattle were slaughtered with this specific permit, the cattle numbers should have been provided (sic)

I admitted then that I was negligent by not obtaining records regularly of slaughtered animal numbers and other info related to the isolated animals at that time for my own records/files to be updated. The reason is that time was always a limited factor in my program, because I was not a full time Animal Health State Veterinarian, but a full time Laboratory Veterinarian responsible for Animal Health diagnostics."

5.1.45 According to Dr Kitshoff, in her Quarantine Notice, she authorised the Complainant to vaccine heifers with S19 between five and six months. She indicated that the heifers in the herd were vaccinated twice with RB51 since 2002, in line with the registration requirements of the product. Since the outbreak, heifers were vaccinated with full doses of S19, and cattle above eight months were revaccinated with low doses of S19. The use of RB51 was stopped.

5.1.46 She highlighted that RB51 was registered for two vaccinations, one between 4 and 10 months and one between 12 and 16 months, contrary to the legal prescripts which indicate that heifers must be immunised once between 4 and 8 months, and that no bovines above the age of eight months may be immunised without the written consent of the responsible State Veterinarian. She further
alluded that MSD and veterinarians even recommend more adult revaccinations with full doses of RB51.

5.1.47 As part of the Quarantine Notice, and further control measures, she recommended the testing and re-testing of heifers and all negative adult animals. This control measure is still implemented and records are available of all tests since 1997. She then indicated that the adult herd was vaccinated with a low dose of S19 in 2012 to limit shedding of organisms and to prevent abortions.

5.1.48 She indicated that the requirements for reporting of animal diseases are stipulated in a Manual for Animal Disease Reporting for Veterinary Services in South Africa. Immediate reporting of outbreaks of certain controlled animal diseases to the Director: Animal Health, on a SR1 form, is required for outbreaks of Foot and Mouth Disease; African Swine Fever; diseases already eradicated in South Africa; diseases which never occurred in South Africa and abnormal outbreaks of Anthrax, African Horse Sickness, New Castle Disease and Rift Valley Fever.

5.1.49 Brucellosis outbreaks which are regarded as endemic in the country, are reported on a List A, B, C form in a coded format by the responsible State Veterinarian. All reports go to the DAFF via the Provincial Director’s office. She contended that she did not report this outbreak, as she assumed that it was reported by Dr Van Rooyen following the initial recording of the disease and based on the Brucellosis status of the herd, as well as discussions and meetings held before June 2011.

5.1.50 She did however report the abnormal occurrence and the confirmed Brucellosis status after a research trial was done on the farm, with the RB51 report given to the Registrar and the Director: Animal Health, where the latter received additional remarks to the report in April 2013. She contended that it was thus not given coincidentally to the Director: Animal Health, as stated in my notice. The research
trial findings showed that RB51 did not help with the control of Brucellosis and/or protect the herd from contracting Brucellosis as an efficient vaccine is supposed to do. She gave the report the name of RB51 Report because the herd became infected with Brucellosis despite the use of a prescribed and registered vaccine against Brucellosis.

5.1.51 According to Dr Kitshoff, the National Director was aware of this case since April 2013 when the sero-positive Brucellosis status of the herd could be confirmed as an outbreak of the field strain of *Brucella Abortus Biovar 1*, and the entire herd was considered as infected.

5.1.52 She further indicated that she initially assumed that the farm was placed under quarantine by Dr Van Rooyen. When she could not obtain a copy thereof, she decided to follow due process and confirm the verbal quarantine with a written Quarantine Notice dated 14 August 2012. She reiterated that she was not a full time Animal Health State Veterinarian and that she had to pick up the ropes of this matter and collect records and relevant information following the request from the Provincial Director to take over the case.

5.1.53 With regard to the use of an unregistered vaccine in the Complainant’s herd, Dr Kitshoff noted that the entire herd was positive for Brucellosis when the unregistered vaccine was used. Secondly, she highlighted that there is no cure or treatment for Brucellosis, thus for the infected herd. She further highlighted that nobody had a solution for the extensive Brucellosis problem in the herd of the Complainant, and it was only the Director: Animal Health that can instruct that the herd should have been slaughtered, which was the alternative, but no instruction was received to slaughter the herd and no proposal was received on how to handle the herd either.
5.1.54 An autogenous vaccine was then presented to the devastated owners by the Company Disease Africa, as a possible answer / solution for them to try anything to improve / change the Brucellosis status of the herd. She highlighted that Table 2 of the Animal Disease Regulations states that “all heifers between the ages of 4-8 months in the Republic shall be immunised with an efficient remedy by the responsible person.” (her emphasis) She highlighted that even though she is aware that all vaccines should be registered, it was not stated as such in the Animal Diseases Act. She suggested that the wording was of the Act could be interpreted as understood or to the letter of the word.

5.1.55 Veterinarians are allowed to produce autogenic vaccines, but section 20 approval is needed for this purpose. The production and use of these autogenic vaccines are thus not prohibited if approval was granted by the Director: Animal Health. She further indicated that no autogenous vaccine is or has been registered under Act 36 of 1947 or any other Act in South Africa. Disease Africa is known to produce autogenous vaccines, and as far as she could ascertain, the DAFF was aware of the establishment of Dr Daan Goosen.

5.1.56 Dr Kitshoff cultured the autogenic vaccine provided to the Complainant to determine the risk of introducing live Brucella. The Bloemfontein Veterinary Laboratory was a DAFF approved laboratory at the time and was competent to culture and confirm Brucella Abortus spp. There was no growth found on the Brucella cultures prepared from the autogenous vaccine used by the Complainant and therefore, it was regarded as posing no risk. It could only cause positive titres on Brucellosis serological tests which was already the case.

5.1.57 Furthermore, Dr Kitshoff alluded that some years ago, a study or research was done to produce a killed Brucellosis vaccine and the finding was that it may be effective as a booster, but cause positive titres on the Brucellosis blood tests. The same finding can be made with the use of an unregistered vaccine. The use of
the unregistered vaccine was stopped at her request when a decision was made to vaccinate heifers with S19 and the adult herd with a low dose S19.

5.1.58 Dr Kitshoff concluded that the statement that she never implemented control measures should thus be corrected as what she had outlined proved beyond reasonable doubt that she did implement control measures. She further contended that all the control measures implemented by her had proven to be successful, and thus denied any improper conduct and / or maladministration.

Evidence adduced by MSD (the registration holder of RB51)

5.1.59 Dr Schultheiss the former Ruminants Veterinary Technical Manager at MSD said he was first informed of the outbreak on the Behrens farm when he was called by Dr Wessels, the private veterinarian of the Complainant. He informed him to report the outbreak to the State Veterinarian. Normal procedure would then be to brand all the infected animals with a "C" on the left side of the neck, and slaughter. He indicated that during his visit to the farm with Dr Van Rooyen, they discussed various things with the Complainant. They discussed control measures such as the separation of positive from negative animals, and suggested that the Complainant get a new calving pen. They also discussed the option of the slaughtering of positive animals;

5.1.60 The Complainant refused all the suggestions that were tabled. He testified that the Complainant indicated that it was not viable to separate infected animals from the negative animals, as their herd was separated into different camps – high production cows in one camp, low production cows in another, animals in lactation in another camp etc. The Complainant refused to mix the different groups. The Complainant further made it clear that the slaughtering of the animals was simply not an option;
5.1.61 It was further suggested that the Complainants keep testing their animals, as research indicated that animals may later become positive again. He further emphasised that, at no stage was a suggestion made that no action should be taken for a period of a year. MSD offered to assist the Complainant with serological testing and a one year supply of free vaccines, but the Complainant rejected its offer;

5.1.62 MSD further questioned the biosecurity on the Behrens farm. They indicated that animals such as meerkat and the Complainant’s dog (boerboel) were found eating the aborted foetuses. There was a high prevalence of flies on the farm. Dr Schultheiss highlighted however that the role flies can play in the spread of the disease was never examined in literature;

5.1.63 Dr Schultheiss further acknowledged that he was baffled, he could not believe what had happened on the Complainant’s farm. He noted that in all his years of experience, he never encountered anything as what happened on the Complainant’s farm. In an attempt to understand what transpired in this case, he convened a meeting in Harrismith with several other experts, but no answers could be found;

5.1.64 MSD further highlighted that, as the State can only test heifers at an age of eighteen (18) months, there is a delay in the detection of the disease. They also mentioned the possibility that calves could become infected prior to vaccination;

5.1.65 In conclusion, they noted that everything MSD did after it became aware of the outbreak on the Complainant’s farm, was done to assist the Complainant. According to them, the Complainant wanted to control the disease on her own terms, in the earlier stages of the outbreak.
Evidence obtained independently from Prof Abernethy

5.1.66 The Public Protector obtained independent evidence from Prof Abernethy who is currently the Dean of the Faculty of Veterinary Sciences at the University of Pretoria who wrote his doctoral thesis on the risk factors of *Bovine Brucellosis* and has published several articles on the subject matter.

5.1.67 Prof Abernethy indicated that the speed of intervention definitely makes a difference in the spread of *Brucellosis*. *Brucellosis* is most commonly spread through abortions. He indicated that about two thirds through the pregnancy of a cow, the cow will abort, and everything that comes out with the foetus, is contaminated. The environment also becomes contaminated, and this will infect other animals;

5.1.68 Some animals will not become infected, some will abort within a short period of time and in some animals, the *Brucella* bacterium will stay dormant for some time, and the animals will only show symptoms later. He indicated that *Brucellosis* is, in this sense, a very difficult disease;

5.1.69 In the Complainant’s matter, he indicated that, implementing control measures speedily might well have prevented the sudden escalation of the disease in her herd. He did however further indicate that, if there were so many infected animals initially, the disease might have spread despite the proper implementation of control measures. He indicated that animals might test negative, but can already be infected, and in such instances, a blood test, or a milk ring test will not pick it up if the animal is already infected. In this sense, he further indicated, that there is no perfect test for *Brucellosis*; and

5.1.70 He suggested that the government can better control the disease by putting in place proper identification and traceability systems. Resources should be
allocated to ensure that Government is in a position to enforce legislation, and one such measure can be to move from a voluntary Brucellosis scheme to a compulsory scheme.

Conclusion

5.1.71 From the evidence submitted by the Complainant, the DAFF, the Free State DARD and other stakeholders, the following is apparent:

a) The first confirmed cases of Brucellosis, by an accredited laboratory, on the Complainant’s farm were in May 2010. The Complainant reported the outbreak to the State Veterinarian, Dr Louis van Rooyen. The farm was only declared positive for Brucellosis in October 2010, thus five (5) months after the initial testing indicated a prevalence of Brucellosis in the herd;

b) The outbreak was never reported to the Director: Animal Health.

c) The farm was verbally quarantined.

d) The Complainant was never provided with a prescription for low doses of S19 to vaccinate contact animals;

e) In June 2011, Dr Kitshoff took over on the farm. Again the farm was verbally placed under quarantine. Verbal instructions were given about the control measures which needed to be implemented by the Complainant;

f) The outbreak was reported only to the Director: Animal Health in April 2013, almost two years after Dr Kitshoff took over on the farm from Dr Van Rooyen;
g) Verbal arrangements were made with the Ventersburg Abattoir for the
slaughtering of the cows.

h) The first quarantine notice was only served in August 2012.

i) A prescription for low doses of S19 to vaccinate contact animals was only
given to the Complainant in August 2012.

j) The use of an unregistered vaccine in the herd of the Complainant was
allowed;

k) It also appears as if the Complainant started slaughtering portions of her
herd from June 2010 onwards. This was prior to the herd being formally
declared positive for Brucellosis (which was only in October 2010), but after
bleeding of the herd already indicated the presence of the disease. The farm
was not quarantined at this stage and, in the absence of any records that a
Red - Cross Permit was issued allowing the movement of the animals, it
appears that the cows were slaughtered without the necessary permit
allowing the movement of the animals;

5.1.72 Even subsequent to the questions posed by the Public Protector regarding the
failure to follow due process, the situation persisted, which is evident from an
email from Dr Kitshoff to the Complainant in September 2015: -

"Goeie more Ronel. Ek is eintlik vandag in die moeilikheid weens my
nalatigheid. Die goeie nuus is egter dat dit vir my lyk of jou saak nou aandag
geniet by Dieregesondheid. Hou dit egter konfidensiële – ek dink dit is seker
op grond van die OB se navrae en Mnr Ramesodi se opvolg van die saak. Dr
Maja soek weer inligting oor julle huidige situasie. Onder ander moet ek
inligting verskaf oor diere geslag uit die Jersey kudde waarvoor ek
rooikruspermits moes uitreik vir elke beweging. Kan jy asseblief die volgende
inligting verskaf vir die afgelope jaar of dan ten minste vir 6 maande: Watter koeie en of verse is geslag (nommers), watter datum vir elke lot en waar. Ek het al die ander inligting bymyekaar. Baie dankie Ronel.”

Application of the relevant legal framework

5.1.73 The Animal Diseases Act\(^4\) defines an animal disease as a disease to which animals are liable and whereby the normal functions of any organ of the body of an animal is impaired or disturbed by any protozon, bacterium, virus, fungus, parasite, other organism or agent.

5.1.74 It further defines a controlled animal disease as any animal disease in respect of which any general or particular control measure has been prescribed, and any animal disease which is not indigenous or native to the Republic. A control measure is any measure prescribed by the Minister in relation to any controlled purpose.

5.1.75 Section 2(1) tasks the Director: Animal Health to exercise the powers and perform the duties conferred or imposed by and under this Act. Any powers or duties under the Act can be performed by the Director herself, or by an official with the necessary delegation from the Director, known as an authorized person, as envisioned by section 2, read with section 3, of the Act.

5.1.76 In terms of Table 2 of the Regulations\(^5\) issued under the Animal Diseases Act, Brucellosis is a controlled animal disease and the Act, read together with the Regulations issued in respect thereof, places certain obligations or duties on the State once a suspected outbreak of a controlled disease occurs. These duties include the following:

\(^4\) Act 35 of 1984. The definition is listed in section 1.
\(^5\) GG10469, 28 September 1986.
5.1.76.1 A State Veterinarian must report any suspected outbreak of a controlled animal disease, which was reported to him or her by the owner of such animal, immediately to the Director: Animal Health;

5.1.76.2 Section 14 authorises the Director: Animal Health, whenever she deems it necessary for any controlled purpose, to serve upon the owner of the land a written Notice that she will take control of the land as from a specified date. After the Notice has been served, the Director will have the authority to enter upon and occupy the land, and in addition, to use any suitable place on the land for the destruction or other disposal of any controlled animal or thing;

5.1.76.3 In terms of section 9(1)(c) of the Act, read with Regulation 26, the Director: Animal Health has a duty to quarantine the farm / place where the suspected outbreak occurred. A quarantine notice must indicate the controlled animal disease concerned, control measures, affected animals, the area and the period within which these control measures would apply;

5.1.76.4 Table 2 of the Regulations directs that all contact animals (a susceptible animal that was in contact with, or reasonably believed to be in contact with an infected animal) must be isolated and tested by an officer or an authorised person, and all bovines reacting negatively, may, with the written consent of the responsible State Veterinarian, be immunised with an efficient remedy under the supervision of the State Veterinarian;

5.1.76.5 Section 24(1) of the Act inter alia provides that a copy of any permit and related documents shall be stored safely for the periods which are fixed in terms of the Archives Act, 1962;
5.1.76.6 Section 9(2)(c) of the Animal Diseases Act, read with Regulation 20 of its Regulations, requires that a Red Cross Permit be issued by a State Veterinarian authorising the movement of infected animals to an abattoir;

5.1.76.7 Section 10 of the Act authorises the Minister to establish Animal Health Schemes in respect of any controlled purpose or for the improvement of animal health. In terms of this section, Regulations relating to a Bovine Brucellosis Scheme were promulgated.

5.1.76.8 In terms of Regulation 3 of the Bovine Brucellosis Scheme the objective of the Scheme is to promote the eradication of bovine brucellosis for the advancement of human and animal health. It subsequently further indicates that the eradication of bovine brucellosis shall be promoted by:-

a) Subjecting all bovines in the Republic to a brucellosis test;
b) Identifying and slaughtering all infected bovines;
c) Isolating all infected herds until bovine brucellosis has been eradicated in such herds;
d) Isolating any bovine suspected of being infected with bovine brucellosis until a final diagnosis can be made;
e) Preventing contact between infected bovine or any bovine suspected of being infected with bovine brucellosis, and any other bovines;
f) Informing all responsible persons and other interested persons of the control measures relating to bovine brucellosis contained in the Regulations, and the measures set out in the Scheme.

5.1.76.9 Regulation 10 obliges a State Veterinarian to, as soon as he or she is notified of an outbreak or suspected outbreak of Brucellosis, to serve on the owner an

16 GG11611, 09 December 1988.
order to isolate the infected animals from those not infected. The effect of such isolation would be that no animal may be moved from the place of isolation without the written authority of the State Veterinarian. In addition, all infected animals must, without delay, be branded on the right side of the neck with a C-brand.

5.1.76.10 In terms of Regulation 12, all stables, barns, kraals, crushes, mangers, water-troughs and other structures on the land on which bovines are kept in isolation, shall be disinfected with a remedy prescribed by the State Veterinarian and at such intervals as the State Veterinarian may determine.

5.1.76.11 Admission to the Scheme is granted on application by the owner in accordance with Regulation 15.

5.1.76.12 Paragraph 4.7.1 of the Brucellosis in Cattle Manual\(^{17}\) sets out the procedure(s) to be followed after an infection has been determined as follows:

"Quarantine: According to the Standing Regulations in terms of Act 35 of 1984, the onus rests with the stock owner to keep, in cases where a disease mentioned under Annexure 2 has been determined or is suspected such animals in quarantine until a State veterinarian authorises their release. The issuing of a written quarantine notice is therefore not obligatory, but to obviate any doubt it is advisable to issue a written quarantine notice in the prescribed manner."

5.1.77 The Animal Diseases Act, its Regulations and the Bovine Brucellosis Scheme place certain duties on the Director: Animal Health, alternatively the State

Veterinarian when there is an outbreak or suspected outbreak of Brucellosis. These include the obligations to, in the case of a State Veterinarian, to immediately report the outbreak to the Director: Animal Health; to quarantine the farm where the outbreak occurred by issuing a formal quarantine notice on the owner, to notify the owner of the control measures that he or she needs to apply – including but not limited to the isolation, branding and slaughtering of infected animals, and to test and vaccinate contact animals. State Veterinarians are also obliged to keep proper records of actions taken and instructions given after a notifiable disease was reported, and animals could only be moved from a quarantined area if a Red Cross Permit for such movement had been issued by the State Veterinarian.

5.1.78 I identified two periods within which there should have been compliance with the legislation after the outbreak occurred. The first period was the period May 2010 to June 2011, when Dr Louis van Rooyen was the State Veterinarian attending to the farm, and the second period was the period from June 2011 onwards, when Dr Petra Kitshoff was the State Veterinarian attending to the farm. These periods are dealt with separately.

*The period between May 2010 and June 2011*

5.1.79 I have taken cognisance of the evidence alluded to by all the parties pertaining to the period between May 2010 and June 2011, when Dr Van Rooyen was the State Veterinarian responsible for the farm. The evidence indicated that Dr Van Rooyen failed to report the outbreak to the Director: Animal Health, he verbally quarantined the farm, he verbally informed the Complainant of certain control measures, he failed to ensure that these control measures were implemented and he failed to provide a prescription for the vaccination of contact animals.
5.1.80 The evidence as was submitted to me could not be independently verified by any records. The Free State DARD could not provide any records of what instructions were given to the Complainant, and what actions were taken by Dr Van Rooyen during this period. The Free State DARD could also not provide an explanation for the fact that it had no records to produce on what transpired on the Complainant's farm for this period.

5.1.81 The Free State DARD in this regard failed to ensure proper record – keeping by Dr Van Rooyen.

Period from June 2011 onwards

5.1.82 Dr Kitshoff reported the outbreak, coincidently, with the handing over of the report on the suspected lack of inefficiency of the RB51 vaccine to the Registrar. This was in April 2013, almost two years after she took over from Dr Van Rooyen.

5.1.83 In June 2011, the farm was verbally quarantined and verbal instructions were given regarding the control measures which should be implemented. The first formal quarantine notice was only served on the Complainant in August 2012, a year after Dr Kitshoff started working on the farm.

5.1.84 Dr Kitshoff issued informal instructions and made verbal arrangements for the slaughtering of the animals. The Complainant was slaughtering animals from June 2010, but Dr Kitshoff only issued the first Red – Cross Permit for the movement of animals from the Complainant's farm in August 2012. This huge delay remain unexplained.
5.1.85 In addition, the role of Dr Kitshoff to "allow" the Complainant to vaccinate her herd with an unregistered (illegal) vaccine for three months in 2011, is also a cause of concern.

Conclusion

5.1.86 For the period May 2010 to June 2011, the Free State DARD failed to ensure proper record keeping by the attending State Veterinarian, as required by section 24 of the Animal Diseases Act.

5.1.87 For the period June 2011 onwards, the State Veterinarian, Dr Kitshoff, failed to implement control measures as prescribed by the Animal Diseases Act, its Regulations and the Bovine Brucellosis Manual.

5.1.88 As a general observation, I noted that there is a discrepancy between the requirements for the setting of quarantine in terms of the Animal Diseases Act and the Bovine Brucellosis Manual.

5.2 Issue 2: Regarding whether the Director: Animal Health failed to intervene on the farm when the outbreak was brought to her attention by the Complainant, and whether such failure constitutes maladministration: -

Issues in dispute

Evidence adduced by the Complainant

5.2.1 The Complainant alleged that, when nothing was done on her farm, she reported the outbreak directly to the Personal Assistant of the Director: Animal Health on
29 December 2010. In substantiation, the Complainant provided the Public Protector with a copy of the email sent, which states:


5.2.2 Just prior to sending this email, the Complainant alleged to have spoken to a certain Sandra at the DAFF telephonically, during which conversation she was requested to send an email and provided with the email address that she sent the mail to.

5.2.3 The Complainant further alleged that, about a week before, she had telephonic discussions about the situation on her farm with a certain Dr Ungerer of the DAFF.

Evidence adduced by the DAFF

5.2.4 The DAFF initially disputed that the Director: Animal Health was informed about the outbreak in December 2010. DAFF alleged that the Director: Animal Health only received information about the outbreak in April 2013, when Dr Kitshoff handed over a report on the suspected lack of efficiency of the RB51 vaccine to the Registrar;

5.2.5 The DAFF explained that Provincial Departments are supposed to report outbreaks of controlled diseases by submitting monthly statistical reports to the DAFF. These reports are usually expected by DAFF 30 days after the end of the month;
5.2.6 In a written response to questions posed during a meeting held on 18 February 2015, the DAFF however indicated that "[t]he outbreak was reported in their normal monthly reports to the DAFF."

5.2.7 In a later written response, DAFF indicated that "[t]o provide further clarity on the previous question on whether the Free State had reported this case to the Director, we managed to establish that this farm was NEVER reported in the prescribed format to the Director. The first report was that which was sent to the Registrar Act 36 of the complaint about the efficiency of the vaccine." (sic)

5.2.8 During a meeting held on 31 March 2015, the Director: Animal Health was requested to explain what action was taken after she obtained knowledge of the outbreak, allegedly in April 2013. She explained that DAFF visited the farm on 15 April 2013 (it is however noted that she was not part of the delegation that visited the farm, and that the farm was visited by the Registrar in relation to the complaint of the efficiency of RB51). It was further indicated that Drs. Kitshoff (State Veterinarian: Free State) and Mojapelo (Director: Veterinary Services: Free State) held discussions regarding the outbreak on the farm and possible assistance to the Behrens family in September 2013, during which engagements it was agreed that Dr Kitshoff will provide a full epidemiological report on the farm so that DAFF could assist. Dr Kitshoff allegedly only provided a literature overview.

5.2.9 In a later response, dated 14 November 2016, the Director: Animal Health indicated as follows:

"According to our records, the email dated 29 December 2010 sent at 12:48 PM from Ronel Behrens was received by the Personal Assistant for the then Acting
Director: Animal Health. The Personal Assistant has no recollection of having spoken to Mrs Behrens or of having any previous contact with her. [...] The Directorate was not able to find any record of the Acting Director responding to the email from Ms Behrens.

5.2.10 In addition, the Director: Animal Health indicated:

"... The Directorate has a prescribed way of reporting disease occurrence. Even though the Director Animal Health was aware of the disease occurrence on the farm, Brucellosis is endemic in South Africa and the control thereof is delegated to the provinces as per the Constitution. The Director Animal Health does not get involved unless specifically requested to either guide or intervene. The meeting in September 2013 in Thaba Nchu was therefore an attempt to understand the extent of the problem and to establish if the Free State required our intervention."

5.2.11 Later, in the same response dated 14 November 2016 from the Director: Animal Health, the Director indicates that:

"Please note that the Directorate: Animal Health is not required to make decisions for the control measures applied on the farm as the implementation and control of a programme or disease control scheme is the mandate of the Provincial Veterinary Services. The Directorate: Animal Health would only provide advice or guidance to the Provincial Veterinary Services is requested."
The Director: Animal Health’s response to the notice in terms of section 7(9) of the Public Protector Act, 1994

5.2.12 The Director: Animal Health (DAH) responded to my section 7(9) Notice on 28 February 2019. She submitted that my findings against the Director: Animal Health did not have any basis in law or in science and that it was not supported by facts.

5.2.13 The DAH indicated that the theme of my provisional findings suggested that the DAH failed to intervene on the Complainant’s farm when the outbreak was brought to the attention of the Personal Assistant of the DAH in an email dated 29 December 2010. She alluded that I made this provisional finding without stating whether the said email in fact reached the previous or current DHA, and without indicating how the DAH should have acted upon receipt of the said email. She also suggested that I made the provisional finding without taking proper account of the role of the Province in dealing with the outbreak.

5.2.14 The DAH contended that I have given little or no consideration at all to the role of the Complainant in the outbreak. I have made no mention of the statutory responsibilities that she had in terms of section 11 of the Animal Diseases Act, and that I did not scrutinise her unlawful act to administer an unregistered vaccine in her herd. The DAH argued that I did not investigate the role of the Complainant in the outbreak, the maintenance and the containment thereof, as well as explore why there was a need for the Complainant to switch from the more affordable S19 vaccine to the more expensive R51.

5.2.15 The DAH further indicated that none of my provisional findings against her was supported by the evidence presented by my own independent expert, Prof. Abernethy.
5.2.16 Since July 2002, two (2) vaccines against Brucellosis are available and registered for use in South Africa. The S19 vaccine should be used in young heifers four (4) to eight (8) months of age. Its use in older animals may induce persistent antibody titres that interfere with interpretation of serological test results. RB51 does not elicit interfering antibody titres and has been registered for use in heifers and adult cows. The DAH reiterated that, according to Table 2 of the Regulations to the Animal Diseases Act, vaccination of adult cattle can only take place with the permission of the state veterinarian.

5.2.17 The degree of immunity conferred by S19 and RB51 can be considered similar for all practical purposes. It should however be remembered that the efficiency of vaccination is limited. The main effect of vaccination is to limit the spread of an existing or introduced infection in a herd by preventing abortions and decreasing the number of bacteria shed into the environment. Vaccination alone will not be able to prevent or eradicate the disease in an infected herd, and regular serological testing followed by culling of reactors remain essential control measures.

5.2.18 It was submitted that, similarly, negative herds that are properly vaccinated will be partially protected against infection, but this immunity can be overcome by a high infection pressure if large numbers of bacteria are present in the environment. Good management practices thus remain essential, especially with regard to new animals, which should be sourced from certified clean herds, as well as quarantined and tested after introduction onto the farm and before mixing with other animals.

5.2.19 The DAH further indicated that, whilst vaccination alone will never be able to eradicate Brucellosis, effective immunisation of susceptible animals remains one of the main strategies to combat the disease in the individual herd, as well as on a national basis. Increasing the immunity of as many cows as possible limits the
spread of the infection, thereby protecting clean herds and controlling the disease in infected herds. This is the reason why vaccination of heifers was declared compulsory in legislation.

5.2.20 The DAH confirmed that Brucellosis is difficult to control and that this was confirmed by workers in countries which have succeeded in eradicating the disease after prolonged, difficult and expensive campaigns. The control strategy used in South Africa, namely vaccinate, test and slaughter, has proved effective in the control and eradication of the disease in other countries. In all cases, the cooperation between the farmer, animal health technician, veterinarian and laboratory had been found to be absolutely necessary for success.

5.2.21 It was further contended that national and regional eradication of Brucellosis may take a long time. Individual herds can mostly be cleared of the disease within two (2) years provided there is good cooperation from the owner, especially with regard to the isolation and slaughter of positive animals. Even if there is good cooperation, a percentage of problem herds which take longer to clear must be expected, especially if the animals are managed under intensive conditions and the infection pressure is high. Control is based on providing animals with immunity and removing the infected animals from the herds timeously to prevent spread of the infection to clean stock.

5.2.22 The DAH indicated that animal control and diseases are Functional Areas of Concurrent National and Provincial Legislative Competence under Schedule 4 of the Constitution. The Animal Diseases Act does not supersede the Constitution and should rather be read to give effect to the Constitution. In terms of this concurrent function, the national directorate formulates guidelines for the management of controlled animal diseases and the provincial veterinary services are responsible for the implementation of those disease control guidelines and the disease control measures within their provinces. These guidelines are often
called procedural documents or manuals. These documents, purposefully, allow some flexibility in implementation depending on the unique situation of each farm and each province.

5.2.23 This means that Brucellosis outbreaks in cattle are managed by the provincial veterinary services according to the Bovine Brucellosis Scheme, 1988, and the supporting procedural documents available at the time. The DAH will only give guidance and assistance of the disease control measures on a farm, if this is specifically requested by the Provincial Veterinary services.

5.2.24 The implementation Protocol for Veterinary Services between the Department of Agriculture and the Provincial Departments of Agriculture 2008, was drawn up to help clarify the roles of the veterinary services and ensure its functions in compliance with the Constitution of South Africa. In terms of this Implementation Protocol, the National Directorate has to:

- Set norms and standards;
- Formulate Policies and schemes in consultation with Provincial Veterinary Services; and
- Audit Provincial Veterinary activities and offer technical advice and / or guidance on disease control.

5.2.25 In this respect, the National Directorate serve as the only official chief communicator on disease outbreaks to trading partners and proper, timeous reporting to the OIE.

5.2.26 The Provincial Veterinary Services are expected to:
- Conduct disease monitoring, control and prompt reporting as prescribed to enable the National Directorate to report to trading partners and to international standard setting bodies;

- Ensure food safety in the food of animal origin, with special emphasis on abattoir management and good hygiene practices;

- Ensure Provincial laboratories are well equipped with the necessary resources, human, financial and equipment to enable them to monitor diseases in their respective provinces;

- Assist the National Directorate in the administering the Animal Identification Act, through proposed rollout programmes; and

- Rollout of the Primary Animal Health Care Programme once a Policy has been adopted.

5.2.27 The delegations that are given to Provincial Veterinary Services officials are to enable them to perform their functions under the Animal Diseases Act but in line with the dictates of the Constitution. Therefore, the DAH contended that, although the Provincial Veterinary Services are given delegations to perform the duties of under the Animal Diseases Act, the DAH cannot simply intervene, take over or dictate the control measures to be applied on a farm. The DAH thus contended that she does not agree that she was ultimately responsible for the actions or omissions of the Provincial Veterinary Service.

5.2.28 The DAH further reiterated that at no stage did the Provincial Veterinary Service state that it was unable to handle the outbreak, and at no stage did it formally or officially seek the intervention of the DAH.
5.2.29 According to the DAH, an outbreak of Brucellosis in cattle is not a disease for which immediate notification of the outbreak is required. Brucellosis outbreaks are reported routinely on a monthly basis to DAFF by the Provincial State Veterinary Services for monitoring and international disease reporting purposes only. Currently, South Africa has more than one thousand eight hundred (1800) farms that are affected by Brucellosis. These routine monthly reports are not regarded as requests for assistance by the Provincial Veterinary Services.

5.2.30 A Brucellosis outbreak on Tweelingskop Farm, which is assumed to be the outbreak on the Complainant’s farm, was reported as part of the monthly provincial report to the DAH in 2010. There was no indication in this report that the Provincial Veterinary Services required any assistance on disease control measures. Further, the DAH contended that she was not aware of any communication from the Province regarding the farm of the Complainant until April 2013 when the *Report on the Suspected Lack of Efficacy of RB51 Vaccine With Reference to a Case Study which involved Dairy Cattle from May 2012 – January 2013* was forwarded by Dr Petra Kitshoff.

5.2.31 This report only raised concerns regarding efficacy of RB51, it was not a disease outbreak report and not a request for assistance from the Provincial Veterinary Services in respect of disease control measures on the Complainant’s farm. The DAH then attended a meeting in Thaba Nchu in September 2013, in an attempt to try and understand the extent of the problem, to determine whether the Provincial Veterinary Services required any assistance and to understand the situation on the farm in order to provide guidance, if required. According to the DAH, even during this meeting, there was no indication that the Province was not able to handle the outbreak on the Complainant’s farm.
5.2.32 The DAH reiterated that there was no merit in the conclusion that she failed to intervene, as there was no request for intervention. The DAH indicated that I had access to independent scientific advice from Prof Abernethy, which also did not suggest that the intervention from the DAH was necessary. There was therefore no rationale or scientific basis for my conclusion that the DAH failed to intervene.

5.2.33 According to the DAH, section 11 of the Animal Diseases Act provides for the duties of owners regarding the health of their animals. Section 11 provides that owners should take all reasonable steps to prevent the infection of animals, the spreading of infection in animals and steps necessary for the eradication of animal diseases. The owner should also, in respect of such animals, apply the prescribed treatment.

5.2.34 The DAH further indicated that it was clear from my Notice in terms of section 7(9) that the Complainant made certain choices with regard to the containment of the disease on her farm. For one, the evidence suggested that the Complainant refused to separate positive animals from negative animals, which is regarded as essential in the control and eradication of the disease. The biosecurity on the farm was questionable. The Complainant committed a statutory offence by administering an unregistered vaccine in her herd. The DAH contended that I attached no weight, alternatively little weight, to the conduct of the Complainant in this regard.

5.2.35 The DAH noted that:

"Desperation' does not make such actions legally or scientifically sound, especially when legal and acceptable alternatives such as low dose S19 were available and were later legally used by Mrs. Behrens."

5.2.36 In addition, the DAH indicated that I assumed that the vaccination should completely prevent infection, alternatively, if there was infection, that the vaccine
should have prevented any shedding or symptoms of infection. This was not, according to her, a scientifically sound approach. Brucellosis vaccines, it was submitted, were only one of the tools used to help prevent and control Brucellosis and, like with many other vaccines, the degree of protection afforded depends on many factors relating to the organism, the environment, the host and the administrators. Even if all these factors were optimal, vaccines that produce immunity capable of completely preventing any infection, any shedding or any symptoms were uncommon, and as far as she was aware, neither RB51 nor S19, were capable of this.

5.2.37 Concluding, the DAH again reiterated that my Notice did not suggest what actions should have been taken by her during the period 2010 to 2013. This, she suggested, assumed that the Provincial Veterinary Services was not in a position to handle this matter as it was supposed to. Nowhere in my Notice, she contended, did I record that the Provincial Veterinary Services in any way needed the assistance of the National Directorate.

5.2.38 She further stated that my conclusion presupposed that the involvement of the DAH would have resulted in a different outcome, but there was no scientific evidence to support such conclusion. In addition, it was suggested that it cannot be ruled out that the previous DAH might have consulted telephonically or otherwise have interacted with the relevant State Veterinary officials and concluded that there was nothing that the national Directorate was legitimately required to assist with.

5.2.39 The DAH stated that:

"It is recorded that the outbreak was reported only to the Director: Animal Health in April 2013, almost two (2) years after Dr Kitshoff took over on the farm from Dr Van Rooyen. It is therefore submitted that there is no legal basis at all for the
conclusion that the Director: Animal Health delayed in taking action. [...] There is absolutely no basis at all to even consider a monetary compensation in the circumstances of this case*

Application of the relevant legal framework

5.2.40 Section 40(1) of the Constitution\(^8\) creates three distinctive, interdependent and interrelated spheres of Government, namely local, provincial and national government. In terms of section 41(1)(h) of the Constitution, all spheres of government must co-operate with each other in mutual trust and good faith by, _inter alia_, fostering friendly relations, assisting and supporting one another, informing one another of and consulting one another on matters of common interest, and by coordinating their actions and legislation with one another;

5.2.41 Agriculture and animal control and diseases are functional areas listed in Schedule 4 of the Constitution.\(^9\)

5.2.42 Section 2 of the _Animal Diseases Act\(^{20}\)_ authorises the Director: Animal Health to exercise the powers and perform the functions in terms of the Act. Such power conferred or duty imposed may be delegated to the relevant responsible Director: Veterinary Services in a particular province. Section 2(3)(b) further states that any decision made by such officer may be withdrawn or amended by the Director: Animal Health, and shall, until such time as it has been withdrawn, be deemed to have been made by the Director.

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\(^9\) Schedule 4 relates to functional areas of concurrent National and Provincial legislative competence. This means that in these areas, the national and provincial government have concurrent legislative and executive authority – legislative authority referring to the power to enact legal rules and executive authority referring to the power to give effect to legal rules – this explanation was taken from Van Wyk J 2012 (15:5) _PELJ_ 288 289.

5.2.43 In *Manana v King Sabata Dalindyebo Municipality*\(^{21}\) the Supreme Court of Appeal held that a delegation of power does not ordinarily divest the delegator of the power to perform the particular function itself.\(^{22}\) The court explained "*It has sometimes been stated that delegation implies a denudation of authority...This cannot be accepted as an accurate general proposition. On the contrary, the general rule is that an authority which delegates its powers does not divest itself of them...*"\(^{23}\)

5.2.44 The Complainant alerted the Director: Animal Health of the outbreak of *Brucellosis* on her farm on 29 December 2010. The DAFF acknowledged receipt of this notification, and acknowledged that no further action was taken by the Director. No action was taken by the Director: Animal Health until seemingly, September 2013. The Director: Animal Health claims that no further action was required, as the matter was not reported in the prescribed manner, and because disease control is the responsibility of the Provincial Veterinary Services, as per the Constitution, and the Provincial Veterinary Services did not require the assistance or intervention of DAFF.

5.2.45 In terms of the *Animal Diseases Act*, the Director: Animal Health should perform the functions and exercise the powers in terms of the Act. The Director: Animal Health is thus the accountable person in terms of the Act. The Director: Veterinary Service in a particular province, exercises its powers and perform its functions within the regulatory framework set by national government. As the accountable authority, the Director: Animal Health has a duty to exercise an oversight role and remains responsible to ensure compliance. This oversight role is emphasised by section 2(3)(b) of the Act, which grants the Director: Animal Health the authority

\(^{21}\) (345/09) [2010] ZASCA 144 (25 November 2010).
\(^{22}\) At para [16].
\(^{23}\) Nugent J (ibid) quoting an extract from *De Smith's Judicial Review* (6th edition) by the Rt Hon The Lord Woolf *et al.*
to either amend or withdraw any decision made by a Director: Veterinary Services.

5.2.46 When there was a delegation of the functions in terms of the Act, the Director, as the delegator, had a duty to ensure that the delegated function was performed and that such function was performed within the bounds of the delegation given.

5.2.47 Section 195 of the Constitution obliges public administration to be governed by democratic values and principles enshrined in the Constitution, including inter alia, maintaining a high standard of professional ethics, efficient, economic and effective use of resources and responding to peoples’ needs. It further indicates that public administration should be accountable.

5.2.48 When the Complainant reported the outbreak to the Director: Animal Health in December 2010, the principles of good public administration and good governance would have, at least, required that the Director: Animal Health make contact with the relevant province, ascertain facts, ascertain what assistance the Complainant required and to provide guidance. The Director: Animal Health delayed this simple process for a period of almost three years.

Conclusion

5.2.49 The Director: Animal Health’s delay to take action when the outbreak of Brucellosis on the Complainant’s farm was reported in December 2010 falls short of the required standard that good governance and good public administration as envisaged in section 195 of the Constitution.
5.3 Issue 3: Regarding whether the Registrar followed due process in terms of the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947*, to register the RB51 vaccine:

**Issues in dispute**

**Evidence adduced by the Complainant**

5.3.1 The Complainant contended that RB51 was tested at Onderstepoort, and despite indications that it was inefficient; DAFF proceeded to register RB51 and compelled farmers to use it;

5.3.2 She also raised a question pertaining to why the Registrar registered RB51 when its directions for use differs from the requirements set by the Regulations issued in terms of the *Animal Diseases Act*, which only allows vaccination of heifers once between the ages of 4 and 8 months.

**Evidence adduced by the DAFF**

5.3.3 The DAFF indicated that stock remedies are registered based on satisfactory data which prove the quality, safety and efficiency of the product. The data must be generated from studies carried out according to prescribed standards, and once the Registrar is satisfied that the application is compliant, with evidence of safety, efficiency and quality, the registration is approved;

5.3.4 It further indicated that DAFF does not conduct its own tests when evaluating products, but only conducts a scientific review of the data submitted by applicants;
5.3.5 The process that was followed by DAFF in registering RB51 was explained as follows: Intervet South Africa (Pty) Ltd submitted an application for the registration of RB51 in April 2001. The application was supported by scientific data generated in the United States of America (USA). The application was referred to the Registrar's internal Technical Advisors who conducted rigorous scientific evaluation on the product in terms of safety, efficiency and quality;

5.3.6 The application and scientific data were also referred to an external expert, a Microbiologist of the University of Pretoria for a scientific evaluation, who recommended the registration of RB51;

5.3.7 In a parallel process, the same scientific data was also referred to the Directorate: Animal Health, for a risk assessment. The Directorate: Animal Health also recommended the registration of RB51;

5.3.8 According to DAFF, there was no information about the product being ineffective at the time of registration;

5.3.9 The Registrar acknowledged that the Regulations issued in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act,²⁴ requires that the experimental data on the biological efficiency of a stock remedy must be determined under South African conditions. He further indicated that the Registrar may grant exemption from this requirement. He indicated that the World Organisation for Animal Health (OIE) had published principles of vaccine production and testing. Based on these principles, countries may not necessarily request additional tests to be done in their own countries and may rely on data generated in the originating country. This would be to prevent unnecessary disease risk, particularly where the target strain is the same as that of microorganisms occurring on both countries and the vaccine controls the same

²⁴ Act 36 of 1947.
disease. According to the Registrar, this principle is accepted world-wide in both animal and human health and has been practiced for many years.

5.3.10 In a written response to the investigation team on the legal status of the OIE standards in South Africa, the Registrar simply stated “Currently, our approach when it comes to registration of products under Act 36 of 1947, we rely on our own published guidelines together with all internationally recognised guidelines.” And later: “The then Registrar must have been satisfied with the opinions given by the experts that evaluated the dossier. These opinions were that the scientific data, documentation and refereed publications submitted by the applicant were sufficient. The current practice is to waive certain requirement/s provided that the alternative scientific data submitted is deemed to be sufficient to make a decision. No formal written application for an exemption is made or given. According to our records during that time, it also suggests that no formal written application for an exemption was made or given. Therefore, we assume that then Registrar of the time followed the same practice."

5.3.11 The DAFF contended that the Complainant was confusing the registration of RB51 with the trials that were conducted for another possible Brucellosis vaccine, namely Bruvac. Bruvac was tested in South Africa around the same time that RB51 was registered, but Bruvac was not registered by the Registrar.

Evidence adduced by Prof Mouritz van Vuuren

5.3.12 Prof van Vuuren, the Emeritus Professor at the Faculty of Veterinary Sciences at the University of Pretoria and the Microbiologist who conducted the review of the scientific data on behalf of the Registrar, explained that, any applicant who wants to register a stock remedy in South Africa, hands over to the Registrar a docket containing information about the safety, control and efficiency of the product that it intends to register, which the Registrar must evaluate. Due to capacity
constraints, the review of this data is subcontracted. A reviewer must work through the data, summarise it and make a recommendation.

5.3.13 The recommendation of the Reviewer must then also be reviewed by the Registrar’s Technical Advisor, who looks into it and makes a final recommendation to the Registrar.

5.3.14 Prof Van Vuuren further indicated that the then Director: Animal Health, Dr Emily Mogajane, wanted RB51 to be registered in South Africa, and he was put under pressure to finalise the review as soon as possible. The main reason why Dr Mogajane wanted the vaccine registered in South Africa, was because it made the detection of the disease easier. Vaccination with S19, as it was explained, gives antibodies in diagnostic tests, and it is impossible to determine whether the antibodies were because of natural exposure or due to vaccination. In addition, it was explained that any bovine older than eight months vaccinated with S19, test positive for the rest of their lives.

5.3.15 Prof Van Vuuren did not indicate in any way that the pressure that was put on him to finalise the review as soon as possible, influenced his decision to recommend the registration of the product.

5.3.16 It was further explained to the Investigation team that external factors cannot influence the efficiency of a vaccine, as the efficiency relates to the live organism that is in the vaccine. RB51 contains a *Brucella Abortus* Biovar 1 organism (Biovar 1, it was explained, is the most common biovar of *Brucellosis* in South Africa). So, when an animal is vaccinated with RB51, it should produce the same antibodies which will protect the animal against the biovars of *Brucellosis* that is found in South Africa;
5.3.17 Prof Van Vuuren further indicated that he was not aware of the requirement in terms of the Regulations that an application for registration to the Registrar must include experimental data on the efficacy of the stock remedy as determined under South African conditions.

5.3.18 He indicated that, according to him, the Registrar followed the correct procedure to register RB51 in South Africa.

**The Registrar's response to the notice in terms of section 7(9) of the Public Protector Act, 1994**

5.3.19 I received a response to my notice issued in terms of section 7(9) of the Public Protector Act, 1994, from the Registrar on 14 December 2018.

5.3.20 In his response, the Registrar admitted that the OIE standards are guidelines and furthermore, that the Registrar does refer to international guidelines including the OIE standards, provided that they are in sync with the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, and its attendant Regulations.

5.3.21 He further contended that the Act does not make provision for exemption, except to allow the Registrar to register the stock remedy in concert with the applicable regulations and to consider additional conditions as may be determined by him. According to him, Regulation 2(2)(ii)(ee) of GNR 1404 of 01 July 1983, and notwithstanding the provision of Regulation 2(2)(ii)(bb), the Registrar can consider data generated outside of South Africa.

5.3.22 He further indicated that the Act does not have an exemption application process except the utilisation of options provided for in terms of the foregoing Regulation. He then submitted that the application submitted by Intervet, conformed to the
dictates of both the principal Act and its attendant Regulations. Amongst others, he further contended that, as part of any other additional conditions, the Registrar considers the OIE guidelines.

5.3.23 He denied that he relied on an international principle to circumvent a legal requirement under South African Law, but instead relied on section 3(3) of the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, which provides that: -

"Any registration under this section shall be subject to the prescribed and any additional conditions as may be determined by the Registrar..." (his emphasis)

5.3.24 This, he contended, means that the Registrar considered the OIE guidelines in that light as part of the additional conditions.

**Application of the relevant legal framework**

5.3.25 Section 231 of the Constitution\(^{25}\) states that the negotiating and signing of all international agreements is the responsibility of the national executive. An International Agreement binds the Republic only after it has been approved by resolution in both the National Assembly and the National Council of Provinces, unless it is an agreement which falls under section 231(3).

5.3.26 In terms of section 231(3) of the Constitution, an international agreement of a technical, administrative or executive nature, or an agreement which does not require either ratification or accession, entered into by the national executive, binds the Republic without approval by the National Assembly and the National

Council of Provinces, but must be tabled in the Assembly and the Council within a reasonable time.

5.3.27 In terms of section 231(4), an international agreement becomes law in South Africa when it is enacted into law by legislation, but a self-executing provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.

5.3.28 Article 7 of the International Agreement for the creation of an Office International Des Epizooties determines as follows:

"The present Agreement shall be ratified under the following conditions: Each power shall send its ratification to the French Government as soon as possible. The latter shall then notify the other signatory countries thereof. The ratifications shall be deposited in the archives of the French Government. This Agreement shall come into force in respect of each signatory country from the date of deposit of its instrument for ratification."

5.3.29 The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act defines a "stock remedy" as a "substance intended or offered to be used in connection with domestic animals, livestock, poultry, fish or wild animals (including wild birds), for the diagnosis, prevention, treatment or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, but excluding any substance in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965)."

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27 Section 1.
5.3.30 In terms of section 2, the Registrar is an officer in the Department of Agricultural Technical Services, designated by the Minister, to exercise the powers, perform the functions and carry out the duties conferred upon, assigned to or imposed on the Registrar under the Act.

5.3.31 Any application for the registration of a stock remedy is made to the Registrar, in accordance with section 3(1)(a).

5.3.32 Section 3(2) prescribes that the Registrar shall register a stock remedy, if, after consideration of any application and after such investigation and enquiry as he may deem necessary, is satisfied that the stock remedy in respect of which registration is applied for is:

a) suitable and sufficiently effective for the purpose for which it is intended;
b) complies with such requirements as may be prescribed;
c) it is not contrary to the public interest that it be registered;
d) that the establishment where it is manufactured, is suitable for such manufacture.

5.3.33 Section 14 authorises the Minister to designate persons, including officers, as technical advisers who shall advise the Registrar with regard to matters referred to them by the Registrar and analysts to analyse samples of stock remedies referred to them by the Registrar, and to report thereon in the form and manner prescribed.

5.3.34 Table 2 of the Regulations issued under the Animal Diseases Act,28 indicates that the controlled veterinarian act to be performed in respect of susceptible animals;

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28 GG10469, 28 September 1986.
is that all heifers between the ages of 4 and 8 months in the Republic shall be immunised once with an efficient remedy by the responsible person. In addition, no bovine above the age of 8 months shall be immunised against Brucellosis without the written consent of the responsible State Veterinarian.

5.3.35 The Regulations regarding the Registration of Fertilizers, Farm Feeds, Agricultural Remedies, Stock Remedies, Sterilising Plants and Pest Control Operators, Appeals and Imports and Amendments to and Repeal of certain Regulations issued in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act\(^{29}\) sets out how an application for the registration of a stock remedy must be made. Regulation 2 requires that the application must be made to the Registrar in the prescribed manner.

5.3.36 Regulation 2(2)(c)(i)(bb) requires that an application for the registration of a stock remedy must be accompanied by a copy of the experimental data on the biological efficacy of the stock remedy, and of the residues of the stock remedy concerned as determined under South African conditions; provided that the Registrar may grant exemption from the submission of any sample or document referred to.

5.3.37 Regulation 2(2)(iii) further requires that the application for registration be accompanied by the written permission of any person in whose favour a stock remedy has been registered, if the active ingredient and formulation of the stock remedy intended to be registered, is identical to that of a stock remedy already registered.

5.3.38 An application to register RB51 in South Africa was brought in 2001. The application was supported by scientific evidence generated in the United States

\(^{29}\)GN R1449, 01 July 1983.
of America, and was thus never tested in South Africa. The Registrar acknowledged this. The process followed prior to registration was to refer the application to the Registrar’s Technical Advisors, to an external expert for a review, and to the Directorate: Animal Health for a risk assessment. The registration of RB51 was recommended by all three.

5.3.39 The 1983 Regulations required that the data submitted in support of an application for registration of a stock remedy in South Africa, must have been tested under South African conditions. The Registrar contended that compliance with this requirement was waived, in accordance with principles released by the World Organisation for Animal Health (OIE) which provides that countries are not necessarily obliged to request additional tests to be done in their own countries, and may rely on data generated in the originating country. The Registrar thus has a discretion to grant exemption from certain requirements to an applicant who wishes to register a stock remedy in South Africa.

5.3.40 The OIE Standards are adopted by consensus. A decision is reached by a majority vote of member countries, and, once adopted, it is published. These standards are only guidelines, and does not have the status of international law.\textsuperscript{30} DAFF failed to provide clarity on whether these standards were adopted into any policy or guideline document of the DAFF. In addition, South Africa only became a permanent delegate of the OIE on 20 February 2006, almost four years after RB51 was registered in South Africa.

5.3.41 The Registrar acknowledged that Intervet never submitted a formal application for exemption to be considered by the Registrar. The Registrar

\textsuperscript{30} White S \textit{Into the Vold: International Law and the Protection of Animal Welfare} (2013) \textit{Global Policy} 1 5. He indicates that the OIE can most likely be described as an intergovernmental organisation, and further indicates that “the standards are not formally enforceable against members of the OIE, since the standards are non-binding…”
granted the exemption without having regard to any reasons advanced by the applicant on why the exemption should be granted. The Registrar granted an exemption because he was of the opinion that alternative scientific data was sufficient to make a decision.

Conclusion

5.3.42 The Registrar used a non-binding international principle to circumvent a legal requirement under South African law. Although it is acknowledged that the World Trade Organisation (WTO) strongly encourages member countries to base their animal health regulations on the OIE International standards, it is trite that member countries can adopt a higher level of protection.

5.3.43 I noted that the 2006 Regulations on Stock Remedies did away with the Registrar’s discretion and made it compulsory for an applicant to submit data pertaining to the biological efficacy of a stock remedy as determined under South African conditions.

5.4 Issue 4: Regarding whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine, and improperly failed to do so:

Issues in dispute

Evidence adduced by the Complainant

5.4.1 The Complainant contended that, since inheriting the herd from her late father in the 1990’s, she vaccinated her herd with S19. According to the Complainant, they never experienced any problems.
5.4.2 In 2002, on advice from their private veterinarian, they decided to vaccinate with RB51. She explained their reasons for the switch to RB51 as twofold: the first related to the unavailability of the S19 vaccine, and the second related to the fact that S19 showed false positive reactions in serological testing.

5.4.3 The Complainant further alleged that RB51 did not protect her herd from Brucellosis, despite the fact that the herd was vaccinated correctly in accordance with the package insert of the product. According to her, Dr Schultheiss of MSD confirmed that she used the vaccine correctly, stating in an email to the Complainant on 25 October 2010 that “[s]over my kennis strek het hy die entstof korrek gebruik en teen die korrekte dosis.” She alleged that, although the initial source of the outbreak could not be confirmed, her herd was vaccinated correctly, and as such, the vaccine should have protected her herd even when there was a possible threat of an infection from outside.

5.4.4 In addition, the Complainant alleged that representatives from MSD recommended off label uses of the vaccine. She alleged that MSD’s representatives publicly recommended off label uses of the RB51 vaccine, which were not in line with the registration requirements of the product. She referred specifically to articles which appeared in the Dairy Mail of January 2013; the NAMPO of 06 May 2011; Stocksense (Issue 1:2013) and Farmers’ Weekly of 03 October 2003. One such an off label recommendation was that RB51 must be used in conjunction with S19 (only for follow-up or booster vaccinations).

5.4.5 On 02 April 2013, Mr Johan Cloete (an employee of MSD) communicated as follows to the Complainant: “Deur die volgende te doen word die siekte maksimaal bestuur: 1. Ent verse 4 – 8 maande ouderdom (S19) 2. Ent verse 2 – 3 keer hierna met RB51 met tussenposes tot 2 maande voor die dekseisoen [...].”
5.4.6 In addition, it was acknowledged by Colorado Serum (the producer of RB51 and registration holder in America) that further research conducted on the vaccine in the USA, indicated that the efficiency of the vaccine starts to wane four to five years after calffood vaccination. In a response forwarded to the Complainant by Dr Schultheiss of MSD dated 25 October 2010, Colorado Serum indicated as follows:

"We do know that immunity from calffood RB51 vaccination begins to wane after 4 or 5 years. Even though we do not have a label claim for adult vaccination here in the United States, in areas where Brucellosis is endemic adult vaccination does happen. In the Greater Yellowstone Area of the United States (where Brucella is still a problem) the state and federal authorities are recommending adult vaccination every 3 years for cattle in these high risk areas."

5.4.7 According to the Complainant, MSD failed to inform the Registrar of these developments; and subsequently also failed to apply to the Registrar for the amendment of the requirements under which RB51 was registered.

5.4.8 When the Complainant reported this matter to the Registrar, the Registrar undertook to investigate her complaint and furnish her with a report, which was never forthcoming.

5.4.9 In addition, the Complainant alleged that RB51 was banned from certain countries because of its alleged lack of efficiency.
5.4.10 As early as 2004, experts indicated that RB51 was inferior to S19. She referred to a publication by Prof Jacques Godfroidthink in which he indicates that "[d]espite their limitations, S19 and Rev1 have been successfully used in some developed countries to eradicate brucellosis. [...] Concerning protection, controlled experiments show that RB51 is inferior to S19. [...] Although introduced over 12 years ago, no country using RB51 has eradicated cattle brucellosis although success has recently been suggested in Azores, Portugal. However, such field observations are either contradictory or controversial because of the implementation of additional control measures and the absence of appropriate control groups."

5.4.11 It was further alleged that other farmers also experienced Brucellosis infection after vaccination with RB51.

5.4.12 In supporting the evidence of the Complainant, Dr Wessels contended that there is a lot of controversy surrounding the efficiency of RB51. He indicated that, when RB51 was registered, they were informed that it was the new "super" vaccine, as it allowed you to vaccinate at any age and as many times as you wanted to.

5.4.13 He alleged that it was only after the outbreak of Brucellosis on the Behrens farm that MSD started recommendations that RB51 must be used in conjunction with S19.

5.4.14 He indicated that, at some stage, MSD alleged that RB51 failed to protect the Complainant’s herd, as the cold chain had been broken. According to him, Dr Schultheiss undertook to investigate this, but neither he nor MSD ever reverted to the Complainant in this respect. He explained that in America, each vaccine comes with a thermometer which immediately indicates whether and when there

has been a break in the cold chain. In South Africa, the vaccine must be delivered within 24 hours, still sealed. The live culture is activated when one is going to use it and it must be used within six hours.

5.4.15 He further confirmed that, on the Complainant’s farm, the heifers born from positive (infected) mothers stay negative after vaccination with S19. Currently the Complainant has 119 heifers that are still negative (monthly bleeding takes place by Dr Kitshoff and heifers are also bled) which were born from positive mothers.

**Evidence adduced by the DAFF**

5.4.16 In April 2013, Dr Petra Kitshoff, the State Veterinarian in the Free State, handed over to the Registrar a report on the suspected lack of efficiency of the RB51 vaccine, a report which was compiled after she conducted a study on the outbreak of the disease on the Complainant’s farm between May 2012 and January 2013.

5.4.17 In her report, Dr Kitshoff indicated as follows:

“A trial investigation into the efficiency of RB51 vaccine (in a positive Brucellosis herd vaccinated with RB51) was carried out in the Free State Province between May 2012 and January 2013. The preliminary conclusions on the investigation were as follows:

- RB51 vaccine batches used over the years on this farm are suspected as not effective in the prevention of infection, the spread of infection and abortions (after following the proposed vaccination schedule) in the herd;
- The many adapted versions on the schedule, on how often to use the vaccine in comparison with the package insert and the original
prescription when the vaccine was approved in the USA, is also a cause for concern."

5.4.18 Dr Kitshoff further indicated that, Brucella vaccines are probably not effective to prevent Brucellosis, which is exactly what a farmer would expect when vaccinating. She also suggested that the Jersey breed may be more susceptible to Brucellosis.

5.4.19 During a meeting held with the Registrar on 31 March 2015, the Registrar indicated that, when there is an allegation pertaining to the inefficacy of a product, he requires that such allegation be supported by evidence, so that the Department can make an informed decision. According to him, there is no scientific evidence supporting an allegation that RB51 is not an effective vaccine. He reiterated that he does not have a duty to test any product himself.

5.4.20 The relevant process to follow when there is an allegation pertaining to the inefficiency of a product, would be for the Registrar to consult the owner of the product. In this instance, the DAFF approached MSD to furnish it with a report herein.

5.4.21 During a meeting held on 31 March 2015, the DAFF indicated that it received no other complaints pertaining to the inefficiency of the RB51 vaccine. It later appeared that, by 16 April 2014, the Registrar already reported not less than 10 other similar complaints to MSD.

5.4.22 The Registrar indicated that, having regard to the relevant provisions relating to the registration and deregistration of vaccines, the evidence submitted in the study by Dr Kitshoff was not conclusive enough to warrant the Registrar to cancel
the RB51 vaccine, as the evidence contained in the report would not have met the requirements for deregistration specified in the Act.

5.4.23 In addition, the Registrar indicated that the written and oral advertisement of RB51 by MSD was considered likely to be contrary to the approved parameters when the vaccine was registered. An undertaking was made that this will be investigated further, and that the investigation herein will be concluded within four months. However, the Public Protector was never furnished with a report pertaining to this.

5.4.24 The Registrar further made an undertaking that he will continue to monitor the performance of RB51.

Evidence adduced by Prof M van Vuuren

5.4.25 Prof Van Vuuren indicated that the controversy surrounding the efficacy of RB51 emerged around 2003 / 2004. He indicated that, by then, RB51 was already an established vaccine in South Africa. He mentioned that some countries only use RB51 to eradicate the disease.

5.4.26 He contended that post registration surveillance was what led the country down. He indicated that post registration surveillance remains problematic in South Africa due to lack of resources and the fact that it is very expensive. According to him, this includes the user of the product to inform the registration holder that the product is not performing the way it should. The registration holder is then obliged by law to inform the Registrar.
Evidence adduced by Prof D Abernethy

5.4.27 Prof Abernethy acknowledged that the efficiency of RB51 was quite controversial in some places, specifically in Spain. It is used in America and Europe. In this instance, he referred us to trials which he conducted in Portugal,\(^{32}\) and according to the trials conducted, the RB51 vaccine works. The trials indicated that the vaccine works very well if it is used in conjunction with good biosecurity. The effectiveness of a vaccine, he indicated, also depends on the age of an animal and the animal’s immunity. According to him, no vaccine will provide 100% protection against infection.

Evidence adduced by MSD

5.4.28 MSD indicated that RB51 was used in 38 countries around the world. Since the launch of the product, almost 3 million doses were sold in South Africa and around 21 million worldwide.

5.4.29 Since the initial complaint of the Complainant, there have been only three further complaints pertaining to RB51. In all these three cases, it was determined that the herd tested positive for Brucellosis prior to the use of RB51.

5.4.30 MSD highlighted that the State can only test for Brucellosis at 18 months of age, which basically means that there is a delay in the detection of the disease. They also indicated that Mrs Behrens acknowledged that she vaccinated at three (3) months and at nine (9) months, which is a great deviation from the dosing schedule on the package insert of RB51.

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\(^{32}\) Caetano M C et al Control of Bovine Brucellosis from Persistently Infected Holdings Using RB51 Vaccination with Test—and—Slaughter: A Comparative Case Report from a High Incidence Area in Portugal 2016 (63) Transboundary and Emerging Diseases e39 – e47;
5.4.31 The Complainant bought her vaccines directly from a distributor and wholesaler Kruvet Pharmaceuticals, and the vaccine was not delivered directly to her farm. MSD further indicated that the Complainant acknowledged that there were numerous power failures on the farm. MSD collected a sample of the vaccine from the Complainant to test whether the vaccine possibly did not work because the cold chain was broken, but the sample was lost. MSD highlighted that RB51 must be used within 30 minutes after the activation of the live culture.

5.4.32 In addition, MSD indicated that the articles pertaining to the off label uses of RB51 was published after the outbreak of Brucellosis on the Complainant’s farm, and therefore could not have influenced how she used the vaccine. They reiterated that these articles highlighted what veterinarians were doing in practice to eradicate Brucellosis, and was not intended to introduce a new dosing schedule.

5.4.33 MSD further indicated that it was not aware of any further research that was conducted in the USA about the waning of immunity after calfhood vaccination. MSD indicated that it liaised with Colorado Serum in this respect. It was further reiterated that, if there was ever such research done, MSD would have researched this further and conduct trials themselves if there was a need.

Conclusion

5.4.34 The issue whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine is a question of law and will be determined once the applicable legal framework is discussed hereunder.
The Registrar's response to my notice issued in terms of section 7(9) of the Public Protector Act, 1994

5.4.35 The Registrar denied that by April 2014, he already reported 10 similar cases of the inefficiency of RB51 to MSD, but acknowledged that he brought it to the attention of the investigator that additional complaints had since been received.

5.4.36 The Registrar contended that he had noted the statement attributed to him that the written and oral advertisement of RB51 by MSD was considered likely to be contrary to the approved parameters when the vaccine was registered, but alleged that the correctness of the statement could not be ascertained.

5.4.37 According to him, it was inconceivable that the Registrar could have concluded that the advertisement, especially the oral advertisement of RB51 by MSD was likely to be contrary to the approved parameters, since it depended on the circumstances. He indicated that section 7(2)(b) of the Act states that a veterinarian registered under the Veterinary Act, 1933, may vary the use or recommended use of a stock remedy in a manner other than specified or prescribed.

5.4.38 He concluded that it would also have been difficult for the Registrar to provide a report without the necessary circumspection, given that the advertisement could have been targeted towards registered veterinarians.

Application of the relevant legal framework

5.4.39 Section 4 of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act\(^3\) gives the Registrar the authority to cancel the registration of a

\(^3\) Act 36 of 1947.
stock remedy at any time, if he is satisfied that the stock remedy is not of the composition and efficiency specified in the application for registration thereof, does not possess the chemical, physical and other properties so specified and does not comply with any requirements that may be prescribed.

5.4.40 In addition, the registration of a stock remedy can also be cancelled if any incorrect or misleading advertisement is used in connection with such stock remedy.

5.4.41 Section 14 further enables the Minister to designate persons as technical advisors to advise the Registrar in regard to matters referred to them by the Registrar; or as analysts to analyse samples of stock remedies referred to them by the Registrar, and to report thereon in the form and manner prescribed.

5.4.42 The Registrar investigated the allegations pertaining to the alleged lack of efficiency of RB51 with MSD, the registration holder. MSD provided the Registrar with an explanation that could reasonably be true, namely that there were other factors present which could have influenced the performance of the vaccine and this explanation was accepted by the Registrar.

5.4.43 The Registrar however failed to complete the process, because an undertaking was made to specifically investigate whether the advertisement of RB51 by MSD was contrary to the registration requirements of the product, but the Registrar never furnished the Public Protector with a copy of such report in which he made a determination on the advertisement of RB51 by MSD.
Conclusion

5.4.44 The Registrar failed to provide to the Public Protector a copy of his report into allegations that the advertisement of the RB51 vaccine was contrary to the registration requirements of the product.

5.5 **Issue 5:** Regarding whether the Complainant suffered any prejudice as a result of the alleged conduct of the Free State DARD and the DAFF:

**Issues in dispute**

**Evidence adduced by the Complainant**

5.5.1 The Complainant contended that, as Brucellosis is a state controlled disease, the State is liable to compensate her for the damages she suffered because it could not control the disease.

5.5.2 She indicated that, in 2012, she had her losses valued. The valuation report focused on the period January 2010 to December 2012, and included estimated loss relating to reduction in milk production and slaughtering of animals because of infection; low or no milk production and/or reduced fertility. The valuator valued her loss as follows:

5.5.2.1 **Milk production loss:** R23 056 582.00;

5.5.2.2 **Actual loss of animals slaughtered** (basically the difference between the slaughter value and the genetic value of the animal): R3 849 500.00;

5.5.2.3 **Total loss as per the valuator’s report:** R26 906 082.00.
Evidence adduced by the DAFF

5.5.3 The DAFF, in a letter dated 23 October 2014 to the Complainant communicating to her its findings on an investigation into her complaint, indicated that the Animal Diseases Act prescribes that compensation may be considered where animals had been destroyed or otherwise disposed of due to a control measure. DAFF concluded that no animals were destroyed due to the outbreak of Brucellosis on her farm. As such, no compensation was payable to her.

Application of the relevant legal framework

5.5.4 Regulation 13(1)(a) of the Bovine Brucellosis Scheme\(^{34}\) determines that, if the Director of Animal Health so determines, each infected bovine shall be forfeited to the State and slaughtered at an abattoir designated by the Director. In terms of Regulation 13(1)(b), the Complainant may, for own account, also slaughter infected animals with the permission of the State Veterinarian.

5.5.5 In terms of Regulation 13(2), compensation will only be payable when the infected animal was forfeited to the State, and not if the State Veterinarian gave permission for the slaughtering.

5.5.6 Regulation 13(5) of the Scheme states that, if the Director is of opinion that the occurrence of bovine brucellosis in an infected herd cannot be eradicated economically otherwise, he may order that the entire infected herd shall be disposed of.

\(^{34}\) GG 11611, 09 December 1988.
5.5.7 Section 19 of the Animal Diseases Act\textsuperscript{35} authorises an owner of any animal or other thing which has been destroyed or otherwise disposed of pursuant to any control measure by the Director or on her authority, may submit an application for compensation for the loss of the animal or thing to the Director.

5.5.8 Regulation 30 of the Regulations issued under the Animal Diseases Act\textsuperscript{36} determines that, if compensation is payable in terms of section 19 of the Act, the applicable compensation shall:

\begin{itemize}
\item[a)] In the case of an infected animal, be 80\% of the fair market value thereof;
\item[b)] In the case of an animal killed for any controlled veterinary act or for the prevention of spreading of a controlled animal disease, be 100\% of the fair market value thereof;
\item[c)] In the case of an infectious thing, excluding an animal, and a contaminated thing, be 50\% of the fair market value thereof.
\end{itemize}

5.5.9 According to the Complainant, Brucellosis is a state – controlled disease, and as such, the State is liable to compensate her for her loss. DAFF on the other hand, had continuously reiterated that compensation is only payable when animals are slaughtered as a control measure, and on instruction of the Director: Animal Health. No compensation is payable when the instruction to slaughter comes from a State Veterinarian. According to DAFF, the Director: Animal Health did not give any instruction for the slaughtering of any of the Complainant’s animals.

\textsuperscript{35} Act 35 of 1984.
\textsuperscript{36} GG10469, 26 September 1986.
5.5.10 It remains a mystery how Brucellosis was introduced on the Complainant’s farm. I refrain from making a finding on whether RB51 played a role. The only question that I need to determine, is whether the maladministration of the Free State DARD and the Director: Animal Health was the direct and sole cause of the Complainant’s prejudice. Differently put, I needed to determine whether the Complainant would not have suffered the prejudice she suffered, if the Free State DARD and the Director: Animal Health complied with the statutory requirements.

5.5.11 In determining this issue, I also have to consider the conduct of the Complainant. From the evidence presented to me, it appeared that the Complainant was in denial, she wouldn’t accept that what happened on her farm was an occurrence of Brucellosis. Control measures were discussed, but the Complainant found it inconvenient to implement them. I also have to take into account that the Complainant started slaughtering her animals in June 2010, without consent and without the necessary legal document(s). She illegally used an unregistered vaccine on her herd.

5.5.12 The evidence presented by Prof Abernethy indicated that, although the speed of intervention usually makes a difference in how fast the disease spreads, if there were so many positive animals initially, one would not be able to say with certainty that the disease would not have escalated in the manner that it has. His evidence further indicated that it was impossible to have certainty that there were no other animals already infected, apart from the 125 that initially tested sero−positive.

5.5.13 Taking into account the above evidence, I cannot conclude that the conduct of the Free State DARD and the Director: Animal Health, was the sole and direct cause of the Complainant’s prejudice, although the likelihood cannot be excluded that she might have had a remedy to recover her losses had they acted properly and she complied.
5.5.14 In coming to this conclusion, I have cognisance of the fact that, when the Free State DARD failed to report the outbreak to the Director: Animal Health, it deprived the Director: Animal Health of an opportunity to exercise her statutory discretion in terms of Regulation 13(1)(a) on what should happen with this herd, specifically to make a decision on whether the infected herd should be forfeited to the State and slaughtered.

5.5.15 I further have cognisance of the fact that this has been a long journey for the Complainant. She has been hospitalised twice. The herd was inherited from her father and has huge sentimental value for the Complainant. The Complainant’s husband and their daughter have been diagnosed with undulant fever.

5.5.16 The underlying principle of the remedial action that the Public Protector considers in terms of section 182(1)(c) of the Constitution is to ensure that the Complainant is restored to the position that she would have been in had it not been for the maladministration. The Public Protector uses her judgment when applying this principle and seeks to ensure reasonable and fair remedies, taking into account the circumstances of each case. Where it is not possible to place the Complainant in the position that she would have been in but for the maladministration, financial compensation might be considered to provide redress for pecuniary and non-pecuniary consequences of maladministration.37

Conclusion

5.5.17 I have already concluded that the Free State DARD failed to implement control measures during the initial stages of the outbreak of the disease in the Complainant’s farm. Furthermore the Free State DARD failed to report the

37 Draft Technical Notes: Public Protector’s Framework for Measures to ensure Remedial Action, undated.
outbreak to the Director: Animal Health, and deprived the Director: Animal Health an opportunity to exercise her statutory discretion in terms of Regulation 13(1)(a) on what should happen with this herd, specifically to make a decision on whether the infected herd should be forfeited to the State and slaughtered.

5.5.18 These failures had a domino effect and escalated the Complainant’s loss resulting in improper prejudice.

6. FINDINGS

Having considered the evidence uncovered during the investigation against the relevant regulatory framework, I now make the following findings:

6.1 Issue 1: Regarding whether the Free State DARD failed to implement control measures stipulated by the Animal Diseases Act, 1984, when the outbreak of the disease was allegedly reported to it in 2010, and whether such failure to institute control measures constitute maladministration:

The period May 2010 to June 2011

6.1.1 The allegation that the Free State DARD, specifically Dr Louis van Rooyen failed to implement control measures stipulated by the Animal Diseases Act, 1984 in 2010 when the outbreak was reported, is substantiated;

6.1.2 Dr Van Rooyen failed to report the outbreak to the Director: Animal Health. He failed to follow due process to quarantine the farm and failed to issue Red – Cross permits for the movement of the Complainant’s animals to the abattoir.
6.1.3 In doing so, Dr Van Rooyen failed to adhere to the requirements of the Animal Diseases Act, its Regulations and the requirements set in terms of the Bovine Brucellosis Scheme;

6.1.4 His conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

6.1.5 In addition the Free State DARD failed to ensure proper record keeping by the attending State Veterinarian. It failed to ensure proper records are kept pertaining to the actions taken on the Complainant’s farm and the instructions that were given to her;

6.1.6 Further the Free State DARD failed to adhere to section 24 of the Animal Diseases Act;

6.1.7 Its conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

The period June 2011 onwards

6.1.8 The allegation that the Free State DARD, specifically Dr Petra Kitshoff failed to implement control measures stipulated by the Animal Diseases Act, 1984 from June 2011 onwards, is substantiated;

6.1.9 Dr Kitshoff failed to report the outbreak to the Director: Animal Health. She failed to follow due process to quarantine the farm. She failed to issue Red – Cross permits for the movement of the Complainant’s animals to the abattoir. Her
conduct in respect of the Complainant's use of an unregistered vaccine on her herd, knowing that it was not registered, also raises question marks.

6.1.10 In doing so, Dr Kitshoff failed to adhere to the requirements of the *Animal Diseases Act*, its Regulations and the requirements set in terms of the *Bovine Brucellosis Scheme*;

6.1.11 Her conduct constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the *Public Protector Act*.

6.2 **Issue 2:** Regarding whether the Director: Animal Health failed to intervene on the farm when the outbreak was brought to her attention by the Complainant, and whether such failure constitutes maladministration:

6.2.1 The allegation that the Director: Animal Health failed to intervene on the Complainant's farm when the outbreak was brought to her attention in December 2010, is substantiated;

6.2.2 The Director: Animal Health acknowledged that attention was drawn to the outbreak on the Complainant's farm in an email to the PA of the then Director: Animal Health in December 2010, but the Director took no action until, seemingly, September 2013;

6.2.3 The conduct of the Director: Animal Health falls short of the required standard of good governance and good public administration as envisaged in section 195 of the Constitution;
6.2.4 The conduct of the Director; Animal Health constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

6.3 **Issue 3:** Regarding whether the Registrar followed due process in terms of the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947*, to register the RB51 vaccine: -

6.3.1 The allegation that the Registrar failed to follow due process in terms of the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act*, is substantiated;

6.3.2 South Africa became a permanent delegate of the OIE on 20 February 2006. When the RB51 was registered in South Africa in 2002, the OIE’s principles and standards had no legal and binding status in South Africa. The Registrar used this non-binding international principle, with no legal status in South African law, to circumvent the requirements placed upon him by the Regulations issued in terms of the *Animal Diseases Act*. The Registrar failed to follow a proper process prior to granting an exemption to Intervet not to furnish proof of the efficacy of RB51 as determined under South African conditions. The Registrar could not provide justifiable reasons to justify the granting of the exemption to Intervet;

6.3.3 The application for the registration of RB51 was approved even though the application did not adhere to the requirements of Regulation 2(2)(c)(ii)(b) of the 1983 Regulations issued under the *Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act*;
6.3.4 The conduct of the Registrar constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

6.4 **Issue 4:** Regarding whether the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so:

6.4.1 The allegation that the Registrar had a duty to act on the reports about the suspected lack of efficiency of the RB51 vaccine and improperly failed to do so, is substantiated;

6.4.2 The Registrar did investigate the allegations with MSD and was provided with an explanation which could reasonably be true. The Registrar however failed to complete the process as he neglected to investigate whether the advertisement of RB51 was in line with the registration requirements of the product;

6.4.3 In doing so, the Registrar improperly failed to apply his mind to whether there was a reason to consider the cancellation of RB51 under section 4(1)(f) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947;

6.4.4 The conduct of the Registrar constitutes improper conduct as envisaged in section 182(1) of the Constitution and maladministration as envisaged in section 6(4)(a)(i) of the Public Protector Act.

6.5 **Issue 5:** Regarding whether the complainant suffered any improper prejudice as a result of the alleged conduct of the Free State DARD and the DAFF:
6.5.1 The allegation that the Complainant suffered prejudice as a result of the maladministration of the Free State DARD and the Director: Animal Health, is substantiated;

6.5.2 The maladministration by the Free State DARD and the Director: Animal Health caused the Complainant pecuniary loss, frustration, inconvenience and distress;

6.5.3 Their conduct constitute improper conduct as envisaged in section 182(1) of the Constitution and improper prejudice as envisaged in section 6(4)(a)(v) of the Public Protector Act.

7. REMEDIAL ACTION

The appropriate remedial action I am taking in pursuit of section 182(1)(c) of the Constitution, with the view of placing the Complainant as close as possible to where she would have been had the improper conduct or maladministration not occurred, is the following:

7.1 The Director - General to:

(aa) Within twenty – one (21) business days from date of this report issue a written apology to the Complainant, apologising for the manner in which the Free State DARD and the DAFF handled the outbreak of Brucellosis on her farm;

(bb) Within three (3) months from date of this report, and in consultation with the Minister and the Director: Animal Health, make an offer to the Complainant which he deems reasonable in the circumstances as a consolatory payment for the inconvenience, distress and frustration
suffered by the Complainant as a result of the maladministration.

(cc) Upon acceptance of the offer by the Complainant, the Director – General must pay the amount agreed by the parties to the Complainant within sixty (60) working days.

7.2 The Director: Animal Health to:

(aa) Within one (1) month from date of this report, facilitate the process with the Department of Health to test the farmworkers working on the Complainant’s farm for Brucellosis infection, and to ensure that the infected workers get the necessary treatment;

(bb) Within three (3) months from date of this report, put systems in place in all provincial offices to ensure proper record – keeping of notifiable outbreaks and ensure that all instructions, steps, advise are properly recorded for future reference;

(cc) To conduct annual audits on Provincial Veterinary Services to ensure compliance with statutory obligations;

(dd) Within three (3) months from date of this report, address the conflict between the Brucellosis Manual and the Animal Diseases Act, specifically pertaining to the requirements for the setting of quarantine;
(ee) Within three (3) months from date of this report, ensure that the DAFF adopts a policy which provide guidance on when and how intervention of the Director: Animal Health should be sought when there is an outbreak of Brucellosis.

7.3 The Registrar: Agricultural Inputs Control to:

(aa) Take urgent steps to investigate the selling of an unregistered vaccine by Mr Daan Goosen of Disease Control Africa and consider whether it is necessary to institute criminal proceedings against him. The Registrar is required to report back to me on his investigation within sixty (60) days from date of this report;

(bb) To finalise its investigation into whether the advertisement of RB51 was / is contrary to the registration requirements of the product, and to submit to me a report thereon within sixty (60) days from date of this report. This investigation should also include an investigation into the confusion that is or can be created by these off label uses of a product, especially when the off label uses are proposed by the registration holder itself. The Registrar should consider, within thirty (30) days from the date on which he concluded his investigation, whether or not it is necessary for MSD to issue a public retraction of the off label recommendations for RB51;

(cc) Must, in consultation with MSD, liaise with Colorado Serum to satisfy himself of any further research that was conducted on RB51, and must within sixty (60) days consider whether or not it is necessary to amend the registration requirements of RB51 and / or the necessity to test the product in South Africa.
8. MONITORING

8.1 I shall monitor the implementation of her remedial action on a monthly basis until such time as it has been complied with in full.

ADV BUSISIWE MKHWEBANE
PUBLIC PROTECTOR OF THE
REPUBLIC OF SOUTH AFRICA
DATE: 28/03/2019