Report on Appropriateness of Classification of Properties in the *Mycoplasma bovis* eradication response programme

Prepared by:

The Office of the Chief Science Adviser

Ministry for Primary Industries



Executive Summary

There is wide interest in the property classification used in the *Mycoplasma bovis* (*M. bovis*) Response. Given the significant progression in the Response since mid-2017, the associated recommendations of the Technical Advisory Group (TAG), and the level of public and private resource investment, it is timely to review:

- the classification process;
- how classifications are determined; and
- whether improvements can be made in the way classifications are reported.

Briefly, properties can transition on the basis of risk from General Surveillance to either Active Surveillance or Notice of Direction (NOD). A laboratory result identifying the presence of antibodies to *M. bovis* (i.e., ELISA-positive) can escalate the property classification and result in the issuing of a Restricted Place (RP) notice. If *M. bovis* DNA is detected (i.e., PCR-positive), the property will be served with an RP notice and be classified as an Infected Property (IP). These case definitions are being strictly adhered to by the Response team. The properties under NOD, RP, and IP are publically communicated weekly. Until recently, this communication was appropriate.

Since mid-2018, however, when the decision to undertake phased eradication was announced by Government and industry partners, significantly greater resourcing has been provided to the response and there have been minor changes to the schedule of classification escalation. Improvements in our diagnostics platforms, as well as additional laboratory testing and epidemiological research, has led to greater confidence that ELISA testing can accurately identify properties that have been infected and, as a result, increase the speed of the response. This was highlighted by the Technical Advisory Group in their recent report. Further, there was a minor change to the categorisation process in November 2018: Response introduced a 'Transitional NOD' (T-NOD); this allowed MPI to limit the size of the RP placed to the discrete area of a property most likely to be infected and, therefore, minimise the number of animals that needed to be culled from a RP.

Because of the recent introduction of a T-NOD and the decision to depopulate on ELISA (i.e., as a RP), MPI's public communication of RP and IP no longer adequately reflects the number of properties infected. For example, a PCR-positive result with sequencing to *M. bovis* is required for a property to be designated an IP. However, 14 properties have been depopulated based on serology results alone (i.e., ELISA-positive); of these, 12 subsequently returned a PCR-positive result during depopulation. Although now meeting the criteria for an IP classification on laboratory results, all susceptible animals had been depopulated from the property. As there were no susceptible animals remaining, the property could not be classified as IP. This sequence is likely to become more common in future as more properties are depopulated on the basis of their serological results. Therefore, the future reporting of IPs will not reflect the number of properties depopulated.

To simplify this, it is recommended that the reporting of IPs and RPs cease and that new classifications be introduced to reflect the cumulative number of places that MPI are confident have been infected. We recommend three new property classifications for public communication: *'Depopulated', 'Pending Depopulation'*, and *'Confirmed places''*. The 'Confirmed places' classification is the combination of 'Depopulated' and 'Pending Depopulation'. This will provide a truer representation of the number of properties that have been or will be depopulated because of infection. A second recommendation is that a review is undertaken of the database needs of a biosecurity response and whether current database infrastructure and use is 'fit for purpose'.

Glossary

- ARDB Animal response database
 EDIR exotic disease investigation report
 ELISA enzyme-linked immunosorbent assay
 ICP Manager Incident Control Point Manager
 IP Infected property
 M. bovis Mycoplasma bovis
- MPI Ministry for Primary Industries
- NOD Notice of direction
- PCR polymerase chain reaction
- RP Restricted place
- TAG Technical Advisory Group
- T-NOD transitional notice of direction

Part 1: Introduction

On 21 July 2017, samples collected from a dairy herd in South Canterbury tested positive for *Mycoplasma bovis* (*M. bovis*), a bacterium that causes disease in cattle. *M. bovis* is an economically significant pathogen, and the animal welfare and disease management implications of it are, potentially, severe. While widespread internationally, *M. bovis* had not, previously, been detected in New Zealand.

On 28 May 2018, the decision to eradicate *M. bovis* from New Zealand was announced by the New Zealand Government; this decision was taken collectively by Government and the dairy and beef industries. Key messages in the announcement¹ included that eradication will involve:

- Culling all cattle on all infected properties, along with cattle on most restricted properties;
- All infected farms identified in the future will also be depopulated.

The MPI-produced factsheet, 'Phased Eradication of *Mycoplasma bovis*'², further clarified that the animals to be culled "will be animals from known and future infected farms we discover, and also highly suspect farms: those under Restricted Place Notices".

Eradication reporting and a changing context

MPI reports publically on *M. bovis* against three classifications:

- Properties under Notice of Direction (NOD);
- Properties under Restricted Place (RP) Notice; and
- Infected Property (IP).

These case definitions are being strictly adhered to by the Response team. The properties under NOD, RP, and IP are publically communicated weekly. Those directly affected by *M. bovis* and the wider public alike have high interest in this reporting.

Until recently, this communication strategy was appropriate. Since mid-2018, however, when the decision to undertake phased eradication was announced by Government and industry partners, significantly greater resourcing has been provided to the response; improvements in our diagnostics platforms, as well as additional laboratory testing and epidemiological research, there is greater confidence that ELISA testing can accurately identify properties with the disease and, as a result, increase the speed of the response. Further, there was a minor change to the categorisation process in November 2018: Response introduced a 'Transitional NOD' (T-NOD); this allowed MPI to limit the size of the RP placed to the discrete area of a property most likely to be infected and, therefore, minimise the number of animals that needed to be culled from a RP.

Given the wide interest in property classification, the significant progression in the Response since mid-2017 and recent recommendations from the Technical Advisory Group (TAG), and the level of public and private resource investment, it is timely to review the classification process, how classifications are determined, and whether improvements could be made in the way classifications are reported.

¹ https://www.beehive.govt.nz/release/plan-eradicate-mycoplasma-bovis

² https://www.mpi.govt.nz/dmsdocument/29303/send

This review report considers:

- The basis upon which properties suspected of *M. bovis* infection are presently classified, including the underpinning testing and science (Part 2);
- How consistently the classifications are applied (Part 3); and
- Whether any changes to the classifications, and the basis upon which properties are classified, should be made (part 4)

It also seeks to identify whether changes to the classification definitions are necessary or whether changes to the communication of farm classifications would be beneficial (Part 5).

Methodology

In undertaking this review, staff and contractors within the *M. bovis* programme were interviewed, documents defining *M. bovis* classification and scientific documents have been reviewed, as required, and, the farm classification database has been interrogated.

Part 2: Present classification of properties suspected of *M. bovis* infection

Diagnostics used to assist with property classification

Two different diagnostic testing methodologies are used to determine whether animals on a property have been infected with *M. bovis*:

- Real-time polymerase chain reaction (PCR) is used in defining an IP; PCR is a technique used to detect the presence of *M. bovis* DNA and determines the issuing of an IP; and
- Enzyme-linked immunosorbent assay (ELISA) is used to determine whether antibodies are present that indicate if animals on the property have been exposed to *M. bovis*; ELISA results and/or PCR results determine the issuing of a RP.

At the beginning of the Response, PCR was the only test available, as a reliable ELISA test had, at that point, not been validated. A PCR positive result was, therefore, the most appropriate indicator for a property to be classified as infected and depopulated. ELISA testing began in August 2017³.

Overview of classifications of properties

Properties in New Zealand are classified into the categories of: General Surveillance, Active Surveillance, NOD, RP, or IP (for detailed definitions of these classifications, see Appendix 2).

Active surveillance and NODs are enacted when data indicate an increased risk of *M. bovis* presence, primarily because animal movements from Restricted Places⁴ have been traced to these properties. In comparison, for a property to be classified as either a RP or an IP, laboratory diagnostics have to provide proof of exposure to the pathogen (ELISA-positive) or the presence of the pathogen (PCR-positive).

³ Appendix 1 presents an overview of PCR and ELISA diagnostic testing.

⁴ Note that all IPs are RPs.

A RP can be declared by issue of notice under Section 130 of the Biosecurity Act 1993. For a property to be declared a RP, it must contain cattle that have a high likelihood of being infected with *M. bovis*, based on the results of diagnostic testing. A RP can be placed on the entire farm, or if appropriate, on smaller areas of the farm⁵. A RP notice prohibits unauthorised movements of farm stock and other risk goods onto and off of the area where the RP notice has been placed.

Unlike the classification RP, the classification 'Infected Property (IP)' is not a legal classification and is not defined in the Biosecurity Act 1993. All properties classified as IP will also have been issued with a RP notice; all IPs are RPs; therefore, restrictions on IPs and RPs are the same. The only difference between the classifications IP and RP is that IPs have a PCR-positive test result with confirmed genetic sequencing to *M. bovis*.

Reporting of disease status in the Animal Response Database

As part of the surveillance process, properties are assigned a 'Disease Status' in the Animal Response Database (ARDB). Farms can be assigned as: Null [no status in ARDB], Resolved, At-risk farm, Pending negative, Testing in progress, Negative, Pending positive, and Confirmed positive.

Disease Status is not permanent; as casing information and laboratory results become available, the status of properties is re-evaluated and a new status designated as appropriate. Because of the complexity of these categorisations, ARDB disease status is not publically reported.

For full definitions of the disease status categories, see Appendix 3. Briefly, the case definition for Confirmed Positive is assigned to any property following return of a positive PCR result with sequencing to *M. bovis*⁶. Pending positive places are places where two or more rounds of serological testing have returned a result above the herd-level threshold for one or more at-risk management groups. A place with a 'Pending positive' disease status, therefore, becomes a RP.

Part 3: Consistency of classification application

For the most part, property classification and escalation to depopulation has been consistently applied over time. Exceptions include:

- criteria to classify a property as a RP changed at the beginning of the response from based on risk to based on laboratory diagnostics;
- occasions when properties were depopulated as RPs; and
- occasions when properties were depopulated before being classified as RP and, therefore, could not be recorded as either RP or IP.

It should be noted that at any point in time the number of Confirmed Positives (disease status) and the number of IP recorded in ARDB may differ. This is not an issue of consistency of classification, *per se*. The main factors that contribute to this difference include:

⁵ Information gained whilst a property is classified as a T-NOD is intended to inform the placing of a RP.

⁶ The case definition for confirmed positive has changed over time. Versions preceding Version 2.14 of the Surveillance specifications also included provision for the epi and lab team, in some instances, to classify the status of a property as confirmed positive on the basis of serological testing in absence of PCR.

- time lags between the entering of the confirmed positive result in ARDB and notices being served; and
- confirmed positive being a temporary status.

It is also possible for a farm to be set to Confirmed Positive when there are no remaining susceptible animals, because the PCR-positive result was detected at slaughter.

By way of example, on 25/02/2019, there were 26 more Confirmed Positives than IPs in the ARDB. By 13/03/2019, many of these properties had been classified as IP and a number had their status changed (to Resolved; or as testing results suggest, to Negative, Pending Negative, or Testing in Progress). Some properties remained unchanged; however, we note that some of these are likely to become IPs in the future.

Is the classification of Infected Properties an adequate measure of infection?

When first established, the classification of IP was an appropriate measure to communicate the extent of infection. However, due to greater confidence in ELISA testing as way to reliably identify infected properties and the potential for properties with evidence of infection to be depopulated before they are classified as an IP and/or RP, the use of 'IP' as the measure to communicate the extent of infection should be revisited. We explain, further, our reason for this view in upcoming subsections.

RP classification criteria changed

At the beginning of the Response, RP notices were served on a limited number of related properties on the basis of risk rather than diagnostic testing, as it is now. This no longer occurs.⁷ The properties served a RP on the basis of risk were all 'owner-other' properties (defined as those owned or managed by those who also have ownership or responsibility for a RP), and were considered highly likely to have been exposed to infection because of their proximity to and interactions with the original identified property. Notices were served to immediately restrict movements on and off the properties to limit the risk of spreading infection.

While owner-other properties are no longer automatically served a RP on the basis of risk, surveillance, the level of which is determined by risk, still does occur on these properties whereby:

- Owner-other properties that are determined to have a low or medium risk of *M. bovis* transmission due to their relationship with the RP undergo testing under active surveillance in the absence of movement controls;
- Owner-other properties that are determined to have a high or very high risk of *M. bovis* transmission due to their relationship with the RP undergo testing while under an s122 movement control NOD.

⁷ There have, however, been a limited number of instances where RPs have been served on ownerother properties, without testing being completed on each separate farm. For example, if a farmer has three farms, and it is known that he or she has split an infected mob across all three farms, then not all three farms will require testing for a RP to be served to that place.

Depopulation of properties

Properties that return a positive PCR result with sequencing for *M. bovis* are depopulated. However, properties have also been depopulated on the basis of their serological results (i.e., a RP) without IP status. The recent Technical Advisory Group (TAG) report⁸ supported this action, stating that "Serological tests based on the presence of antibody to *M. bovis* will provide greater sensitivity than tests to detect the presence of the bacteria (PCR) for detection of infected herds". The first instance of a property being depopulated based on serology alone was in October 2018 (two properties in October).

To date, 14 properties have been depopulated without the presence of a PCR-positive test result; 12 of these properties, subsequently, returned a PCR-positive result at slaughter sampling. As there were no infected animals left on the properties when the PCR-positive test result was returned, the properties did not meet the definition of an IP and could not be classified as such; as a result, these properties, by definition, cannot be recorded as IPs in the database. The individual status of these properties in ARDB may or may not be Confirmed Positive (due to the presence of a PCR-positive result), depending on other property-specific factors⁹.

Depopulation before RP/IP classification

There have been occasions when a property has been depopulated <u>before</u> that property was classified as either a RP and/or an IP. These properties were, however, served with a NOD to decontaminate (NOD to C&D). Some of these properties went on to produce a sequence-positive PCR during depopulation (i.e., slaughter sampling).

In these situations, as there were no infected animals left on the properties when the PCR-positive test result was returned, the properties did not meet the definition of a RP or IP; these properties were not served a RP notice or classified as an IP and, therefore, are not recorded as either designation in the database.

These properties may or may not be classified in ARDB as Confirmed Positive (due to the presence of a PCR-positive result), depending on other property-specific factors.

⁸https://www.biosecurity.govt.nz/dmsdocument/32914-tag-report-january-2019

⁹The disease status of the property post Confirmed Positive depends on factors including whether: the property has been depopulated, undergone cleaning and disinfection (C&D), the necessary stand-down period post-C&D; and whether there are other susceptible animals on the property which may require testing to confirm their status

Part 4: Possible new classification based on 'Case Number'

A possible new classification for 'infection' could be derived from the field in ARDB titled 'Case Number'.

The field 'Case Number' has been allocated to all properties where the presence of disease has been detected, with confidence, by any means. The Case Number is permanent. The allocation of a case number does not rely on the drawing of RP boundaries, the presence of animals, or disease detection by PCR. This means that a single filter can be applied to the data to return all properties where *M. bovis* has been reliably detected.

Further work and analysis would be required before proceeding with this proposed use of Case Numbers. However, at this point, the classification appears to be reliable and a fit for purpose measure of infection.

Part 5: Recommendations

Recommendation 1: The reporting of RP and IP should be discontinued; new Property Classifications that more accurately reflect the number of infected properties should be used in publically released statistics.

The reasons for potentially divergent views on property classifications relate to:

- RPs being depopulated on the basis of serology, which renders separate reporting of IPs and RPs no longer meaningful;
- the timing of when properties become an IP relative to the PCR-positive result; and
- the potential for properties previously infected with *M. bovis*, albeit not actively infected, to not be publically communicated (NODs -> C&D).

We, therefore, recommend that public communication of Response statistics be changed to represent the number of properties that MPI are confident are infected with *M. bovis*, the number of properties that have been depopulated, and the number of properties pending depopulation. The new classifications would be:

- Cumulative 'Confirmed places' can be enumerated from the 'Case Number' field in the ARDB;
- 'Depopulated' be used to enumerate the cumulative number of 'Confirmed places''' that have been depopulated (updated weekly);
- *'Pending depopulation'* be used to enumerate the number of *'Confirmed places'* that MPI are confident are infected but are not yet depopulated (updated weekly);

If deemed appropriate, the response can still report on:

- Active S122 NODs (i.e., movement control NODs; updated weekly); and
- Revoked S122 NODs (updated weekly).

These recommendations are consistent with those of the TAG in their February 2019 report: "The distinction between a RP and an IP is currently based on PCR testing and as an IP is not a legally defined entity and is not useful in the response, this terminology should be discontinued".

If this recommendation were to be supported by the *M. bovis* Governance Board and key stakeholders, further work would be required to refine the reporting process and to confirm the resultant number of propertied deemed to be 'Confirmed places''.

Recommendation 2: There is a need for a fit for purpose response information management system.

- Current data management systems, data protocols and processes, and data reporting, should be reviewed;
- The (manual) process by which a property becomes an IP should be reviewed to determine any potential for increases in efficiency.

Appendix 1: Overview of diagnostic testing

Two different types of diagnostic testing are used in the Response: polymerase chain reaction (PCR), which is a technique used to detect the presence of *M. bovis* DNA, and enzyme-linked immunosorbent assay (ELISA), which is used to determine whether antibodies are present that indicate that animals on the property have been exposed to *M. bovis*. At the beginning of the Response only PCR testing was available as a diagnostic tool; ELISA testing began in August 2017.

PCR

Mycoplasma bovis PCR detects the presence/absence of DNA of the bacteria in the samples tested. When *M. bovis* DNA is detected by PCR from a sample(s) from a newly identified farm, AHL performs secondary confirmatory testing called sequencing for further assurance.

PCR kits used

At the beginning of the response, AHL performed in-house *M. bovis* PCR that required multiple reagents. In August 2017 AHL carried out validation work using commercially available kits to improve efficiency and to reduce potential operator errors. Based on the test performance and ease of use, the current kit was selected and has been used since. AHL has another *M. bovis* PCR kit in stock as backup for any unpredicted shortages of the current kit.

Challenges

Although *M. bovis* PCR is known to be very sensitive and specific, the test can result in an inconclusive result when the level of *M. bovis* in the sample(s) is very low, or when it reacts to other organisms that are somewhat similar to M. bovis. Also, collecting the right type of samples in different populations, e.g. age groups, herd types, has been identified as a main factor that defines the test performance. The nature of the disease caused by M. bovis, often sub-clinical or latent, adds a complexity in the M. bovis PCR.

The current *M. bovis* PCR cannot differentiate viable *M. bovis* from non-viable *M. bovis*, which is critical in particular with germplasm samples. The presence of DNA is not always an indication of live *M. bovis*. AHL has been working on the development of 'Viable PCR' that can differentiate viable organisms from non-viable organisms but this is not available currently.

ELISA

The ELISA test for *Mycoplasma bovis* (*M. bovis*) is used to show when a cow has had an infection to *M. bovis*. Unlike PCR or culture for *M. bovis*, the ELISA does not detect the bacteria itself. ELISA detects the cow's response to the infection, and shows that an immune response has happened and that antibodies have been produced.

If the cow has been infected and has antibodies in its blood, then there is a colour change which indicates 'positive'. The bigger the colour change the more antibodies present; no colour change indicates no infection or negative. There is a control cut-off point in the colour change which indicates if the cow is positive or negative.

ELISA kits used

There have been three different ELISA kits used in the Response to date. In 2017, AHL tested the performance of two commercial ELISA kits: Biovet and Biox. Biovet was superior to Biox, and so

became the first ELISA test kit to be deployed in the Response (August 2017). However, approximately 9 months later, the manufacturer of Biovet could no longer produce the same antigen. A significant change like this to an ELISA required revalidation to ensure that the test is working appropriately. As AHL already had validation data for Biox, Biox was used when Biovet became unavailable (for a period of approximately 3 months, May 2018 - July 2018). During this time, another ELISA kit, IDvet, became available. AHL tested the performance of this kit and concluded that it was superior to all previously tested assays, and the new Biovet kit. Response therefore replaced the use of the Biox kit with the IDvet kit (late July 2018). The IDvet kit will be used for the remainder of the casing and tracing phase of the response.

Challenges

An infection takes time to spread through a herd, and an immune reaction also takes time to show up after an infection happens (i.e., it takes time for antibodies to show up). So, in a farm that has been infected, not all animals in the herd will have antibodies that detectable by ELISA, either because some cows have not yet been infected or there has not been enough time to make antibodies. There is always a time lag. In some rare cases the cow doesn't develop antibodies that can be detected; this variation is similar to what happens in people with the flu, where some will have mild symptoms while others will get very sick. In most *M. bovis* infected herds it is typical to see 30-70% ELISA-positive animals.

Some animals that have not been infected with *M. bovis* have other antibodies (from other infections) that will cross-react and give a colour change in the ELISA. This is because the *M. bovis* proteins used in the test 'look' the same as those from the other infection¹⁰. Typically 0-5% of the animals in an uninfected herd will give a colour change due to this cross-reactiveness of the antibodies.

For these reasons, results must be considered at the herd level, as it is easier to see the difference between an infected (more than 30% of animals present a positive result) compared to a negative herd (less than 5% of animals give a positive result).

Another issue with an ELISA test is uncertainty around cut-off points, and how to make a scientific decision when results are just either side of a cut-off point. Resampling and retesting animals at a later date (monitoring the herd over time) helps to overcome this issue.

¹⁰ To describe this in terms of a jigsaw puzzle, the antibodies from other infection bind like miss-fitting pieces of the puzzle. While not a perfect fit, in the test it creates a colour change.

Appendix 2: Overview of Classifications

General Surveillance

Properties classified as being under general surveillance are all cattle holding properties in New Zealand that are not subject to any of the other classifications. Farms involved in the national bulk milk surveillance and the calf rearers survey are also included in this category until evidence of exposure to *M. bovis* results in an alternative classification. As part of general surveillance, all mastitis milk sent to laboratories is also tested for *M. bovis*.

Active Surveillance

Properties on active surveillance are those considered at-risk of exposure to *M. bovis* because of some connection to properties known to be infected with *M. bovis* cattle. This includes properties that:

- are contiguous to a restricted place;
- are owned or managed by people who also own or have responsibility for a restricted place;
- have received animals or potentially infected milk from RP properties ;
- have reported suspected cases of *M. bovis* disease to the Pest & Disease hotline.

At-risk animals on these properties undergo at least two rounds of testing three weeks a part. A Notice of Direction will be issued on properties if it cannot be confirmed that *M. bovis* is not present. Depending on testing results, properties under active surveillance may also receive a Restricted Place notice at this time.

Notice of Direction (NOD)

A Notice of Direction (NOD) is a legal notice issued to a person (usually the farm/animal owner or farm manager) under sections 121 or 122 of the Biosecurity Act 1993. A NOD is utilised to treat, destroy, or prevent the spread of an unwanted organism, or for sampling and testing purposes. The most common types of NODs issued in the *M. bovis* response to date include:

- Movement Control NOD, restricting the removal of cattle and risk goods from the property;
- NOD to examine, directing the owner to submit (multiple) cattle for slaughter sampling to determine if *M. bovis* is present;
- Transition Movement Control NOD (T-NOD), restricting the introduction and removal of cattle and risk goods to and from the property. A further requirement of a T-NOD is that a Census of animals present and an Exotic Disease Incursion Report (EDIR) be conducted;
- NOD to depopulate, directing the owner to cull cattle on the property;
- NOD to decontaminate, directing the owner to clean and disinfect (C&D) the property.

Only after a minimum of 2 clear rounds of ELISA testing and the slaughter of any trace animals can a movement control NOD be revoked.

Restricted Place (RP)

A Restricted Place (RP) can be declared by issue of notice under Section 130 of the Biosecurity Act 1993. This section defines that:

If an inspector or authorised person believes or suspects, on reasonable grounds, that a pest or unwanted organism is, or has been, in a place, the inspector or authorised person may, by notice given in accordance with subsections (2) and (3), declare that place and any other place in the neighbourhood the inspector or authorised person considers necessary, to be a restricted place.

A RP notice is issued on places that contain cattle that are suspected of being highly likely infected with *M. bovis*. A place becomes a RP when:

- two or more rounds of serological testing have returned positive results in at least one atrisk management group; and/or
- one or more samples collected have returned a positive PCR result, with genome sequencing to *M. bovis*.

A RP can be placed on the entire farm, or if appropriate, on smaller areas of the farm¹¹. A RP notice prohibits all unauthorised movements of farm stock and other risk goods onto and off of the area where the RP notice has been placed.

Infected Property (IP)

The classification 'Infected Property (IP)' is not a legal designation and is not defined in the Biosecurity Act 1993. All IPs are RPs; both are issued with a Restricted Place notice under section 130 of the Biosecurity Act 1993.

MPI has defined that a RP becomes an IP once it meets two conditions:

- 1. a PCR sample from one or more animals or milk from the property returns a positive result for *M. bovis*; and
- 2. the PCR-positive result has confirmed sequencing to *M. bovis*.

¹¹ Information gained whilst a property is classified as a T-NOD is intended to inform the placing of a RP.

Appendix 3: Disease status categories and definitions, Surveillance Specifications Version 2.14

| Status | Definition |
|--------------------------|--|
| Null [no status in ARDB] | Farm not at risk |
| Resolved | A place that has been cased by NCC Casing or traced by NCC Tracing that is determined by NCC Surveillance or NCC Epidemiology to not being at risk because: |
| | The trace cattle were never on that place |
| | The trace cattle and their in-contacts are no longer on the place |
| | The place does not contain cattle |
| | The contiguous property contains cattle that are not at risk of contact with the RP boundary |
| | The place has been incorrectly traced or cased |
| | • The movement occurred outside of the risk period of the RP |
| At-risk farm | Identified as being an at-risk place through NCC Intelligence. NCC Casing changes the status from 'Null' to 'At-risk farm' once casing for a property is complete. |
| Pending negative | A place where a minimum of one round of diagnostic testing performed according to the surveillance work instructions or as directed by NCC Surveillance in the ARDB that has returned a negative result for all at-risk management groups as determined by NCC Surveillance, with input from NCC Epidemiology where required, where sampling of any trace animals at slaughter has returned a negative result, and where any previous diagnostic rounds of diagnostic testing have returned negative results. NCC Surveillance or NCC Epidemiology changes the status from 'At-risk farm' to 'Pending negative'. |
| Testing in progress | A place where one or more rounds of serological testing performed according to the surveillance work instructions or as directed by NCC Surveillance in the ARDB has returned a suspicious herd-level result as determined by NCC Surveillance, with input from NCC Epidemiology. NCC Surveillance or NCC Epidemiology changes the status from 'At-risk farm' to 'Testing in progress', or 'Pending negative' to 'Testing in progress' where required. |
| Negative | A place where two sequential rounds of testing performed according to the surveillance work instructions or as directed by NCC Surveillance in the ARDB have returned negative results for all at-risk management groups as determined by NCC Surveillance, with input from NCC Epidemiology where |

| | required. It also is dependent on no new risk movements occur during the testing period. NCC Surveillance or NCC Epidemiology changes the status from 'Pending negative' to 'Negative' or 'Testing in progress' to 'Negative' where required. |
|--------------------|---|
| Pending positive | A place where two or more rounds of serological testing performed according to the surveillance work instructions or as directed by NCC Surveillance in the ARDB have returned a result above the herd-level cut point for one or more at-risk management groups as determined by NCC Surveillance, with input from NCC Epidemiology. NCC Surveillance or NCC Epidemiology changes the status from 'Testing in progress' to 'Pending positive' where required. A place with a 'Pending positive' disease status becomes a RP. |
| Confirmed positive | A place where one or more samples collected according to the surveillance work instructions or as directed by NCC Surveillance in the ARDB have returned a positive PCR result with sequencing to <i>M. bovis</i> . |
| | A place with a 'Confirmed positive' disease status becomes a RP, and may be referred to within the programme as an Infected Place (IP). |