

## DISCLAIMER

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## Self-declaration by Japan of freedom from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovids

Declaration submitted to the World Organisation for Animal Health (WOAH, founded as OIE) on 11 April 2022 by Dr OKITA Masatsugu, the Delegate of Japan to WOAH, Director of International Animal Health Affairs Office, Animal Health Division, Ministry of Agriculture, Forestry and Fisheries (MAFF).

### 1. Introduction

The objective of this self-declaration is to declare freedom from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovids (bovine brucellosis) that covers the whole country in accordance with the provisions of Article 8.4.4. of the *Terrestrial Animal Health Code 2021 (Terrestrial Code)*.

The starting date of the self-declaration is 1 April 2021.

### 2. Evidence that bovine brucellosis is a notifiable disease in Japan

Bovine brucellosis is designated as one of the notifiable diseases which are called "Domestic Animal Infectious Diseases" under Article 2, Paragraph 1 of Act on Domestic Animal Infectious Diseases Control (hereinafter referred to as "[the Act](#)"). Under the Act, domestic animals that have contracted "Domestic Animal Infectious Diseases" are designated as "affected animals", while animals that are suspected of infection are designated as "suspected animals". In accordance with Article 13, Paragraph 1 of the Act, any veterinarians who have diagnosed or conducted post-mortem inspection of such animals must notify the prefectural governor.

### 3. History

#### a. Population of cattle in Japan

As of 1 February 2020, approximately 2,555,000 beef cattle in 43,900 farms, and 1,352,000 dairy cattle in 14,400 farms are kept in Japan. There are approximately 220 water buffalos in 11 farms. There are no bison farms in Japan.

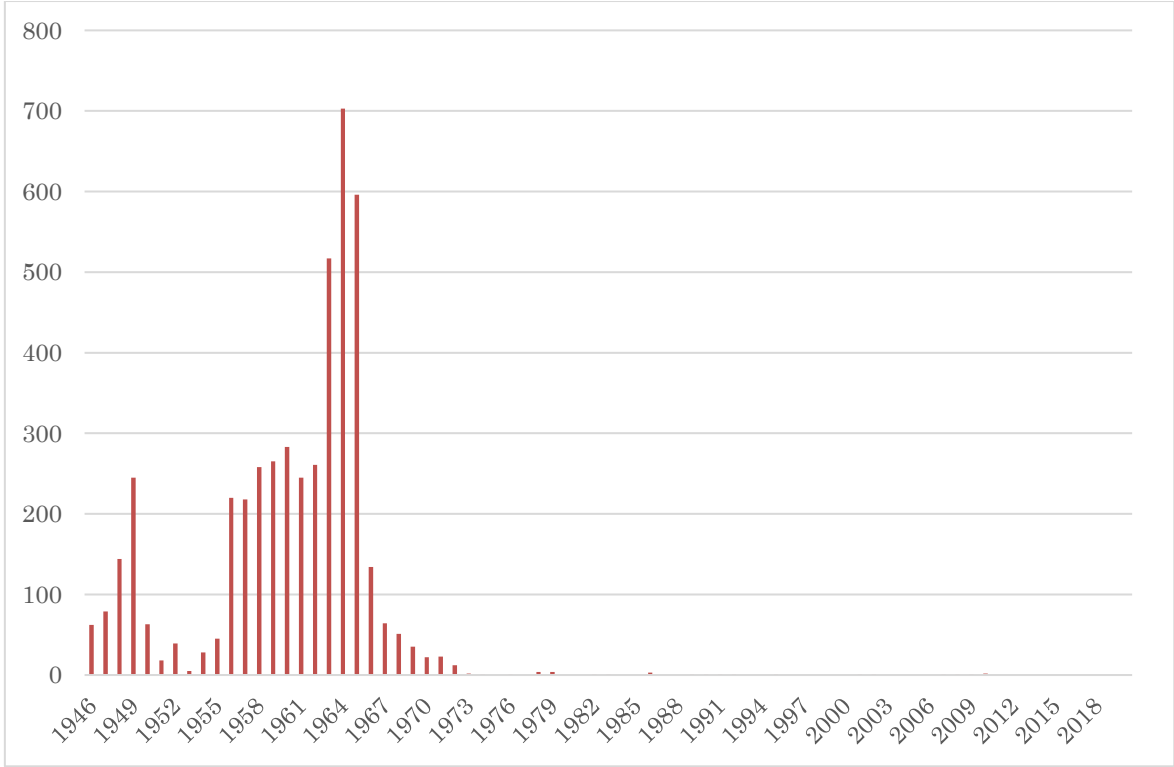
#### b. Eradication history

##### - Outbreak history

Bovine brucellosis had been reported continuously from 1946 to 1974. The number of outbreaks drastically decreased following the peak in 1964. From 1975 to 2010, a small number of outbreaks were recorded infrequently. However, it should be noted that a detection of a suspect case on the basis of positive results for serological testing, which therefore does not meet the case definition in the *Terrestrial Code*, might have been

recorded as an outbreak of bovine brucellosis in Japan. The last case in accordance with the case definition described in Point 5 of Article 8.4.1. was confirmed in Hokkaido Prefecture in 1970, and the outbreaks thereafter were all considered to have been caused by singleton reactors. Suspect cases of bovine brucellosis were killed for purposes of confirmatory diagnosis. There has been no evidence of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in wildlife in Japan, which was supported by all-negative test results in a nationwide sero-surveillance targeted for wild deer and wild boars (a total of 2,433 samples) between 2014 and 2018.

**Chart 1. Bovine brucellosis outbreaks in Japan (1945 to 2018)**



In Japan, there is no approved vaccine for brucellosis and the vaccination has never been implemented.

In 1956, regular testing of dairy cattle and bulls at least once a year started as a national eradication program in accordance with the Act. In 1975, the frequency of the testing was changed to at least once every two years. After that, from 1998, all dairy cattle, bulls and other cattle kept on the same farm were subjected to testing at least once every five years. As a result of this eradication program, the number of outbreaks had been decreased, and a surveillance program for demonstrating freedom from bovine brucellosis was implemented from April 2018 to March 2021 in accordance with the relevant provisions of the *Terrestrial Code*. Since freedom was confirmed by the aforementioned surveillance, a new surveillance program for maintaining freedom from bovine brucellosis was initiated in 2021. Details and results of the surveillance are described in the following section.

**4. Early warning systems and surveillance for bovine brucellosis**

**a. Inspection at slaughterhouse**

Brucellosis is a disease subject to inspection at slaughterhouse under [the Slaughterhouse Act](#)<sup>1</sup>. At slaughterhouses, all cattle are subjected to (1) ante-mortem inspection, (2) post-mortem inspection before processing, and (3) post-mortem inspection of carcass and offal by veterinary officials, and when necessary, microbiological, parasitological, histopathological and blood test are also conducted.

**b. Passive surveillance on farm**

In accordance with the provisions of 1 d) of Article 8.4.4. of the *Terrestrial Code*, all abortion cases and abnormal birth cases reported from cattle farms to the Livestock Hygiene Service Center (LHSC) are tested for brucellosis.

<sup>1</sup> Available in Japanese

After receiving the report from farms, official veterinarians of the LHSC or private veterinarians visit the farm for sampling. Blood samples are taken from dams. Vaginal swabs, lochia, and fetus are also sampled if available. Blood samples are tested for antibodies against bovine brucellosis using plate agglutination test and enzyme-linked immunosorbent assay (ELISA). Fetuses are autopsied and their tissues are examined histologically, and the swab samples are taken for antigen tests. For the antigen detection, bacterial isolation and initial biochemical tests (i.e. Gram's staining, catalase test and oxidase test) are performed at the LHSC using tissue samples from fetuses and swabs. When the results of initial biochemical tests indicated infection with *Brucella spp.*, the sample is sent to National Institute of Animal Health (NIAH) for confirmation. Dam that tested positive for two consecutive ELISA tests using blood samples will be culled at the LHSC to perform autopsy and sampling. Among 971 abortion cases that were tested between April 2018 and March 2021, which is equivalent with three entire Fiscal Years 2018 through 2020 (n.b. in Japan a Fiscal Year is from April to March in the following year.), at the LHSC, 970 were negative in screening tests, and one bacterial isolate with inconclusive results was sent to the NIAH and confirmed negative for brucellosis using PCR and 16S rDNA sequencing (Table 1).

**Table 1. Summary of test results of abortion cases for three Fiscal Years**

	Screening test at LAHSC		Confirmation test at NIAH	
	Tested	Positive	Tested	Positive
<b>FY2018</b>	376	1	1	0
<b>FY2019</b>	291	0	0	0
<b>FY2020</b>	304	0	0	0
<b>Total</b>	971	1	1	0

### c. Import quarantine measures

Currently, only Australia and New Zealand are eligible for exporting live cattle to Japan. These countries are considered to be free from bovine brucellosis and the Animal Health Requirements (see below) are applied for importation of cattle from those countries.

After arrival, cattle imported into Japan (hereinafter referred to as “the imported cattle”) are kept in a quarantine facility operated by the Animal Quarantine Service of MAFF for a minimum of 15 days. During that period, clinical inspection of all animals is conducted. Laboratory testing is also performed on a proportion of apparently healthy imported cattle in addition to cattle showing any clinical signs of infectious disease. After negative results of these tests were obtained, import permit will be granted.

#### - Animal Health Requirements

##### 1) Australia (The last outbreak was reported in 1989)

For breeding cattle ;

- The cattle for export to Japan were born, raised and continuously resident in Australia.
- Australia has been free from bovine brucellosis (*Brucella abortus*).

For feeder cattle;

- There has been no clinical, microbiological or serological evidence of bovine brucellosis at the farms the cattle for export to Japan were born and/or raised for 12 months before pre-shipment examination.
- The cattle for export to Japan must be kept isolated in the embarkation-quarantine facilities approved by the Australian government authorities as a secured and guaranteed place from an animal health point of view for at least 21 days before exportation. During this period, cattle are subjected to pre-export examination including tube agglutination test for brucellosis (excluding steers).
- The cattle for export to Japan have not been vaccinated against brucellosis.

2) New Zealand (The last outbreak was reported in 1989)

For breeding cattle, feeder cattle and cattle for direct slaughter;

- The cattle for export to Japan shall have been born and raised only in New Zealand.
- New Zealand has been free from bovine brucellosis, and vaccination against brucellosis is prohibited.

**- Results of import inspection**

1) Australia

	# of imported cattle		# of positive
	Breeding cattle	Feeder cattle	
2018	1,716	12,756	0
2019	3,226	14,523	0
2020	664	14,253	0
2021*	687	12,219	0

\*Note: Figures for 2021 are provisional.

2) New Zealand

Since 2010, no cattle have been imported into Japan.

For importation of bovine semen and embryo, specific requirements in line with relevant provisions of the *Terrestrial Code* need to be established with exporting countries.

**d. Surveillance in eradication phase**

As part of the national brucellosis eradication program, nationwide serological surveillance was started in 1956 by law. All lactating and beef breeding cattle were serologically tested every year. In this surveillance, cattle that tested positive for consecutive two plate agglutination tests were culled with compensation. Since the number of positive cases decreased to almost zero, the sampling frequency was reduced to at least once in two years in 1975. Sampling frequency was further reduced to at least once per five years in 1998. The number of positive cattle detected since 1946 are shown in Chart 1. From 2018, new surveillance to demonstrate freedom from brucellosis was conducted as described in the next section.

**e. Surveillance for demonstrating freedom**

In accordance with the provisions of 1 c) of Article 8.4.4, national surveillance to demonstrate freedom from bovine brucellosis was conducted for three consecutive years from April 2018 to March 2021. As the *Terrestrial Code* requires to demonstrate brucellosis freedom in at least 99.8% of the herds representing at least 99.9% of bovines in the country, the sample size was planned to demonstrate freedom in 99.9% of farms as assuming these farms representing at least 99.9% of bovines in the country. Therefore, at least 3,000 farms were defined as the sample size for the 3-year surveillance to detect at least one farm with more than 95% probability when the farm level prevalence was more than 0.1%. The sample size was then allocated for each prefecture in accordance with the number of dairy and beef cattle farms in each prefecture. The number of samples in tested farms was defined in such a way that can detect at least one infected animal with 95% probability when more than 10% of animals in the farm posing the detectable level of antibody. The defined number per farm depending on the farm size was shown in Table 2. In total, 43,691 cattle in 3,167 farms were tested until the end of March 2021. As a result, all samples were confirmed to be negative for brucellosis.

Regarding the diagnostic methods, buffered plate agglutination test and enzyme-linked immunosorbent assay (ELISA) were used for screening to identify a suspect case and culture and polymerase chain reaction (PCR) were used for confirmation in active surveillance for farms. For the abortion surveillance, ELISA using serum from dams that had abortions, culture using vaginal swab samples or aborted foetal tissue, and PCR were applied for confirmation.

**Table 2. Sample size per farm**

Breeding cattle in farm	Sample size
1 – 15	All
16 – 20	16
21 – 40	21
41 – 100	25
101 – Inf	30

**f. Control measures**

In accordance with the Act,

- Owners of the affected or suspected animals should isolate them without delay.
- Affected animals should be culled with compensation. Suspected animals should be culled with compensation and subjected to autopsy.
- Farms that keep affected and suspected animals should be disinfected. The farms where affected animals were kept within 60 days prior to the diagnosis are also to be disinfected.
- Animals kept in the same farm with the affected animals should be tested with ELISA test. Animals kept in the same farm with the suspected animals should be tested with rapid agglutination test or ELISA test.

**5. Measures for maintenance of free status**

**a. Surveillance for maintenance of freedom**

In accordance with the provisions of point 2 of Article 8.4.4., testing of all abortion cases reported to the LHSC will be maintained after April 2021 with the same procedures as previously conducted.

In addition, a new risk-based surveillance program was started in April 2021 to maintain the freedom. In this surveillance, imported breeding cattle and donor bulls for artificial insemination (AI) are defined as the target animals. As the test for imported breeding cattle, all cattle should be tested one year after their import once in their lifespans. As the test for donor bulls, all bulls registered as donor animals for semen distribution for AI should be tested once in their lifespans. Blood samples are taken from each animal and subjected to the ELISA test.

**b. Import quarantine measures**

To prevent the incursion of bovine brucellosis from overseas, import quarantine measures continue to be implemented.

**6. Conclusions**

Considering that:

- Infection with *Brucella abortus*, *B. melitensis* and *B. suis* in animals is a notifiable disease in the entire country;
- No case has been recorded in bovids for at least the last three years;
- Regular testing of all herds has been in place for the past three years; and this testing has demonstrated that during this period, infection with *Brucella abortus*, *B. melitensis* and *B. suis* was not present in at least 99.8% of the herds representing at least 99.9% of bovids in the country;
- Regulatory measures have been implemented for the early detection of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovids, including at least the regular submission of samples from abortion cases to diagnostic laboratories;

- No bovids have been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis* for at least the past three years, and no bovids introduced into the country have been vaccinated in the past three years;
- Bovids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18. of the *Terrestrial Code*;
- Infection is not known to be established in the feral and wild animals of Japan;

**The WOAH Delegate of Japan declares that the country is free from infection with *Brucella abortus*, *B. melitensis*, and *B. suis* in bovids as of 1 April 2021 in compliance with the provisions of Article 8.4.4. of the *Terrestrial Code* (2021 edition).**

Statement to be included in the self-declaration document.

I, the undersigned, Dr. OKITA Masatsugu, the Delegate of Japan to the World Organisation for Animal Health (WOAH, founded as OIE), takes responsibility for the self-declaration of freedom from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovids in accordance with the provisions of Chapter 8.4 of the *Terrestrial Animal Health Code*.

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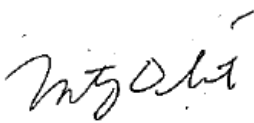
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Drawn up on 11 April 2022

Signature of the Delegate:

  
OKITA Masatsugu