

## DISCLAIMER

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## Self-declaration by Japan of freedom from infection with *Mycobacterium tuberculosis* complex in bovids

Self-Declaration submitted to the World Organisation for Animal Health (WOAH) 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 *Mycobacterium tuberculosis* complex in bovids (referred to as bovine tuberculosis) that covers the whole country in accordance with the provisions of Article 8.11.4. of the *Terrestrial Animal Health Code 2021 (Terrestrial Code)*.

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

### 2. Evidence that infection with *M. tuberculosis* complex is a notifiable disease in Japan

Bovine tuberculosis 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 (see annex 2).

### 3. History

#### a. Population of cattle in Japan

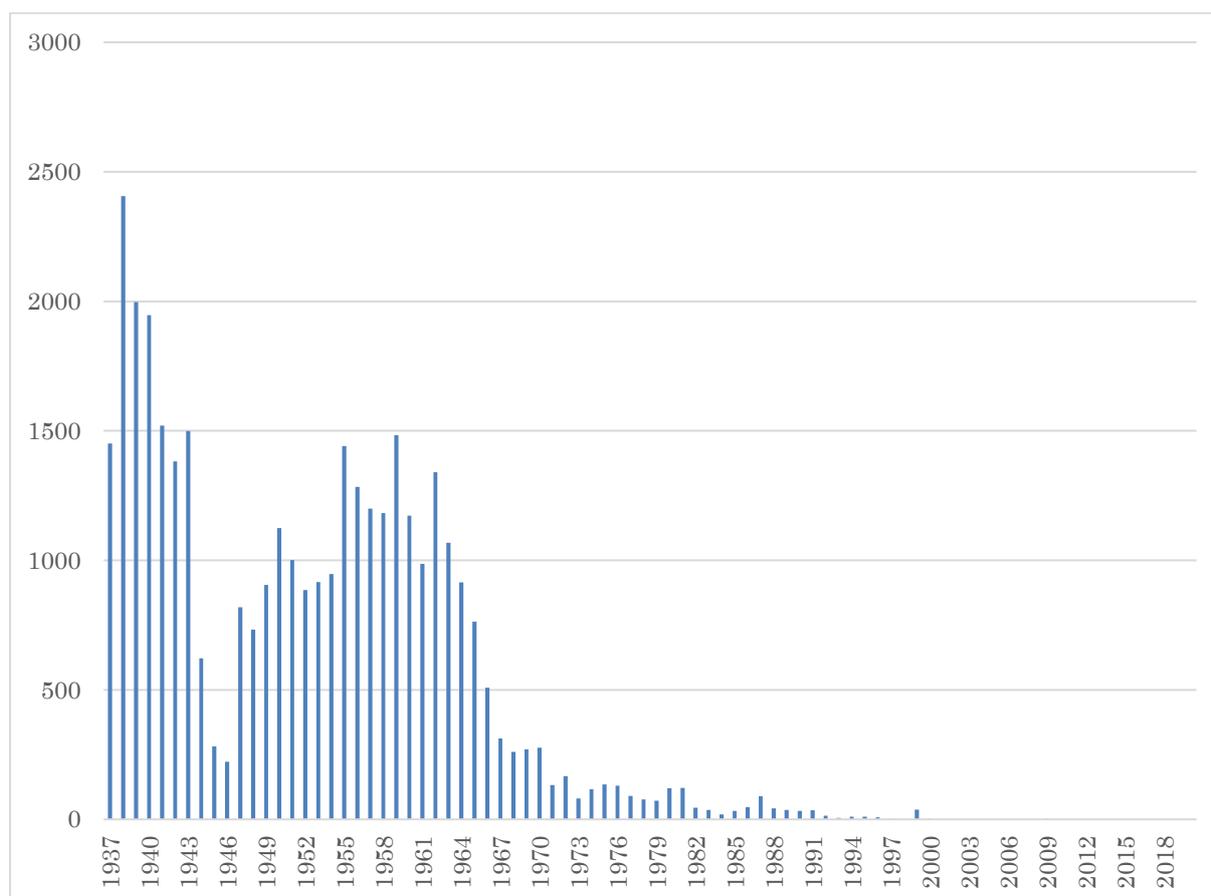
As of 1 February 2020, approximately 2,555,000 beef cattle in 43,900 farms, and 1,352,000 dairy cattle in 14,400 farms are kept in Japan. There are approximately 220 water buffaloes in 11 farms. There are no bison farms in Japan.

#### b. Eradication history

##### - Outbreaks

Bovine tuberculosis had been reported continuously from 1937, and the number of outbreaks gradually decreased from 1962. The last outbreak was reported in Hyogo Prefecture in December 2014. In addition, there has been no evidence of infection with *M. tuberculosis* complex in wildlife in Japan.

**Chart 1. Bovine tuberculosis outbreaks in Japan since 1937**



In 1901, 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 testing was changed to at least once every two years. After that, from 1998, all dairy cows, 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 decreased, and a surveillance program aiming at demonstrating freedom from bovine tuberculosis 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 tuberculosis was initiated in 2021. Details and results of the surveillance are described in the following section.

#### 4. Early warning systems and surveillance for bovine tuberculosis

##### a. Inspection at slaughterhouse

Bovine tuberculosis is a disease subject to inspection at slaughterhouse under [the Slaughterhouse Act](#). 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 tests are also conducted.

##### b. Import quarantine measures

Currently, only Australia and New Zealand are eligible for export of live cattle to Japan. 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 examination 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 diseases. After negative results of these tests are obtained, an import permit is granted.

## - Animal Health Requirements

### 1) Australia (The last outbreak was reported in 2002)

For breeding cattle:

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

For feeder cattle ;

- There has been no clinical, microbiological, or serological evidence of bovine tuberculosis 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 have been subjected to tuberculin intradermal reaction test with negative results for bovine tuberculosis within 70 days before shipment to Japan.

Details are described in the "[Animal Health Requirements for breeder cattle to be exported to Japan from Australia](#)" and "[Animal Health Requirements for cattle to be exported to Japan from Australia](#)" (the latter is for cattle other than breeder cattle).

### 2) New Zealand

For breeding, feeder and cattle for direct slaughter

- There has been no clinical, microbiological or serological evidence of bovine tuberculosis at the farms the cattle for export to Japan were born and/or raised for 12 months before entry to the embarkation-quarantine facilities authorized by the government authorities of New Zealand.
- The cattle for export to Japan have been subjected to tuberculin intradermal reaction test with negative results between 60 and 30 days before the shipment to Japan.

Details are described in the "[Animal Health Requirements for feeder cattle and slaughter cattle to be exported to Japan from New Zealand](#)" and "[Animal Health Requirements for cattle \(except for feeder cattle and slaughter cattle\) to be exported to Japan from New Zealand](#)".

## 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.

\* Caudal fold tuberculin (CFT) test was applied for feeder cattle showing clinical signs and 20 % of breeding cattle in each lot. If the CFT test was not negative, culture and PCR were performed for confirmation. Diagnostic tests were conducted in accordance with the *Terrestrial Manual*.

### 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.

### c. Surveillance in eradication phase

As part of the national bovine tuberculosis eradication program, nationwide surveillance using delayed hypersensitivity test was started in 1901 by law. All lactating and beef breeding cattle were tested every year by caudal fold tuberculin (CFT) test using heat-concentrated synthetic medium (HCSM) tuberculin. In this surveillance, cattle that tested positive for consecutive two CFT 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 since 1937 are shown in Chart 1. From 2018, new surveillance program to demonstrate freedom from bovine tuberculosis was conducted as described in the next section.

### d. Surveillance for demonstrating freedom

In accordance with the provisions of 1 b) of Article 8.11.4., national surveillance to demonstrate freedom from bovine tuberculosis was conducted for three consecutive years from April 2018 to March 2021 by CFT using HCSM. As the *Terrestrial Code* requires to demonstrate freedom from infection with *M. tuberculosis* complex in at least 99.8% of the herds representing at least 99.9% of bovinds in the country, the sample size was planned to demonstrate freedom in 99.9% of farms which represented at least 99.9% of bovinds 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 if 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 to detect at least one infected animal with 95% probability if at least 10% of animals on the farm have a detectable level of immunity against *M. tuberculosis* complex. The defined number of tested animals per farm according to the farm size is shown in Table 1. In total, 43,357 cattle in 3,164 farms were tested until the end of March 2021. As a result, all tested cattle were confirmed to be negative.

Between April 2018 to March 2021, over 3 million cattle were recorded as slaughtered in authorised slaughterhouses in Japan (approximately 1.05 million each year). In the same period, 53 samples\* were collected from animals with tuberculosis-like lesions and subjected to agent identification tests for confirmation in laboratories. All the submitted samples tested negative for *M.tuberculosis* complex.

\* In some cases, more than one sample could have been taken from an animal for testing.

**Table 1. 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

### e. 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 on the same farm as the affected and suspected animals should be tested with tuberculin test.

## 5. Measures for maintenance of status

### a. Surveillance for maintenance of freedom

In accordance with the provisions of point 2 of Article 8.11.4., ante- and post-mortem inspection by official veterinarians in all slaughterhouses will be maintained with the same procedures as described in 4.a.

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. The tuberculin test will be conducted for all these animals by injecting bovine tuberculin PPD at their mid-neck. For cattle that were not negative for the tuberculin test, blood samples are taken from each animal and tested to confirm the presence of antigen-specific immune reaction using the gamma-interferon assay. Cattle tested positive for the gamma-interferon assay will be sent to Livestock Hygiene Service Centers (LHSC) and culled as a suspected animal with compensation. Tissues and other samples of all suspected cattle will be sent to the National Institute of Animal Health (NIAH) for confirmation by bacterial isolation and identification. Any cattle identified as infected with *M. tuberculosis* complex will be confirmed as a case of bovine tuberculosis.

### b. Import quarantine measures

To prevent the incursion of bovine *tuberculosis* from overseas, import quarantine measures continue to be implemented in accordance with Articles 8.11.7., 8.11.10. and 8.11.12. of the *Terrestrial Code*.

## 6. Conclusions

Considering that:

- Infection with *M. tuberculosis* complex in animals is a notifiable disease in the entire country;
- A surveillance programme based on regular testing of all herds has been in place for at least three years and for the past three years this testing has demonstrated that infection with *M. tuberculosis* complex was not present in at least 99.8% of the herds representing at least 99.9% of the bovids in the country;
- A surveillance programme in accordance with Chapter 1.4. is in place to detect infection with *M. tuberculosis* complex in the country through ante- and post-mortem inspections of bovids as described in Chapter 6.3.;
- Regulatory measures have been implemented for the early detection of infection with *M. tuberculosis* complex in bovids;
- Bovids and their germplasm imported into the country comply with the recommendations in Articles 8.11.7., 8.11.10. and 8.11.12.

**The WOA Delegate of Japan declares that the country is free from infection with *M. tuberculosis* complex in bovids as of 1 April 2021 in compliance with the provisions of Article 8.11.4. 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 *Mycobacterium tuberculosis* complex in bovids in accordance with the provisions of Chapter 8.11 of the *Terrestrial Animal Health Code*.

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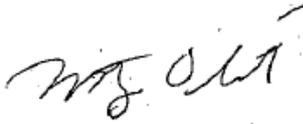
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Drawn up on 11 April 2022

Signature of the Delegate:

  
OKITA Masatsugu