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## **APHIS Evaluation of the Foot and Mouth Disease Status of Japan**

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(retrieved 4 April 2021)

**Animal and Plant Health Inspection Service**

**Veterinary Services**

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## Abbreviations

AIDPL	Animal Infectious Disease Prevention Law
AQS	Animal Quarantine Service
APHIS	Animal and Plant Health Inspection Service
ELISA	Enzyme-linked immunosorbent assay
FAO	Food and Agriculture Organization
FMD	Foot and mouth disease
GFMD	Guidelines for the Control of Foot and Mouth Disease
LBPE	Liquid-phase blocking ELISA
LHSC	Livestock Hygiene Service Center
MAA	Mutual Aid Association
MAFF	Ministry of Agriculture, Forestry and Fisheries
MRZ	Movement restriction zone
NIAH	National Institute of Animal Health
OIE	World Organization for Animal Health
RT-PCR	Reverse-transcription polymerase chain reaction
SLCFMD	Special Law for Countermeasures against Foot and Mouth Disease
SRZ	Shipment restriction zone

Kawaminami area: Area consisting of Kawaminami-cho, Tsuno-cho, Takanabe-cho, Shintomi-cho, and parts of Hyuga city, Kijo-cho, Saito city, and Miyazaki city; became the vaccination area.

## **Executive summary**

On 20 April 2010, Japan's Ministry of Agriculture, Forestry and Food (MAFF) reported an outbreak of FMD in Miyazaki prefecture. The Animal and Plant Health Inspection Service (APHIS) immediately implemented an administrative ban on importation of commodities from Japan that could harbor FMD virus. APHIS later supported this action by issuing an interim rule that removed Japan from the list of regions considered free of FMD in title 9, Code of Federal Regulation, section 94.1. Over the course of 11 weeks, MAFF reported infection on a total of 292 farms within the prefecture, resulting in the depopulation and burial of 211,608 infected and susceptible animals. The last affected farm was depopulated on July 5; on October 6, MAFF requested that APHIS reinstate Japan to the list of FMD-free regions. This assessment examines the current status of Japan with regard FMD, including the measures taken to control and eradicate the disease.

Japan's official veterinary services addressed the FMD outbreak through a stamping out policy that involved movement restrictions, culling, active surveillance, and ultimately vaccination. Several factors contributed to the duration and extent of the outbreak, including delayed detection of the first case and delayed depopulation of affected farms due to difficulties identifying suitable burial sites. The latter led to the decision to vaccinate and destroy all susceptible animals within a target area; however, implementation was hindered by the need for special legislation to allow the official veterinary services to conduct precautionary culling of apparently healthy animals. Vaccination ultimately occurred from May 22 to 26 and all vaccinated animals were depopulated and buried by June 30.

The official veterinary services conducted active surveillance for detection of FMD-infected animals and to reestablish FMD freedom, both in Miyazaki prefecture and throughout the country. Surveillance consisting of both clinical inspections and serologic testing was conducted prior to lifting movement restrictions on affected areas and also to reestablish disease freedom in Miyazaki prefecture. Sentinel animals placed on 175 farms in the affected area were monitored and tested, with negative results. No evidence to suggest continued circulation of FMD virus was detected.

The source of the virus has not been definitively identified; however, MAFF suspects that it was introduced through contaminated people or personal goods from a nearby affected country. The agency has taken steps to increase biosecurity and inspection measures for travelers and luggage arriving from affected regions, as well as biosecurity at the farm level.

APHIS concludes from this assessment that Japan successfully eradicated FMD virus introduced in 2010. The recent outbreak considerably heightened public awareness, which increases the likelihood of early detection in the event of a future FMD outbreak, and MAFF is taking actions to address the logistical difficulties that extended the course of the 2010 outbreak.

## Hazard identification

The hazard under consideration in this assessment is FMD virus. FMD is a contagious and economically damaging disease of cloven-hoofed animals, including domestic ruminants and pigs, as well as over 70 wildlife species [1]. The disease is endemic in large areas of Africa, Asia, and South America, and outbreaks are not uncommon in previously free areas throughout the world [2]. The FMD virus belongs to the family Picornaviridae, genus *Aphthovirus*, and 7 distinct serotypes with indistinguishable clinical effects have been identified: O, A, C, SAT1, SAT2, SAT3, and Asia1 [3]. FMD virus is stable under cold conditions [4, 5].

The incubation period for FMD is 2-14 days [6]. The virus initially multiplies in the pharyngeal area and is then carried to the regional lymph nodes and the bloodstream for distribution throughout the body [2, 7]. Subsequent viral amplification occurs within the cornified stratified epithelium of the skin, particularly on the feet, mammary gland, and tongue, as well as in the myocardium of young animals. Saliva, feces, urine, and breath are sources of the virus, and virus may be present in milk and semen up to 4 days before clinical signs appear [6].

Other sources of viable virus are meat and meat products in which the pH has remained above 6.0, as well as convalescent animals, exposed vaccinates, and carrier animals, particularly cattle and water buffalo. The FMD virus survives in lymph nodes and bone marrow at neutral pH, but is destroyed in muscle when the pH is less than 6.0 [6]. Pig meat does not consistently reach as low an ultimate pH during carcass maturation as beef, so the inactivation of FMD virus in pig meat may not be as complete as that occurring in beef [8]. Virus inactivation has not been examined in detail in small ruminant meat [2]. The virus can persist in contaminated fodder and the environment for up to 1 month, depending on the temperature and pH conditions.

Susceptible livestock may be infected with FMD virus as a result of direct or indirect contact with infected animals or an infected environment [2]. Indirect transmission may occur via movement of people, wild or domestic animals, or inanimate objects (vehicles, farm implements, clothing), and long-range airborne transmission is also possible. Transmission of FMD virus via meat or meat products is well documented. For example, a review of 627 known sources of FMD outbreaks throughout the world from 1870-1993 found that 411 of the outbreaks (66%) were attributable to infected meat, meat products, or garbage [9].

Laboratory confirmation is essential during outbreak situations, since FMD cannot be distinguished from other vesicular disease such as SVD, vesicular stomatitis, and vesicular exanthema of swine on the basis of clinical findings [2]. The classical form is characterized by fever and vesicles with subsequent erosions in the mouth, nares, muzzle, feet, or teats. However, serological field surveys and experimental investigations have shown that FMD in small ruminants may be clinically inapparent in a significant proportion of animals [10, 11], and certain strains of the virus may be of low virulence in some species [12]. FMD generally causes low mortality in adult animals but mortality may be high in young animals due to myocarditis.

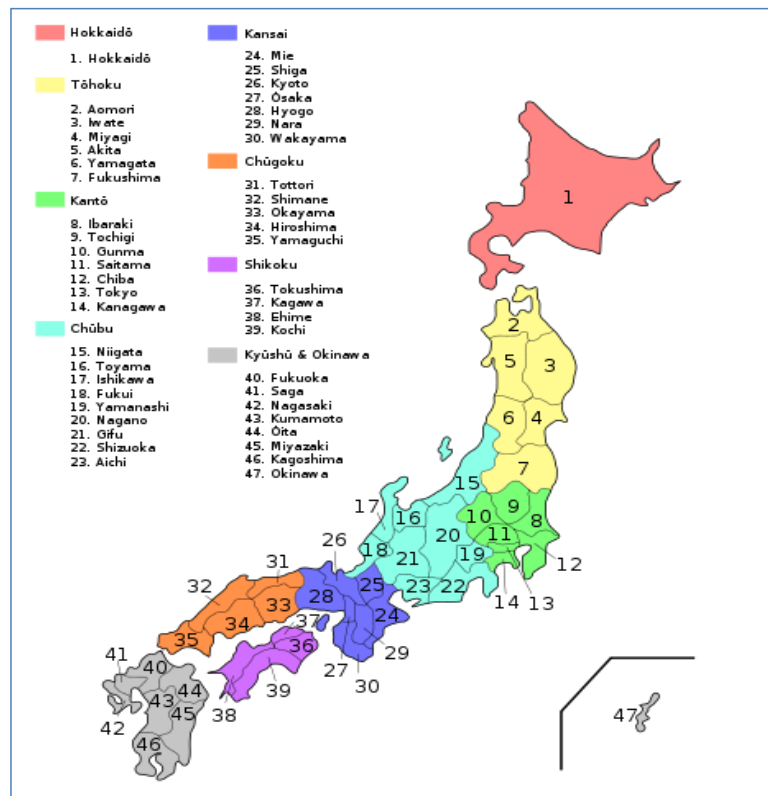
## Release assessment

### 1. Introduction

Japan is an archipelago of 6,852 islands [13]. The four largest islands, from north to south, are Hokkaido, Honshu, Shikoku, and Kyushu; these islands account for 97 percent of Japan's land area. Roughly 70 to 80 percent of Japan is forested, mountainous, and unsuitable for agricultural, industrial, or residential use due to steep elevations, climate, and risk of landslides [13]. As a result, the habitable zones—located mainly in coastal areas—have extremely high population densities.

Japan is divided into 47 prefectures, each overseen by an elected governor, legislature, and administrative bureaucracy (see Figure 1.1). The prefectures are further divided into cities, towns, and villages (collectively called municipalities). Although Japan is a constitutional monarchy, the power of the Emperor is very limited; rather, the Prime Minister is the head of the national government [13]. Japan's legislative organ is the National Diet, a bicameral parliament with a popularly-elected House of Representatives and House of Councillors.

Figure 1.1: Administrative divisions of Japan



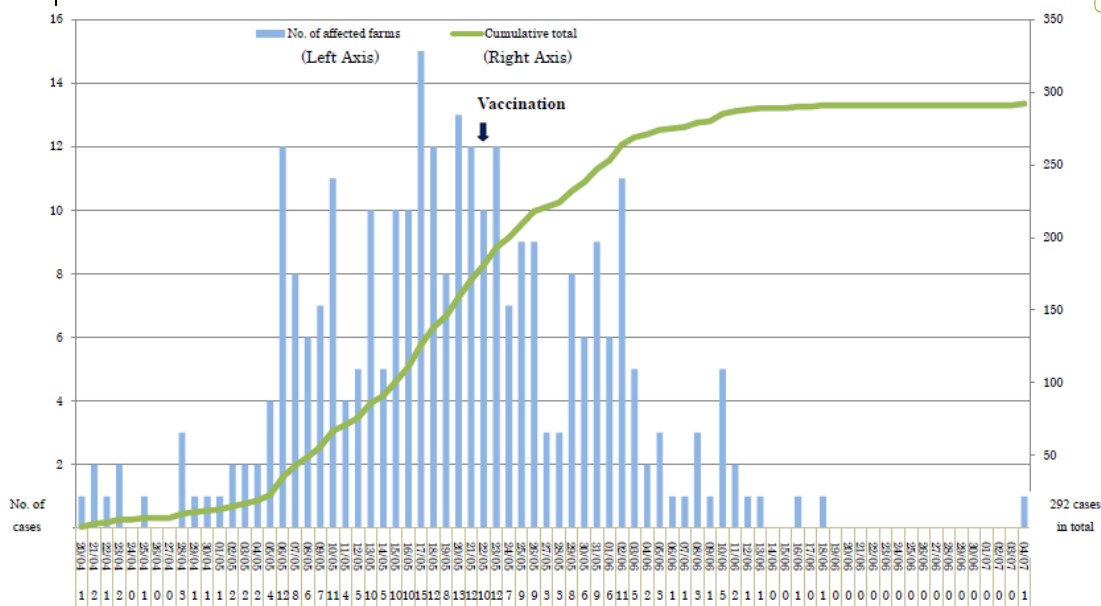
## 2. Disease history

On 20 April 2010, Japan reported an outbreak of FMD in Miyazaki prefecture, located on the eastern coast of Kyushu Island (see Figure 1.1, no. 45); this was the first FMD outbreak in Japan since 2000 [14]. A detailed chronology of events is provided in the Annex.

The initial detection occurred on a farm with 16 beef cattle (case: Tsuno-cho 2); however, the Ministry of Agriculture, Forestry and Fisheries (MAFF) estimates that animals on at least 10 other farms were infected by April 20 [15, 16]. Between April 20 and 26, infection was confirmed on 6 additional farms within the 10 kilometer movement restriction zone (MRZ) around the first farm. An epidemiological investigation identified the presumed index case, a farm with 42 buffalo and 2 pigs (case: Tsuno-cho 1). MAFF estimates that the virus was introduced onto this farm around March 19.

The first affected swine farm was confirmed on April 28 (case: Kawaminami-cho 6), the same day that officials confirmed the first affected farm outside of the initial MRZ (case: Ebino city 1). The incidence of new case farms increased rapidly from that point, climbing to 15 cases in a single day on May 17 (see Figure 2.1) [16]. The official veterinary services conducted emergency vaccination against FMD from May 22 to 26 in the Kawaminami area.<sup>1</sup> The number of outbreaks subsequently took a downward turn, with the last affected farm detected on 4 July 2010 and depopulated the following day (case: Miyazaki city 3).

**Figure 2.1: Chronology of the outbreak**

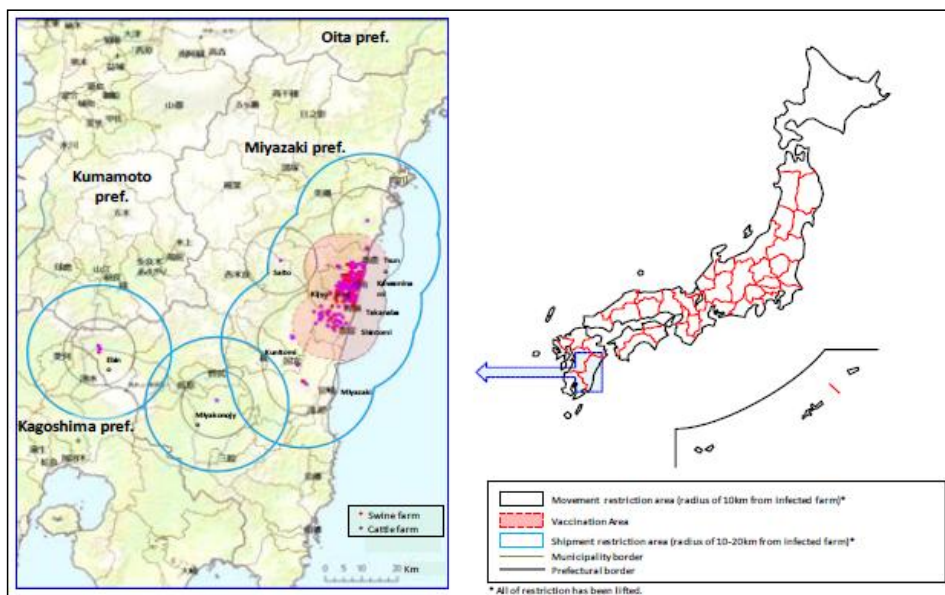


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<sup>1</sup> Kawaminami area: Area consisting of Kawaminami-cho, Tsuno-cho, Takanabe-cho, Shintomi-cho, and parts of Hyuga city, Kijo-cho, Saito city, and Miyazaki city; became the vaccination area.

Ninety-four percent of the affected farms were located in Kawaminami-cho (197) and the adjacent towns of Tsuno-cho (30), Kijo-cho (5), Takanabe-cho (25), and Shintomi-cho (17) (see Figure 2.2) [14, 16]. Cases also occurred in neighboring Hyuga city (1), Kunitomi town (1), Miyazaki city (3), Saito city (8), and the more distant Ebino city (4) and Miyakonojo city (1).

**Figure 2.2: Distribution of FMD outbreaks**



The official veterinary services adopted a policy of stamping out through movement controls, culling, active surveillance, and ultimately vaccination (see Section 5) [15, 16]. Prefectural officials established MRZs and shipment restriction zones (SRZs) that extended 10 and 20 kilometers around affected farms, respectively. When infection was confirmed outside of an existing MRZ, a new MRZ and SRZ were established.

All told, FMD infection was confirmed on 292 farms over a period of 11 weeks; all 211,608 infected and susceptible animals residing on those farms were depopulated [16]. All vaccinated animals were also depopulated (see Section 8). The primary species affected in the 2010 outbreak were cattle and swine, with minor involvement of sheep (8), goats (14), and water buffalo (42) [14, 16].

The official veterinary services conducted active surveillance for detection of FMD-infected animals, both in Miyazaki prefecture and throughout the country (see Section 7) [15, 16]. Veterinarians also conducted active clinical and serological surveillance to reestablish freedom from FMD around affected



farms—prior to lifting movement restrictions—and throughout Miyazaki prefecture, as well as targeted wildlife surveillance.

The National Institute for Animal Health (NIAH) and the Food and Agriculture Organization (FAO) World Reference Laboratory for FMD determined that the circulating virus was serotype O [14, 16]. The most closely related reference strain was O/MYA/7/98, similar to recent serotype isolations from Hong Kong, Republic of Korea (Korea), and Russia (see Section 6). An epidemiological study conducted by the NIAH estimated that the virus entered into Japan in mid-March, most likely via contaminated people or personal goods from a nearby affected country, although no source of the virus has been definitively identified.

Prefectural officials lifted the movement restrictions around the last affected farm (case: Miyazaki city 3) on July 27 [14, 16]. On 6 October 2010, MAFF declared Japan once again free of FMD. On 4 February 2011, the World Organization for Animal Health (OIE) reinstated Japan to the list of countries free of FMD without vaccination [17].

### **3. Authority, organization, and infrastructure of the veterinary services**

#### **3.1 Organization**

##### **3.1.1 National level**

The national veterinary authority in Japan is MAFF, specifically the Animal Health Division [16, 18]. MAFF has headquarters in Tokyo and 7 regional offices, as well as branch offices in each prefecture that gather statistics, organize subsidies, and provide support to farmers and to the local veterinary services. MAFF develops animal health plans and emergency response policies in conjunction with consultative committees. MAFF also provides assistance to the prefectural governments for improvement and maintenance of veterinary facilities and organizes training for local veterinary officers. Within MAFF, the Animal Quarantine Service (AQS) administer import and export functions (see Section 9).

During the 2010 FMD outbreaks, the national government implemented 3 emergency management groups [15]. The first, established at MAFF headquarters on April 20 with the Minister of MAFF directing, provided guidance to the prefectures regarding onsite control measures. The second, directed by the Prime Minister, served to coordinate other national and prefectural agencies involved in the response. The third, consisting of representatives from the national office gathered at the prefectural level with the Vice-Minister of MAFF directing, focused primarily on financial support.

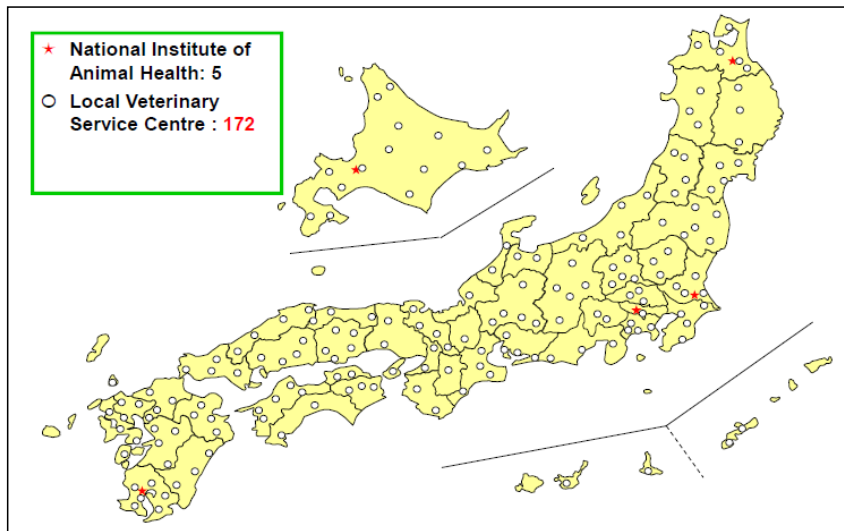
##### **3.1.2 Prefectural level**

The prefectural governments establish Livestock Hygiene Service Centers (LHSCs) as the front line in livestock health protection efforts and implement specific measures for animal health protection [15, 19]. As of 31 March 2009, there were 172 LHSCs established in the Japan's 47 prefectures, employing a total of 2,147 local veterinary officers (see Figure 3.1).

The Miyazaki LHSC serves the central Koyu area of Miyazaki prefecture (see Figure 3.2), where most of the outbreaks occurred, as well as the Chuba and Minaminaka areas to the south [20]. The Miyakonojo and Nobeoka LHSCs serve the remainder of the prefecture. Each LHSC has 3 divisions—management and

feed safety, animal health, and disease diagnostics—and consists of a Director, a Deputy Director, local veterinary officers, technicians, and administrative staff. The Miyazaki LHSC has an onsite laboratory with BSL-2 capability.

**Figure 3.1: Location of animal health facilities [19]**



**Figure 3.2: Detail of Miyazaki prefecture and Koyu area (in orange)**



During the FMD outbreak, Miyazaki prefecture established emergency operation centers at the Miyazaki LHSC and the prefectural veterinary service headquarters in Miyazaki city [15]. The Miyazaki LHSC served as a local headquarters for the response effort. Secondary headquarters in Kawaminami-cho and Shintomi-cho served as the frontline for response actions. Each municipality—cities, towns, and villages—established their own centers that operated under instructions from the prefectural veterinary service. Response measures were primarily enacted by the prefecture, with national support.

### **3.1.3 Municipal level**

Each municipality has a voluntary self-defense promotion committee consisting of designated veterinarians (200 in Miyazaki Prefecture) who have received special training at a prefectural LHSC, as well as representatives of the local livestock industries [15]. These committees aid in emergency response through communications and logistics.

## **3.2 Authority**

The primary legal act concerning animal health is the Animal Infectious Disease Prevention Law (AIDPL) [21]. The AIDPL grants prefectural governors the primary authority and responsibility for animal health issues, including emergency response during foreign animal disease outbreaks. Prefectural governors typically delegate such authority to the Directors of the LHSCs (Article 61). MAFF retains the authority to instruct any prefecture to take critical response or prevention actions if deemed necessary (Article 47). The AIDPL also requires animal owners, caretakers, and veterinarians to immediately report a suspect or confirmed case of a foreign animal disease—including FMD—to the prefectural authorities (Articles 4 and 13). Prefectural authorities must then notify MAFF and the mayors of affected and neighboring municipalities.

Under the AIDPL, prefectural governments have the legal authority to enact or require disease control measures such as quarantine of affected farms, movement restrictions and traffic control in affected areas, depopulation and disposal of infected and susceptible animals on affected farms, and cleaning and disinfection (Chapters II and III) [21]. Prefectural governors are obligated to loan local veterinary officers to an affected prefecture for emergency response, upon request (Article 48-2). A prefectural governor may also request that MAFF AQS officers temporarily assume the duties of local veterinary officers (Article 48).

The AIDPL carries a penalty of up to 3 years in prison or 1 million Yen (12 thousand USD) for failure to report a suspect FMD case [21]. The penalty for noncompliance with movement restrictions during an outbreak is up to 1 year in prison or 500 thousand Yen (6 thousand USD).

Based on the AIDPL, MAFF develops guidelines that function as standard protocols for the prefectural veterinary services to follow with regard to routine and emergency animal health measures [16, 19]. Specific animal infectious disease control guidelines—such as the Guidelines for the Progressive Control of Animal Infectious Diseases (GAID) and the Guidelines for Control of FMD (GFMD)—are developed by the national government, the prefectural governments, research institutions, and other entities in a collaborative framework.

The GAID describes the basic measures to be taken by MAFF and the governments of prefectures, cities, towns, and villages to prevent and control animal infectious diseases [16]. The GFMD outlines critical

control measures in the event of an FMD outbreak based on a stamping-out policy. Specifically, the GFMD describes the measures to be adopted at first notification of a suspect case, when the case is confirmed, and at the place(s) of the outbreaks, as well as procedures for tracing susceptible animals, controlling animal movements, and conducting epidemiological surveys. The GFMD also describes a basic communication plan to allow information sharing among domestic stakeholders and promote public awareness of the disease outbreak.

The GFMD contains general provision for vaccination against FMD, stipulating that vaccination will be considered when (1) it may be difficult to control FMD with only movement restrictions and culling of infected and susceptible animals, and (2) vaccination is a vital tool to attain early establishment of FMD freedom [19]. However, neither the GFMD nor the AIDPL provide the legal authority for the official veterinary services to conduct precautionary depopulation of apparently healthy animals, vaccinated or otherwise.

On 4 June 2010, the Diet enacted a new law—the Special Law for Countermeasures against FMD (SLCFMD)—to allow for precautionary depopulation of susceptible animals in a specific area designated by the MAFF Minister [16]. Under the SLCFMD and upon request by the Governor of Miyazaki, the MAFF Minister designated the Kawaminami area as a vaccination practicing zone. The legislation also included funding for compensation of affected farmers. MAFF subsequently published the Implementation Manual for Control of FMD to strengthen the control measures in place and to implement certain provisions of the SLCFMD [16, 19].

### 3.3 Infrastructure

#### 3.3.1 Human and material resources

##### *Personnel*

According to the Japan Veterinary Medical Association, there are about 36,000 active veterinarians in Japan [22, 23]. Approximately 9,100 veterinarians (25 percent) work as public officials with the national government, prefectural governments, or municipal governments (see Table 3.1). Another 6,700 work for private organizations and approximately 15 thousand are private practitioners. The number of veterinarians working with food animals is gradually declining; however, the percentage on Kyushu Island (20.7 percent) is almost double the national average (11.7 percent) [23].

**Table 3.1: Number of veterinarians employed in the public sector [22]**

Field	National level	Prefectural level	Municipal level
Agriculture	277	3,160	142
Public health	151	3,784	923
Other	36	357	273
Total	464	7,301	1,338

A total of 7,618 veterinarians participated in the outbreak response, organized into separate teams for surveillance, epidemiology, vaccination, and depopulation [15]. The Miyazaki prefectural government requested official veterinarians from other prefectures as allowed under the AIDPL and also recruited

veterinarians in private practice and at universities. MAFF detailed AQS officers to the response effort as well. The Miyazaki LHSC informed the prefectural government of the specific staffing needs for the next day and the government requested the appropriate number of veterinarians. The Governor of Miyazaki also requested Japan Self Defense (military) forces on May 1. These persons assisted with excavation of burial sites, carrying out cleaning and disinfection, and manning disinfection points.

#### *Education and training*

Sixteen colleges and universities in Japan offer a veterinary medicine curriculum [22]. The curriculum spans 6 years with students entering directly from high school. Graduates must pass a national exam administered by MAFF for licensure. Completion of the 6-year curriculum and passing the national exam confers a master's degree. Approximately 1,000 graduates become newly licensed veterinarian each year, half of which are female.

Local veterinary officers participate in foreign animal disease simulations and training organized by MAFF and the NIAH [15]. MAFF conducted quality control exercises with all prefectures in late 2010, after the FMD outbreak, and also in February 2011. The purpose is to verify details of the emergency response plans and address any weaknesses detected.

#### *Financial resources*

The cost of the 2010 outbreak response was largely assumed by the Miyazaki prefectural government, with assistance from the national government [15]. The outbreak resulted in estimated losses of 235 billion Yen (2.8 billion USD) to Miyazaki prefecture—including the economic impact on related industries—and 60 billion Yen (724 million USD) to the national government.

#### *Communications*

The official veterinary services have full access to telephone, internet, and email for communication purposes [15]. During the 2010 outbreak, MAFF and Miyazaki prefecture followed a basic communication plan developed after the 2000 outbreak. The prefectural government supplied information to the municipalities, who then conveyed it to individual farmers. When new zones were established, the LHSCs notified affected farmers by telephone and requested compliance, which is considered legally binding under the AIDPL. The prefecture posted changes to the restricted areas on their internet homepage and issued media releases every day for 70 days. These releases described confirmed cases and changes to the movement and shipment restriction zones, and referred people to the prefectural website for up-to-date information.

#### *Monitoring and audit programs*

The Japanese government established an Independent Committee for Verification of the Containment and Eradication of FMD in Miyazaki Prefecture [15]. The Independent Committee consisted of researchers, consumer organizations, mass media representatives, and others; MAFF and Miyazaki prefecture were not represented. The Chairman of the Japanese Veterinary Medical Association moderated the discussions.

The recommendations of the Independent Committee focused on prevention of FMD introduction, ensuring early detection and reporting, and effective initial response [24]. Among other things, the

Independent Committee noted that biosecurity measures in place at ports and on farms prior to the outbreak were not sufficient to prevent FMD introduction, and that such measures should be strengthened. The Independent Committee also noted that the roles of the national government, prefectures, and municipalities during an outbreak response should be defined more specifically, with the national government taking a greater role in both preparedness and response.

In addition, the Independent Committee emphasized the high cost of the delays in detecting FMD, depopulating and disposing of affected animals, and implementing vaccination [24]. The Independent Committee made several recommendations for improving passive surveillance and emergency preparedness, as well as changes to the AIDPL—including a permanent provision to allow for preventive vaccination and/or culling of healthy animals—that MAFF and the Diet are considering [15]. MAFF is also considering changes to the AIDPL that would require each farmer to identify a viable burial site to use in the event of an outbreak.

### **3.4 Discussion**

The official veterinary services of Japan are hierarchically organized, with considerable autonomy at the prefectural level. The AIDPL allots primary responsibility for emergency response to the prefectural governors, with MAFF providing guidance and support. However, it appears that the practical roles and responsibilities of MAFF and the prefectures were not clearly defined prior to the 2010 outbreak, which caused some confusion in the initial stages. Earlier and more cohesive involvement of MAFF at the prefectural level—including teams with expertise in epidemiology, biosecurity, and other disease control measures—could promote a more effective initial response.

The official veterinary services have sufficient legal authority to conduct routine animal health activities and most emergency response measures. However, the AIDPL does not include provisions for certain actions that may be required to control a disease outbreak, including precautionary culling of apparently healthy animals. The Diet therefore had to enact additional legislation—the SLCFMD—to provide the legal authority for the official veterinary services to depopulate susceptible animals in the vaccination zone, which delayed the outbreak response. Revising the AIDPL and dependent guidelines to include comprehensive provisions for emergency response could aid in avoiding such delays in the future.

The infrastructure of the official veterinary services appears sufficient to carry out routine activities, although it is concerning that Miyazaki prefecture—where both the 2000 and 2010 FMD outbreaks occurred—has the lowest ratios of official veterinarians to animals and to farms among the prefectures. The 2010 outbreak placed considerable strain on the resources of the official veterinary services, particularly regarding personnel, suggesting that these resources could be overwhelmed in a larger outbreak. Although MAFF officials declined an offer by the FAO to send a specialist team to Miyazaki prefecture to help contain the virus, and expressed hesitance to recruit foreign veterinarians due to the language barrier, it would appear prudent to investigate these resources further.

APHIS concludes that the authority, organization, and infrastructure of Japan's veterinary services were sufficient to address the 2010 FMD outbreak, although opportunities for improvement exist.

## 4. Livestock demographics and marketing practices

Miyazaki prefecture is a major agricultural area, ranked fourth in Japan in gross agricultural output [16]. It is Japan's 2<sup>nd</sup> largest pig-farming region and 3<sup>rd</sup> largest producer of beef cattle. Prior to the outbreak, livestock production accounted for 58 percent of gross agricultural output of the prefecture.

### 4.1 Livestock population of Japan

As of February 2009, there were approximately 4.42 million cattle, 9.9 million swine, and 26 thousand small ruminants in Japan (see Table 4.1) [16]. The majority of dairy cattle are located in the northern Hokkaido prefecture, as are many of the large beef operations. However, the majority of beef cattle are located on smaller farms on the southern island of Kyushu, particularly in Miyazaki and Kagoshima prefectures.

**Table 4.1: Livestock demographics in Japan and Miyazaki prefecture [16]**

Species		Japan		Miyazaki	
		Farms	Animals	Farms	Animals
Cattle	Total	100,400	4,423,000	10,734	297,000
	Dairy	23,100	1,500,000	434	19,000
	Beef	77,300	2,923,000	10,300	278,000
Swine		6,890	9,899,000	650	901,000

Swine are farmed primarily in the Kanto area located east of Tokyo, as well as southern Kyushu Island, including Miyazaki and Kagoshima prefectures [16]. Sheep and goats are raised on a few commercial farms in Hokkaido and on small-scale farms scattered throughout Japan.

Japan has actively followed policies designed to increase herd size in recent years, in order to improve productivity and strengthen competitiveness in international trade [24].

### 4.2 Livestock population of Miyazaki prefecture

As of February 2009, there were approximately 297 thousand cattle on 10,734 farms in Miyazaki prefecture (see Table 4.1 above) [16]. There were also over 900 thousand swine on 650 farms. Kawaminami-cho—in which the majority of the FMD outbreaks occurred—was one of the most densely inhabited areas of swine production prior to the outbreak, with over 141.5 thousand swine. The average distance between livestock farms in some areas is less than 500 meters.

### 4.3 Marketing practices

Beef in Japan is produced from 3 primary types of cattle: purebred Wagyu (39 percent), Wagyu hybrid bred from a Wagyu male and a dairy female (24 percent), and dairy (37 percent) [25]. Wagyu breeding cattle are typically kept on small farms averaging 10 animals; in 2008, there were approximately 667 thousand Wagyu breeding cattle on 64 thousand farms. Wagyu feedlots purchase feeder cattle at 8 to 9 months of age and sell them directly to an abattoir at 29 to 30 months (around 700 kilograms) [15]. Feedlots average 100-200 animals.

Wagyu hybrid cattle and male dairy cattle may be raised on a rearing operation then sold to a fattening operation [25]. Alternatively, some farms both rear and fatten Wagyu hybrid cattle and/or male dairy cattle. Aged Wagyu and dairy cows are also sold for beef production.

Prefectures are divided into regions served by a particular livestock market [15]. Although not legally required, most farmers sell their animals through the market that serves their region; buyers come from throughout Japan. The Koyu Livestock Market services the Koyu area in which the majority of the FMD outbreaks occur. Most farmers also buy their feed through the local branch of a national agricultural cooperative that services their region.

#### **4.4 Animal identification and traceability**

Japan has had a mandatory animal identification program for cattle in place since December 2003 [19]. All domestic and imported cattle receive a tag in each ear that bears a unique 10-figure individual identification number and barcode. The identification numbers are recorded in a central database. Producers are required to notify MAFF when animals are added to or removed from their herd. Producers must keep a record of births, deaths, purchases, and sales, including the premises number of the seller or buyer. Slaughter plants must provide the identification numbers of slaughtered cattle to MAFF and keep a record of all cattle slaughtered. The animal identification number stays with the carcass throughout slaughter and processing, and is displayed on the product label. Using this number, consumers can access an animal's entire production history.

To date, there is no standard identification system for swine in Japan that would allow tracing of individual animals [15]. However, each prefecture maintains a database of the location and type of livestock premises, as well as the number of animals on each farm. Swine moving across prefectural boundaries must be accompanied by a certificate attesting to the status of the herd and animal(s) for Aujeszky's disease. MAFF regional officials conduct annual on-farm inspections to audit animal identification and movement records.

#### **4.5 Biosecurity**

The report of the Independent Committee suggests that farmers in Miyazaki prefecture did not follow sound biosecurity practices, thereby facilitating virus spread [24]. During the outbreak, local veterinary officers throughout Japan worked with farmers to increase on-farm biosecurity measures, as observed by the APHIS site visit team [15]. The Independent Committee recommended that farmers, veterinarians, and others in the livestock industries be held to more stringent biosecurity standards in the future.

#### **4.6 Discussion**

The large number of susceptible animals in close proximity in Miyazaki prefecture, particularly swine, likely facilitated virus spread. Conversely, the localized marketing and feed supply practices may have helped to limit the geographic extent of the outbreak to within Miyazaki prefecture, and largely within the Koyu region. As a result of the 2010 outbreak, livestock farmers throughout Japan are currently implementing on-farm biosecurity measures that may aid in preventing or limiting future outbreaks.



Herd registration systems are in place at the prefectural level, although such records may not have been scrupulously maintained in Miyazaki prefecture [24]. Japan's cattle identification system ensures adequate trace-back capability in the event of an animal disease outbreak. No standardized system is in place to efficiently track swine movements or the number of swine on each holding; however, current practices ultimately appeared sufficient for traceback during the 2010 outbreak.

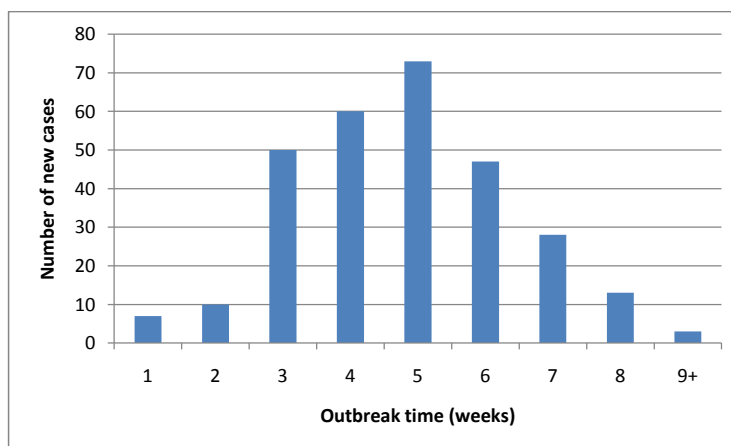
## 5. Emergency preparedness and response

Control measures during the 2010 FMD outbreak were directed towards stamping out the virus. This section addresses factors critical to an effective response, including quarantine and movement control, epidemiology, biosecurity measures, depopulation and euthanasia, appraisal and compensation, disposal, and cleaning and disinfection. Surveillance and vaccination are described in Section 6 and 7, respectively.

### 5.1 Epidemiology

The 2010 FMD outbreak lasted approximately 11 weeks from the time the first case was confirmed (April 20) to depopulation of the last known affected farm (July 5) [16, 19]. MAFF estimates that at least 10 farms were infected by April 20. The number of confirmed infected farms increased gradually during Weeks 1 and 2 (April 20 to May 3), then exponentially starting in Week 3 (see Figure 5.1). Week 4 saw the greatest number of new case farms in a single day on May 17 (15 cases) whereas the weekly incidence peaked in Week 5. The number of newly confirmed cases declined progressively starting in Week 6. The last outbreaks were detected in Miyazaki city on June 18 and July 4.

**Figure 5.1: Cumulative weekly incidence of affected farms**



#### 5.1.1 Investigation of affected farms

Once infection was confirmed on a farm, prefectural officials commenced trace-in and trace-out investigations to determine the source and potential spread of infection [15]. Investigators assumed an

average incubation period of 10 days for swine and 7 days for cattle, with a maximum of 14 days for both species. However, each epidemiological investigation traced animal movements onto and off of the farm for 21 days prior to detection of infection.

An epidemiologically-related farm was one which received animals from the affected farm in the 21 days prior to detection of infection, was visited by persons who had been on the affected farm in the past 7 days, or which received any goods derived from the affected farm [19, 26].

#### **5.1.2 Investigation of source of infection**

MAFF conducted an epidemiological investigation to determine the source of the virus; however, at the time this report was written, the source and mode of introduction remain unknown [15, 16]. The working theory is that the virus was brought into Japan from another Asian country through the movement of people or goods. This is supported by the fact that the causative virus strain is closely related to strains isolated from Korea, Hong Kong, and Russia earlier in 2010 (homology of 99.22, 98.59, and 98.9 percent, respectively). NIAH confirmed that cases distant from the main focus of infection in Miyazaki prefecture (e.g., in Ebino city and Miyakonojo city) were caused by the same strain as was isolated from the first case.

#### **5.1.3 Analysis of causes of spread**

A major cause of virus spread was delayed detection [15, 16, 19]. A MAFF report estimates that the virus was introduced into Japan in mid-March, about 4 weeks before the first detection of an infected animal. The delay in detection was compounded by the high density of cattle and swine farms in the area, which facilitated dissemination to other farms [15, 16]. MAFF officials suspect that spread between farms was caused by movement of contaminated people, vehicles, animals, manure, and feed. The virus may also have traveled short distances as droplet nuclei, although limited air sampling detected no virus.

The MAFF report found an epidemiological link between affected farms in the Kawaminami area and some of the outbreaks in outlying areas (cases: Ebino city 1, Saito city 6, and Hyuga city 1), namely movement of people and vehicles belonging to a feed transport company [15, 16]. MAFF also indicated that outbreaks on farms in Saito city and Miyazaki city may have been caused by movement of people and vehicles from the Kawaminami area.

A second significant cause of virus spread was delayed destruction of infected animals, which allowed continued discharge of the virus into the environment [15, 16]. MAFF officials suspect that the affected area of Kawaminami-cho was contaminated with large quantities of virus due to this delay. MAFF considers it unlikely that wildlife played an important role in spreading the infection, since wildlife density in the affected area is low, many farmers use barrier fencing, and surveillance did not detect infection in wildlife (see Section 7).

#### **5.2 Quarantine of individual farms**

Suspect and affected farms were quarantined in accordance with the AIDPL and GFMD [15, 16]. Prefectural officials may issue legally-binding quarantines by telephone upon notification of a suspected infected animal, prior to visiting the farm. Movement of animals, carcasses, milk, bedding, feed, genetic

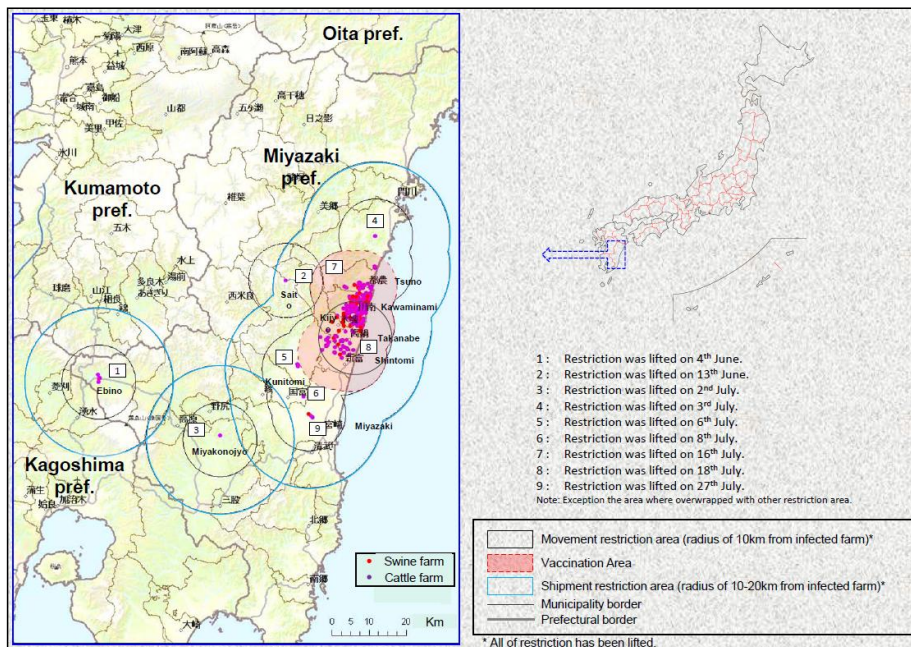
products, and animal waste from quarantined farms is prohibited. Movement of people and other goods onto and off of the farm is restricted.

## 5.3 Movement controls

### 5.3.1 Establishment

Prefectural officials established an MRZ and an SRZ around the first affected farm on 20 April 2010 (case: Tsuno-cho 2) [15, 16]. National guidelines allow for variation in size of these zones between 5 and 30 kilometers; based on known livestock movement patterns, MAFF and Miyazaki prefectural officials decided on an MRZ encompassing a 10 kilometer radius around the affected farm and an SRZ extending another 10 kilometers beyond the boundary of the MRZ. As additional cases occurred within the first MRZ, the perimeter of both the MRZ and SRZ were expanded to maintain the set radii [15, 16]. For example, the initial MRZ in Tsuno-cho progressively expanded as new cases occurred until it encompassed the entirety of the Kawaminami area, which ultimately became the vaccination area (see Section 8). Prefectural officials placed a new MRZ and SRZ around each case that occurred outside of an existing MRZ.

Figure 5.2: Movement control areas [27]



Movement of susceptible animals, carcasses, genetic material, bedding or manure within an MRZ is prohibited by law [16]. Movement of milk from affected farms and high-risk neighboring farms is also prohibited. In addition, slaughter plants and livestock markets are closed, livestock events are canceled, and farmers may not share livestock pasturage.

Movement of susceptible live animals out of an SRZ is also prohibited [16]. Auctions and other livestock events are suspended, although prefectural officials may allow slaughter plants to operate for welfare purposes. Only people working or conducting business should enter farms with susceptible animals, with standard disinfection measures at entry and exit.

By the end of the outbreak, prefectural officials had established 9 primary MRZs (see Figure 5.2) [16]. The MRZs involved 16 municipalities in Miyazaki prefecture, as well as 2 municipalities in Kagoshima prefecture and 1 in Kumamoto prefecture. The SRZs covered 20 municipalities in Miyazaki prefecture, 5 in Kagoshima prefecture, and 4 in Kumamoto prefecture.

### 5.3.2 Release

With one exception, the prefectural government released movement restrictions a minimum of 21 days after the last affected and/or vaccinated farm was depopulated (see Table 5.1 and Figure 5.2), after surveillance as described in Section 7. Movement controls remained in place in areas that overlapped with other restricted areas.

**Table 5.1: Removal of movement controls [16]**

No.	Location	Date last depopulation	Date MRZ released
1	Ebino city	May 13	June 4
2	Saito city 1	May 22	June 13
3	Miyakonojo city	June 10	July 2
4	Hyuga city	June 11	July 3
5	Saito city 2	June 14	July 6
6	Kunitomi-cho	June 16	July 8
7	Kawaminami area	June 21	July 16
8	Takanabe-cho*	July 17	July 18
9	Miyazaki city	July 5	July 27

\*See explanation in text.

One farmer in Takanabe-cho, part of the Kawaminami area, refused to allow vaccination and depopulation of 6 high-value bulls [19]. Depopulation of the last case farm in the Kawaminami area occurred on June 21 and all vaccinated animals were depopulated by June 30. Movement restrictions on the Kawaminami area were lifted on July 16, except around the hold-out farm in Takanabe-cho; prefectural officials established a new 10-kilometer MRZ around this farm. The 6 bulls were depopulated and buried on July 17 under the provisions of the SLCFMD. Since no susceptible animals remained in the area, the movement restrictions were lifted on July 18.

### 5.3.3 The Miyazaki Livestock Improvement Association bulls

The Miyazaki Livestock Improvement Association (MLIA), a semen collection center in the Kawaminami area MRZ, was pivotal in the production of Miyazaki Wagyu beef. The MLIA was home to 254 cattle, including 6 bulls that together accounted for 90 percent of the semen supplied to Miyazaki producers. The herd also included 49 younger bulls undergoing progeny testing.

During the outbreak, the Governor of Miyazaki requested permission from MAFF to move the 6 high-value bulls to a vacant premises in Saito City, located in an existing SRZ [15, 16, 19, 26]. No other livestock farms existed within 5 kilometers of the proposed destination premises and only 2 were located within 10 kilometers. MAFF agreed on the conditions that (1) the bulls tested negative prior to movement; (2) the movement occurred under strict biosecurity conditions; and (3) farmers around the destination farm agreed. The bulls were moved on May 13 and from that point forward were kept separate from one another, with different caretakers, feed, bedding, and equipment for each.

FMD infection was confirmed at the MLIA on May 16 (case: Takanabe-cho 4), three days after the 6 bulls were moved to Saito City [15, 16, 19, 26]. Over 6,000 local farmers signed a petition opposing depopulation of the 49 junior bulls on the grounds that it would cripple the Wagyu breeding industry in Miyazaki prefecture. The bulls were ultimately destroyed on June 7.

Samples were taken from the 6 MLIA bulls on the Saito city premises on May 15, 17, 19, and 20 [15, 16, 19, 26]. One bull was positive on samples taken on May 19 and 20 (case: Saito city 2); this bull was destroyed on May 22 and buried on the premises. The remaining MLIA bulls underwent daily RT-PCR testing for 14 days after the infected bull was destroyed, with negative results. Serum samples were collected for LPBE at 14 days and 21 days after May 22, again with negative results. The bulls tested negative one more time on September 4, when two were moved to Takabaru-cho.

Prefectural officials established an MRZ around the affected Saito city farm but no SRZ, since the route of infection was clearly established, the bulls had been moved under strict biosecurity, and the affected farm was located in a secluded mountain area with little vehicle traffic [15].

#### **5.4 Biosecurity**

In addition to the movement controls described above, Miyazaki and the neighboring prefectures established disinfection stations on the major roads in and around the MRZs [15, 16]. Over 450 separate disinfection stations were established, including 403 in Miyazaki prefecture and 58 in adjacent prefectures (on major arterial roads). Livestock-industry related vehicles, including milk and feed transport trucks, were disinfected when they passed the stations. Disinfection of other vehicles was initially voluntary but became mandatory when the SLCFMD was enacted [16, 19]. In addition, sprinkler trucks sprayed arterial roads in Miyazaki prefecture with disinfectant.

Milk from farms in the SRZs and from unaffected, unvaccinated farms in the MRZs was processed at plants within the same restricted zone [15]. Collection routes were designed to start away from affected farms and move closer. Milk trucks were accompanied by a disinfection truck for spraying the tires and drivers were required to change clothes between farms. Disposition of milk from affected and vaccinated farms is discussed in Section 5.7.

Local veterinary officers throughout Japan notified farmers with susceptible animals about the outbreak in Miyazaki prefecture, by telephone or letter or both [15]. In addition to requesting that farmers report specific symptoms such as drooling and lameness, local veterinary officers asked the farmers to lay down slaked lime at the entrances to farms and increase biosecurity precautions such as restricting visitors and requiring disinfection foot baths.

## 5.5 Depopulation and euthanasia

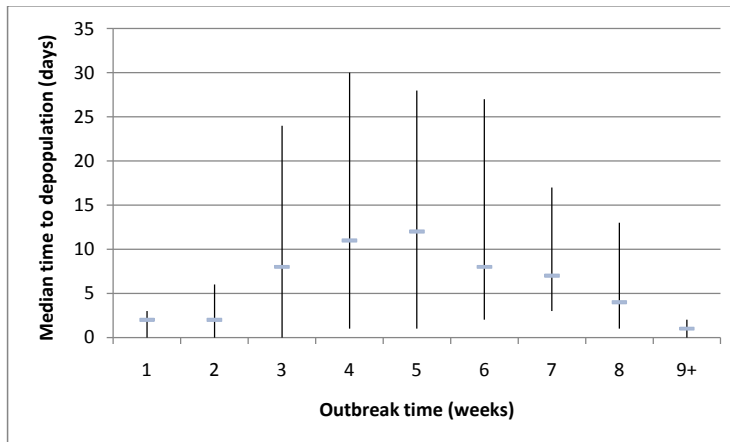
All FMD cases and susceptible animals kept in the same and epidemiologically-related farms were depopulated, amounting to 211,608 animals in total (see Table 5.2) [15, 16]. In addition, all susceptible animals on unaffected, vaccinated farms—76,872 animals in total—were depopulated. Animals on affected farms were destroyed on the farm. Animals on unaffected, vaccinated farms that could not be buried onsite underwent a visual inspection and were sprayed with disinfectant prior to transportation to a nearby burial site, where they were euthanized. The transportation trucks were disinfected between loads.

**Table 5.2: Depopulated animals from affected farms [15, 16]**

Species	No. animals
Cattle	37,412
Swine	174,132
Water buffalo	42
Goats	14
Sheep	8
Total	211,608

During the first 2 weeks of the outbreak (April 20 to May 3), infection was confirmed on 17 farms and the median time from confirmation to depopulation was 2 days (range: 0-6 days) (see Figure 5.3) [16, 19]. However, the pace of the outbreaks rapidly exceeded that of depopulation, due in part to difficulty in identifying and obtaining access to acceptable burial sites. By the fifth week (ending May 24)—in which there were 73 new case farms confirmed—the median time to depopulation had increased to 12 days (range: 1-28 days) and the number of animals targeted for depopulation reached 76,756. The incidence of new cases declined progressively from the sixth week onward, as did the time between confirmation of infection and depopulations. Overall, the median time to depopulation was 9 days (range: 0-30 days).

**Figure 5.3: Time between confirmation of infection and depopulation [19]**



## 5.6 Appraisal and compensation

Owners of animals on affected farms—including affected, vaccinated farms—were compensated by the national government for 80 percent of the market value of the animals killed; the prefectural government supplied the remaining 20 percent [15]. In addition, many farms were insured through the Mutual Aid Association (MAA), which was created by federal law in 1947 and has branches in each prefecture. The MAA provides public insurance to farmers, with 50% of the premiums subsidized by the government. There are different insurance options but all cover natural disasters, fire, and infectious disease. Farmers may choose to have their veterinary services provided through the MAA as well.

If an affected farm was insured through the MAA, the farmer received compensation for depopulated animals at market value from the MAA in addition to the compensation paid by the government [15]. Owners of unaffected, vaccinated farms received 100 percent compensation through the prefecture—actually money allocated to the prefecture by the national government for this purpose—but did not receive insurance money.

## 5.7 Disposal

Since no large-scale incineration or rendering facilities were available, carcasses of animals from affected and vaccinated farms were disposed of by burial within the MRZs [15, 19]. In most cases, carcasses from affected farms were disposed of onsite; however, some carcasses were wrapped in tarps and transported short distances to a common disposal site. The transportation vehicles were disinfected between loads.

The prefecture experienced some difficulty identifying acceptable disposal sites, primarily due to lack of land, opposition by local communities, and unsuitable terrain (rocks, groundwater) [15]. This is reflected in the fact that the number of new case farms peaked on May 17 but the highest prevalence of affected

herds was seen the following week. At the height of the outbreak, the average period between confirmation and burial was over 10 days.

Each burial pit was lined with slaked lime and tarps; carcasses were placed in the bottom and covered with at least 1 meter of soil [28]. The top of the burial mound was covered with more slaked lime. There are 134 burial sites in total, which cannot be disturbed for 3 years [21]. No official environmental analysis was conducted for the burial sites but the prefectural government is monitoring the quality of well water in the area [15].

Contaminated solid waste—primarily manure and bedding—was either buried with the carcasses or composted for a minimum of 40 days on affected farms [15, 16]. Local veterinary officials confirmed an internal temperature of at least 60°C; composted waste that met the time and temperature requirements is being used on fields. Liquid waste and milk from affected farms was treated with citric acid to lower the pH below 5.9 and thereby inactivate the FMD virus. Milk from unaffected, vaccinated farms was similarly treated and then disposed of at industrial waste treatment plants.

## **5.8 Cleaning and disinfection**

Affected farms were cleaned and disinfected with either sodium carbonate or slaked lime, with a target pH of < 5.9 or > 11, respectively [15, 16]. Official crews conducted the initial cleaning and disinfection then farmers were required to conduct 3 additional disinfections at 1 week intervals. An LHSC official checked the farm after the final disinfection.

## **5.9 Recovery**

As discussed above, prefectural officials released movement restrictions a minimum of 21 days after the last affected farm in the zone was depopulated [15, 16]. The last remaining MRZ and SRZ (around Miyazaki city) were lifted on 27 July 2010. Sentinel cattle were reintroduced onto affected farms starting August 31, which were subsequently negative on serological and clinical examination (see Section 7). After a 3-month waiting period, MAFF declared Japan once again free of FMD.

The 2010 FMD outbreak resulted in depopulation of approximately 22 percent of the cattle and 24 percent of the swine in Miyazaki prefecture, including all but 1,400 animals in the Koyu region [15, 29]. As of 20 January 2011, only about 30 percent of the affected farms had started repopulating.

## **5.10 Compliance**

Japanese officials reported very few issues with compliance during the outbreak response [15]. Prefectural officials enlisted the help of police and the municipal self-defense promotion committees in enforcing movement control measures. Several farmers initially refused to allow vaccination and depopulation of their apparently healthy animals; however, veterinary officials either persuaded them to cooperate or seized their animals under the provisions of the SLCFMD.

## **5.11 Discussion**

Once the initial case farm was detected, the official veterinary services implemented disease containment and stamping out measures in accordance with international standards. Initial tracing of epidemiologically-related farms occurred quickly and movement controls were implemented in a timely



manner. Cultural norms, involvement of the local voluntary defense organizations, and police enforcement contributed to high compliance with movement restrictions.

Within 2 weeks, however, the pace of the outbreaks exceeded the pace of depopulation, primarily due to difficulties obtaining access to suitable burial sites. Since Miyazaki prefecture does not contain large-scale rendering or incineration facilities, burial became the preferred option for carcass disposal. The resulting delay in depopulation of affected farms, particularly swine farms, contributed to continuation of the outbreak. Timely application of protective measures such as vaccination and preventive culling was hindered by the absence of legal authority for such actions. Similarly, farmers and the public were not prepared to accept the concept of vaccination-to-kill or the need for scarce land resources—in some cases public land—to be converted to burial sites.

Although the official veterinary services ultimately gained control over the outbreak, comprehensive revision of the AIDPL and GFMD to address the above issues—and hands-on exercises to facilitate implementation—would promote a more effective response in the event of a future outbreak. The special exemption for the MLIA bulls—although perhaps justifiable from the perspective of preserving rare genetics—also created considerable turmoil at the time. Future plans for prefectures to diversify the risk to rare Wagyu genetics—for example, by keeping valuable bulls at several geographically separate sites—would be appropriate.

## **6. Diagnostic laboratory capability**

The animal health laboratory system in Japan consists of the national reference laboratory—the NIAH—and prefectural livestock health laboratories associated with the LHSCs [15, 16]. Prefectural laboratories perform diagnostic tests for common livestock and poultry diseases and typically have facilities for virology (with BSL-2 capability), bacteriology, biochemistry, and pathology. All laboratory tests for FMD diagnosis are carried out in BSL-3 facilities at the NIAH. The laboratory is located in a suburban area outside of Tokyo, with few (if any) livestock in the surrounding neighborhoods.

During the outbreak, local veterinary officers collected samples for FMD testing in accordance with OIE standards and delivered them to the prefectural laboratory [15, 16]. The prefectural laboratories packed the samples, which were then transported by air to the NIAH.

The NIAH supplemented their staff of 8 with 12 staff from the prefectural laboratories during the Miyazaki FMD outbreak but otherwise reported no issues handling the volume of samples. [15]

### **6.1 Identification of agent**

The NIAH tested for FMD virus using reverse transcriptase polymerase chain reaction (RT-PCR), antigen detection enzyme-linked immunosorbent assay (ELISA), and virus isolation, and used antibody detection ELISA and virus neutralization for identification of antibody [15, 16, 27]. The NIAH used RT-PCR for early confirmation of suspect cases, since the test takes only 2.5-6 hours [15]. The RT-PCR targeted the 3D region and was carried out using swabs and/or suspensions of the lesions [16]. The laboratory conducted direct gene sequencing targeting the VP1 gene to analyze homologues. Virus isolation was performed by inoculating swabs and/or suspension of the lesions and/or vesicular fluid into both

primary calf kidney cells and established swine cell lines. The serotype of the isolated viruses was identified using the ELISA Kit for Antigen Detection of FMDV/SVDV.<sup>2</sup>

The FMD virus isolated from the Miyazaki outbreak was serotype O, topotype SEA (South East Asia), and genotype Mya-98 [16, 27]. The base sequence of the VP1 gene was highly related to that of the strains isolated in Hong Kong, Korea, and Russia between February and July 2010.

## **6.2 Identification of antibody**

Once the disease agent was confirmed, liquid phase blocking ELISA (LPBE)—specifically, the ELISA Kit for Serology of FMDV Type O<sup>3</sup>—was used for detection of antibody against FMD [16, 27]. Antibody titers were expressed as the dilution at which the reaction of the test sera results in an optical density equal to 50 percent inhibition of the median optical density of the reaction control well. A titer of less than 1/32 was considered negative, titers greater than 1/90 were positive, and titers in between were nonspecific. The NIAH used the virus neutralization test to elucidate nonspecific results.

The sensitivity of the LPBE is reported to be approximately 99 percent and the specificity 96 percent [19, 26]. The number of nonspecific results requiring further testing was quite low (5 out of 6,006). In each case, the animals were retested after 1 week. Two animals were confirmed negative and 3 others, from a single farm (case: Miyazaki city 3), were confirmed positive via the antigen detection ELISA on the second set of samples.

## **6.3 Discussion**

The NIAH is modern and well-equipped, with well-trained scientific, technical, and administrative staff. Samples in the laboratory can be easily tracked from receipt to final diagnosis and reporting. Biosecurity is good and there is little likelihood that FMD virus could be accidentally carried out of the laboratory. No other laboratory in Japan is approved to work with FMD virus. Tests have been validated and include well-regarded commercial tests kits used in many countries. No tests for non-structural virus proteins were used for diagnosis of cases during the outbreak; however, there was no need to differentiate between field and vaccination strain. Good quality control and assurance programs are in place.

# **7. Surveillance**

## **7.1 Prior to the 2010 outbreak**

Prior to confirmation of the first FMD case on 20 April 2010, Japan relied on passive surveillance for detection and reporting of suspect FMD cases [16]. Unfortunately, it appears that the level of FMD awareness—a key factor in passive surveillance—was low. A private veterinarian reported a cow with erosions in the oral cavity to the Miyazaki LHSC on 9 April 2010 (case: Tsuno-cho 2) and the responding local veterinary officer found clinical signs compatible with FMD, but no samples were taken to test for FMD until April 19 [16]. In the meantime, 2 other cows showed the same clinical signs and the local veterinary officer submitted samples to test for a variety of other diseases. It was only when these tests came back negative that samples were submitted to NIAH for FMD testing.

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<sup>2</sup> Institute for Animal Health, Pirbright, UK.

<sup>3</sup> Institute for Animal Health, Pirbright, UK.

Similarly, buffalo on the presumed index farm (case: Tsuno-cho 1) showed fever, decreased milk production, scars on the udders, and oral erosions by 1 April 2010 [19]. However, local veterinary officials did not test this farm for FMD until April 22, after it was epidemiologically-linked to the first confirmed case farm (case: Tsuno-cho 2).

## **7.2 During the 2010 outbreak**

Veterinary officials conducted active surveillance for detection of FMD-infected animals during the 2010 outbreak, both in Miyazaki prefecture and throughout the country. Japan also conducted active clinical and serological surveillance to reestablish freedom from FMD around affected farms (prior to lifting movement restrictions) and throughout Miyazaki prefecture. Finally, Japan conducted antibody testing of sentinel animals on previously affected farms and targeted surveillance of wildlife in the FMD-affected areas.

### **7.2.1 Disease detection**

#### *Within Miyazaki prefecture*

After the first case was confirmed on 20 April 2010, local veterinary officers conducted telephone interviews of farmers within 3.5 kilometers around the affected farm to ascertain whether their animals were showing clinical signs of FMD [16]. Shortly thereafter, they extended the survey to all farms in the prefecture. Local veterinary officers visited the farms where farmers or veterinarians reported clinically abnormal animals to conduct clinical inspections and collect samples for analysis, which were sent to NIAH. If the samples were confirmed positive, the source farm was recognized as a case and an epidemiological investigation was conducted. Veterinarians also conducted clinical inspections on all farms with susceptible animals in each newly-established MRZ [19].

As the outbreak progressed, veterinary officials noted that the correlation between typical clinical signs of FMD and positive RT-PCR results was very high [16]. Consequently, as of 2 June 2010, suspect animals within the Kawaminami area that showed typical clinical signs of FMD were recognized as cases without laboratory diagnosis. When local veterinary officials found clinical signs compatible with FMD, they took several pictures of the affected parts and sent them to the prefectural veterinary authority and the NIAH, along with a description of the clinical findings and pertinent epidemiological information. If visual confirmation of infection was not possible, samples were taken for diagnostic testing. Laboratory testing confirmed infection in animals on 260 of 292 affected farms in total; conversely, diagnostic testing ruled out FMD infection in suspect animals on 64 of 141 farms. Outside of the Kawaminami area, all suspect animals were subject to laboratory testing.

No additional clinical inspections or serological testing were performed on affected farms once the presence of infection was confirmed; consequently, little data is available to estimate within-herd attack rates on affected farms [15].

#### *Outside of Miyazaki prefecture*

On 20 April 2010, MAFF instructed the veterinary authority of each prefectural government to conduct clinical inspections on all farms with susceptible animals and to take actions to enhance passive surveillance for FMD [16]. Such actions included providing information to farmers and others in the

livestock industry regarding the disease and the Miyazaki outbreak, and requesting that they notify veterinary authorities if animals showed compatible clinical signs. Between 20 April and 3 May, prefectural authorities visited and/or interviewed by telephone farmers with susceptible animals to check for signs of FMD.

These initial surveys resulted in 12 suspect cases, each of which was ruled out on clinical inspection by local veterinary officers [16]. After 4 May, the NIAH received multiple samples from prefectures other than Miyazaki that were tested using RT-PCR (39) and or LPBE (49), with negative results. This rate of sample submission from suspect cases was considerable higher than in 2009 (1), 2008 (1), and 2007 (0) [15, 27].

### 7.2.2 Reestablishing FMD freedom

#### *Around affected farms*

Prior to lifting the restrictions during the 2010 outbreak, prefectural authorities conducted clinical inspections of all susceptible animals in the MRZ [15, 16]. In addition, all remaining farms with susceptible animals located within a 3 kilometers radius from an affected farm were subject to serological testing using LPBE (see Table 7.1). Serological testing started approximately 10 days after the last affected farm was depopulated. Surveillance was not conducted in the zone where vaccination was practiced, since all susceptible animals within the zone were depopulated [16].

**Table 7.1: Surveillance around affected farms\* [16]**

Surveillance Type	Cattle		Swine		Other	
	Farms	Animals	Farms	Animals	Farms	Animals
Serological (3 km)	535 (1)	5,417 (3)	21 (0)	624 (0)	2 (0)	32 (0)
Clinical (10 km)	2,918 (1)	99,997 (1)	207 (0)	299,570 (0)	22 (0)	185 (0)

\*Numbers in () indicate positive results; see explanation in text.

Per MAFF officials, random sampling of the animals on each farm was conducted at a level designed to detect 1 infected animal if the within-herd prevalence was at least 10 percent, with 95 percent confidence [16, 19, 26]. This equated to sampling of all animals on farms with  $\leq 15$  animals, 21 samples on farms with  $\leq 40$  animals, and so on, up to 30 samples on farms with more than 100 animals.

While conducting clinical inspections for release of the Miyazaki city MRZ, veterinary officials detected a single cow with clinical signs of FMD [16]. Serologic testing confirmed infection in 3 animals on the farm—the last case farm of the 2010 outbreak (Miyazaki city 3). The Miyazaki city MRZ was ultimately lifted on July 27.

#### *Miyazaki prefecture*

Clinical surveillance—Between July 22 and August 9, Miyazaki prefecture conducted clinical surveillance targeting all cattle and swine kept in the prefecture [16]. A total of 946,424 animals on 8,076 farms were surveyed: 229,935 cattle on 7,608 farms and 716,489 swine on 468 farms. No evidence of clinical signs typical of FMD was detected.

Serological surveillance—From September 6 to 13, veterinary authorities conducted a final surveillance to reestablish FMD freedom, targeting Miyazaki prefecture as the high-risk area [16, 26]. Surveillance

was conducted on a random sample of 150 cattle farms within the prefecture, at a level designed to detect 1 infected herd if the herd prevalence was at least 2 percent, with 95 percent confidence. Sampling of cattle within each herd followed the protocol as described above. A total of 2,124 samples were tested by LPBE with negative results (see Table 7.2).

**Table 7.2: Final surveillance within Miyazaki prefecture [16]**

Location	No. Farms	No. Animals
Aya town	5	125
Ebino city	10	171
Gokase town	2	23
Hinokage town	2	22
Hyuga city	5	43
Kobayashi city	20	178
Kunitomi town	2	31
Kushima city	6	116
Mimata town	10	152
Misato town	5	56
Miyakonojo city	30	588
Miyazaki city	10	62
Nichinan city	10	206
Nishimera village	3	9
Nobeoka town	10	76
Saito city	4	87
Takachiho town	6	52
Takahara town	10	127
Total	150	2,124

### 7.2.3 Antibody testing of sentinel animals

Between August 31 and October 22, sentinel cattle were introduced onto 175 previously-affected farms [26]. Farmers were required to conduct daily clinical observations of the cattle and local veterinary officers conducted clinical inspections 3 to 4 weeks after introduction. Serum samples collected on the day of introduction and 3 to 4 weeks after were subject to LPBE testing, with negative results.

### 7.2.4 Wildlife surveillance

#### *Wildlife populations*

The FMD-susceptible wildlife species in Japan are sika deer (*Cervus nippon*), wild boar (*Sus scrofa*) and the Japanese serow (*Capricornis crispus*) [16]. Sika deer are distributed throughout Japan, including in the area of the FMD outbreaks. Wild boar are found on Kyushu Island and other areas of Japan. Japanese serows inhabit a mountainous region in the central part of Kyushu Island but are rarely seen in Miyazaki prefecture. Farmers in the prefecture have traditionally erected fencing to limit contact between domestic livestock and wild animals.

A survey by the Japanese National Institute of Forestry found that the range of movement of sika deer on Kyushu Island is no more than 8 kilometers [16]. Similarly, a MAFF survey found that movements of wild boar in Japan are limited to a fairly narrow range.

#### *Surveillance*

Considering the distribution of the FMD outbreaks and the limited range of susceptible wildlife species, surveillance targeting wildlife was restricted in Miyazaki prefecture [16]. Hunting of wildlife is prohibited in Japan except for restrictive measures to cull nuisance species, including sika deer and wild boar. Hunting of Japanese serows, which is a protected species, is prohibited.

Between August 20 and October 25, 145 samples were collected from wildlife hunted as nuisance species, including sika deer (46) and wild boar (99); 63 samples (43 percent) came from animals hunted in municipalities where FMD had occurred in domestic livestock [16, 30]. The samples were tested by the NIAH using LPBE, with negative results.

In addition, the carcasses of dead and injured susceptible wildlife found throughout Miyazaki prefecture were collected and tested for FMD [16]. Fourteen samples were tested by the NIAH—5 sika deer, 7 wild boar, and 2 Japanese serows—using RT-PCR, with negative results. All samples came from animals found in cities and towns where FMD had occurred in domestic livestock.

### **7.3 Discussion**

Failure of passive surveillance to quickly detect FMD contributed substantially to the extent of the 2010 outbreak. While atypical clinical signs of FMD in water buffalo may have contributed to the delay in detection, a low index of suspicion among both farmers and local veterinary officers was likely also a factor. As a result of the outbreak, however, the level of awareness among farmers and veterinarians throughout Japan is now quite high.

All reports indicate that the outbreak virus strain caused overt clinical signs of FMD infection in cattle and swine, lending confidence to the results of clinical surveillance during the 2010 outbreak. Photographing suspect lesions for diagnostic purposes was an innovative solution that likely saved considerable time and resources, considering the high correlation between clinical signs and positive test results. Active clinical and serological surveillance within the restricted zones proved sufficient for detection of additional case farms within Miyazaki prefecture.

Surveillance for lifting restriction zones included serological testing on all farms within a 3-kilometer radius and clinical surveillance of all farms within a 10-kilometer radius. The sampling scheme used for serological surveillance was statistically sufficient to allow 95 percent confidence of detecting FMD infection at the given prevalence level.

Targeting Miyazaki prefecture for final surveillance to reestablish disease freedom was appropriate, considering that 95.5 percent of the outbreaks occurred in the Kawaminami area, which is located more than 20 kilometers away from the prefectural borders. Similarly, targeting wildlife in close proximity to human settlements—and therefore presumably at greatest risk for contracting FMD—was a reasonable decision.

APHIS concludes that Japanese officials carried out comprehensive surveillance for detection of infection and for reestablishment of FMD freedom in the high-risk area. Based on the surveillance results, there is no evidence to suggest that FMD virus continues to circulate in Japan.

## **8. Vaccination practices**

The Japanese government commenced emergency vaccination on May 22, representing the first time animals in Japan were vaccinated against FMD [15, 16]. At the time, the number of outbreaks in the Kawaminami area was increasing rapidly and there was a substantial delay in depopulation and disposal of animals on affected farms, increasing the risk of infection spreading to other municipalities.

### **8.1 Vaccine strain**

A panel of Japanese experts selected an oil-adjuvant, inactivated vaccine against FMD Type O (O1-Manisa) for use in cattle, swine, water buffalo, and small ruminants [16].<sup>4</sup> The correlation between the vaccine strain and the closely-related Hong Kong strain was considered high enough to elicit an effective response ( $r = 0.5$  by the cross-neutralization test). The label potency was at least 6 PD<sub>50</sub> per dose. MAFF routinely stockpiles various FMD vaccines and had 40 thousand doses on hand. Additional vaccine was obtained from the manufacturer.

### **8.2 Vaccination program**

The vaccination program was designed by MAFF experts and prefectural authorities [16]. The target area consisted of the MRZ around affected farms in the Kawaminami area (see Figures 2.2 and 5.2). All susceptible animals within this area—except animals less than 14 days of age—were targeted for vaccination, with swine receiving higher priority than cattle. Vaccination was conducted from the rim to the center of the area.

Vaccination was carried out by designated teams of local veterinary officers, AQS officers, and other veterinarians under official supervision [16]. Each animal was examined for clinical signs of FMD prior to vaccination; if clinical signs were detected, no vaccination occurred and the entire team was transferred to depopulation duties. Each animal was vaccinated only once since they were to be destroyed promptly after vaccination. Vaccination was carried out between May 22 and 26, at which point over 99 percent of the target animals had been vaccinated.

### **8.3 Management of vaccinated animals**

Vaccinated animals were maintained on their respective farms until depopulation [16]. The eartag numbers of vaccinated cattle were recorded and movement of vaccinated animals was prohibited. Depopulation of vaccinated animals started on 5 June 2010, after the SLCFMD was enacted. Depopulation and burial of animals on vaccinated farms was completed on June 30.

A total of 125,668 animals on 1,066 farms—including 45,944 cattle, 79,606 swine, and 118 other animals—were vaccinated [16]. However, FMD was confirmed on 68 farms after vaccination, accounting for 48,796 animals: 15,090 cattle, 33,704 swine, and 2 goats.

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<sup>4</sup> Aptopor by Merial Animal Health Ltd.

#### **8.4 Surveillance of vaccinated animals**

MAFF conducted limited surveillance of vaccinated animals, evaluating seroconversion in 10 animals from 6 vaccinated farms (2 beef cattle, 2 dairy cattle, and 2 swine) using LPBE [15]. Samples were taken 8 to 10 days after vaccination. Approximately 50 percent of the vaccinated animals showed a negative (titer  $\leq 32$ ) or indeterminate (titer  $> 32$  but  $\leq 90$ ) response.

#### **8.5 Discussion**

Considering the logistical issues with regard to disposal and the large number of animals on affected farms awaiting depopulation, the decision to vaccinate to control the spread of FMD and limit virus shedding was appropriate. Infection was detected as soon as 1 day after vaccination, raising concerns that the vaccination teams may have transmitted the virus to other farms. Conversely, infection was detected as late as 19 days after vaccination, with no apparent diminution of clinical signs, raising concerns about the degree of protection conveyed by single vaccination. Nonetheless, the incidence of new cases declined in the sixth week of the outbreak, after vaccination.

### **9. Epidemiological separation from potential sources of infection**

#### **9.1 Disease status of adjacent regions**

Japan is an island nation, with no shared land borders. However, there is considerable movement of people and personal goods between Japan and other Asian countries, including Korea and the People's Republic of China (China).

##### **9.1.1 Korea**

Korea reported outbreaks in January 2010 of FMD serotype A involving 7 farms; this was the first report of FMD since 2002 [14]. Korea also reported 2 outbreaks of serotype O in April 2010, collectively involving 13 farms. It appeared that Korea quickly resolved both the January and April outbreaks; however, FMD serotype O reoccurred in November 2010 and quickly spread throughout the country. In January 2011, Korea began a nationwide vaccination campaign as part of the FMD control efforts.

##### **9.1.2 China**

FMD appears to be endemic in China, with multiple outbreaks occurring each year. In 2010, China reported 18 farms distributed throughout the country affected with serotype O and a single farm affected with serotype A [14]. Outbreaks involving serotype Asia 1 have also occurred in recent years.

##### **9.1.3 Other countries**

Russia reported outbreaks of FMD serotype O in July and September 2010, each involving a single farm [14]. There are also reports of FMD outbreaks in the Democratic People's Republic of Korea beginning in 2007 [14].

#### **9.2 Import practices and trading partners**

MAFF conducts evaluations of the disease status of foreign regions through risk assessment, including a site visit, and decides on any mitigation measures needed and commodity-specific import requirements [15]. MAFF prohibits importation of live susceptible animals and derived products from countries with



rinderpest, FMD, classical swine fever, and other such diseases unless the products are heat treated according to set protocols. Live animals, plants, and associated products must be accompanied by a health document certified by the veterinary authority of the exporting region.

AQS is responsible for import/export inspection, including certificates of export inspection and carries out the pertinent provisions of the AIDPL and other laws [15, 31]. AQS consists of a headquarters office in Yokohama (near Tokyo), 7 branch offices, and 16 sub-branches. As of December 2010 there were 369 AQS officers employed. Each is a licensed veterinarian who has undergone on-the-job training.

### **9.2.1 Animals and animal products**

Japan is a net importer of live animals and animal products [32]. From 2006 to 2010, Japan averaged 21 thousand cattle per year, all from Australia and New Zealand, but exported only 12 cattle. The number of imported swine has remained around 400 per year, from Canada, the United States, and various European Union (EU) Member States. Japan exports less than 30 swine per year.

Japan imports a considerable amount of fresh beef per year, averaging 215 million kilograms [32]. In 2010, Australia and the United States provided approximately 74 and 20 percent of the imported beef, respectively, with the remainder supplied by New Zealand, Canada, and Mexico. Japan exports around 210 thousand kilograms of fresh beef per year, primarily to Hong Kong and the United States.

Japan is also a net importer of fresh pork, averaging over 770 thousand kilograms per year [32]. In 2001, the United States provided approximately 40 percent of the imported pork, with Canada and Denmark contributing 24 and 18 percent, respectively. The remainder was supplied by Mexico, Chile, and various EU Member States. Japan exported 153.6 thousand kilograms of fresh pork in 2010, primarily to Hong Kong.

Although not reflected in recent transactions, Japan also allows importation of live cloven-hoofed animals, genetic materials, and/or meat from several regions that APHIS does not consider free of FMD, namely Singapore, Romania, Croatia, Bosnia Herzegovina, Northern Mariana, and Vanuatu [31].

### **9.2.2 Animal feed**

Contaminated wheat straw was implicated in the 2000 FMD outbreak in Japan and Japan currently allows importation of grain straw and hay for animal feed from regions that APHIS does not consider free of FMD [15, 31]. Most notably, Japan imports substantial amounts of rice straw from China each year, since there is not enough arable land to grow sufficient forage for livestock in Japan. Rice straw from China is processed in dedicated plants with a Japanese inspector onsite to check the core temperature of each lot. The straw is shipped to Japan in sealed containers and tested upon arrival. The failure rate on import testing in 2010 was 0.15 percent, due to a missing seal on one container. Over the past 3 years, no shipment has been refused due to insufficient heat treatment.

### **9.2.3 Inspection practices**

Animals and animal products presented for import must be accompanied by a certificate of inspection issued by the veterinary authority of the exporting country [21]. Live animals undergo inspection by AQS veterinarians and embarkation quarantine, during which time the animals undergo clinical inspection and diagnostic testing [15, 31]. AQS also informs the prefectural veterinary officials for the farm of

destination, who are responsible for follow-up inspections. Live animals denied entry may be reshipped or destroyed with pathological examination.

For meat and meat products, an AQS officer checks the documents and the container seal, selects a pallet to bring to the inspection room, and randomly selects which boxes to open [15, 31]. Heat-treated meat products have a tracer tag that corresponds to a specific MAFF-approved heat-treatment plant in the exporting country. The AQS officer checks the contents and that the company name matches the documentation, and takes a sample to the office to defrost. Heat treatment is tested by cutting the meat and looking for color. If improper heat treatment is suspected, AQS takes samples for testing. Meat and meat products that are denied entry may be reshipped or incinerated.

Consignments of rice straw undergo document inspection and physical inspection by both animal and plant quarantine officers [15]. All consignments are inspected. The officers check the seal on the container, open the container and take a 1 percent sample, check that it really is rice straw and heat treated, and look for plant pests. The officers also verify the tracer tag.

### **9.3 Foreign travelers**

Multiple ports throughout Japan receive travelers from FMD-infected countries, including Korea, China, other parts of Asia, and Russia [15]. MAFF officials consider this to be a primary risk route for introduction of FMD virus into Japan. Consequently, MAFF and AQS have implemented biosecurity measures at airports for all persons arriving from international destinations, from aggressive public awareness campaigns to announcements on inbound flights to floor mats soaked in disinfectant that travelers must cross. AQS also uses trained dogs to detect animal products in hand luggage.

Although the current customs declaration form does not ask about time spent on farms or with livestock, AQS announcements in the baggage claim area request that persons who have been on a farm or have soiled shoes (golf shoes) self-identify and present their shoes for cleaning and disinfection at designated stations [15]. Garbage produced on-flight is either retained on the aircraft and returned or incinerated at designated facilities.

### **9.4 Discussion**

Japan has taken additional precautions since the introduction of FMD virus via wheat straw in 2000 and it appears unlikely that imported straw was again the source. Similarly, although Japan is a net importer of cattle, swine, and derived products, imports in recent years have only originated from regions that APHIS considers free of FMD. However, there is considerable movement of persons and personal goods into Japan daily from regions that are currently experiencing FMD outbreaks, including China and Korea. MAFF and AQS are implementing comprehensive controls and a public education campaign to address the risk of introducing FMD virus via this route.

## **10. Conclusions**

APHIS concludes that the authority, organization, and infrastructure of Japan's official veterinary services were sufficient to control and eradicate the 2010 FMD outbreak. Delay in detection of the first cases allowed considerable virus spread and contamination of the affected area, contributing to the scope of the outbreak. Logistical difficulties regarding carcass disposal and lack of legal authority for

precautionary culling complicated the outbreak response. However, the official veterinary services ultimately overcame these issues and proceeded to stamp out the FMD virus.

The level of surveillance conducted within Miyazaki prefecture prior to 6 October 2010 was sufficient to allow over 95 percent confidence of detecting FMD virus, if present. The fact that no additional cases have been reported in the interim lends confidence to the conclusion that FMD virus is no longer circulating. Clinical inspections and diagnostic testing of suspect cases throughout the rest of Japan found no evidence of FMD infection outside of Miyazaki prefecture.

Once the authority for precautionary culling was obtained, the official veterinary services were able to effectively use vaccination to limit virus production and spread. Since all vaccinated animals were subsequently depopulated, APHIS concludes that Japan is free of FMD without vaccination.

Note: In keeping with OIE guidelines for risk analysis, since the release assessment has demonstrated no significant risk, the APHIS analysis of Japan's FMD status does not extend to exposure and consequence assessments. See the following page for the risk estimate.

## **Risk estimate**

APHIS concludes from this assessment that Japan is free of FMD without vaccination. Japan has also implemented comprehensive controls to address the risk of FMD virus introduction from affected countries. Should such introduction occur, the high level of public awareness generated by the 2010 FMD outbreak would facilitate rapid detection and response. Consequently, there is no risk barrier to reinstating Japan to the list of regions considered free of FMD in title 9, Code of Federal Regulations, section 94.1 (9 CFR 94.1). Live ruminants and swine from Japan would remain prohibited due to Japan's status for bovine spongiform encephalopathy, classical swine fever, and swine vesicular disease. Ruminant meat and fresh pork would also remain prohibited, except for boneless cuts of fresh beef (Wagyu beef) imported in accordance with 9 CFR 94.27.

## References

1. Coetzer J.A.W., G.R. Thomsen et al. 1994. Foot-and-mouth disease. In: *Infectious Diseases of Livestock with Special Reference to Southern Africa*. Coetzer, J.A.W., G.R. Thomsen et al. (Eds). Cape Town, Oxford University Press: 825-852.
2. Alexandersen, S., Z. Zhang, et al. 2003. The pathogenesis and diagnosis of foot-and-mouth disease. *J Comp Pathol* 129(1): 1-36.
3. Belsham, G. J. 1993. Distinctive features of foot-and-mouth disease virus, a member of the picornavirus family; aspects of virus protein synthesis, protein processing and structure. *Prog Biophys Mol Biol* 60(3): 241-60.
4. Bachrach, H. L., S. S. Breese et al. 1957. Inactivation of foot-and-mouth disease virus by pH and temperature changes and by formaldehyde. *Proc Soc Exper Bio Med* 95: 147-52.
5. Cottral, G. E. 1969. Persistence of foot-and-mouth disease virus in animals, their products and the environment. *Bulletin OIE* 70: 549-68.
6. OIE. 2011. Technical disease card for FMD. World Organization for Animal Health. Available on the internet at: <http://www.oie.int/en/animal-health-in-the-world/technical-disease-cards/>.
7. Burrows, R., J. A. Mann, et al. 1981. The pathogenesis of natural and simulated natural foot-and-mouth disease infection in cattle. *J Comp Pathol* 91(4): 599-609.
8. Farez, S. and R. S. Morley. 1997. Potential animal health hazards of pork and pork products. *Rev Sci Tech OIE* 16: 65-78.
9. APHIS. 1994. Foot-and-mouth disease: Sources of outbreaks and hazard categorization of modes of virus transmission. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Center for Epidemiology and Animal Health.
10. Barnett, P. V. and S. J. Cox. 1999. The role of small ruminants in the epidemiology and transmission of foot-and-mouth disease. *Vet J* 158(1): 6-13.
11. Donaldson, A. I. and R. F. Sellers. 2000. Foot-and-mouth disease. In: *Diseases of Sheep*, 3rd edition. W. B. Martin and I. D. Aitken (Eds), Blackwell Science, Oxford: 254-258.
12. Donaldson, A. I. 1998. Experimental and natural adaptation of strains of foot-and-mouth disease virus to different species. Session of the Research Group of the Standing Technical Committee, European Commission for the Control of Foot-and-Mouth Disease: 18-22.
13. CIA. 2011. The World Factbook. Central Intelligence Agency, Langley, VA. Available on the internet at: <https://www.cia.gov/library/publications/the-world-factbook/index.html>.
14. OIE. 2011. World Animal Health Information Database. World Organization for Animal Health. Available on the internet at: <http://web.oie.int/wahis/public.php?page=home>.
15. APHIS. 2011. APHIS site visit report - Japan FMD: January 17-21, 2011. Animal and Plant Health Inspection Service, Veterinary Services, Regionalization Evaluation Staff.
16. MAFF. 2010. Recovery of FMD country free status: Japan's report to the World Organization for Animal Health (OIE) to recover country freedom from FMD without vaccination. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Dated October 6, 2010.
17. OIE. 2011. Official disease status: FMD. World Organization for Animal Health. Available at: <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/lossreinstatement-of-status/>.
18. MAFF. 2011. Ministry of Agriculture, Forestry and Fisheries webpage. Available on the internet at: <http://www.maff.go.jp/e/index.html>.
19. MAFF. 2011. Answers to the questions of the USDA. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Received January 17, 2011.

20. Miyazaki LHSC. 2011. Miyazaki Livestock Hygiene Service Centers handout. Document provided to the site visit team on January 19, 2011.
21. Government of Japan. 1951. Domestic Animal Infectious Disease Control Act (Act No. 166) (as amended).
22. JVMA. 2010. Overview of veterinary medicine in Japan. Japan Veterinary Medical Association. Available on the internet at: <http://nichiju.lin.gr.jp/international/docment/2009.pdf>.
23. Sugiura, K., S. Shinkawa, and J. Mago. 2008. Current supply and demand of veterinarians in Japan. *Veterinaria Italiana* 44(2): 297-304.
24. Anon. 2011. Report of the Independent Committee for Verification of the Containment and Eradication of FMD in Miyazaki Prefecture (Executive Summary). Document provided to the APHIS site visit team on January 21, 2011.
25. MAFF. 2011. Beef production in Japan. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Received January 17, 2011.
26. MAFF. 2011. Answers to the questions of the CFIA. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Received January 17, 2011.
27. Sakamoto, K. 2011. 2010 FMD outbreak in Japan. Presentation provided to the APHIS site visit team at the National Institute for Animal Health on January 21, 2011.
28. Miyazaki Agriculture and Fisheries Department. 2010. Operational manual for the burial of culled FMD animals. Document provided to the APHIS site visit team on January 20, 2011.
29. Miyazaki Agriculture and Fisheries Department. 2011. The impact of FMD. Document provided to the APHIS site visit team on January 19, 2011.
30. MAFF. 2011. Additional wildlife surveillance data. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Received January 21, 2011.
31. AQS. 2011. The outline of the Animal Quarantine Service. Presentation provided to the APHIS site visit team on January 17, 2011.
32. GTA. 2011. Global Trade Atlas. Global Trade Information Service, Inc. Available on the internet at: <http://www.gtis.com/english/>.

## **Annex: Outbreak chronology**

**March 19**—*Estimated date of introduction of FMD virus.*

**March 31**—*First symptoms reported on index farm in Tsuno-cho*—A farmer in Tsuno-cho reported diarrhea and fever in 1 of his 42 water buffalo to the Miyazaki Livestock Hygiene Service Center (case: Tsuno-cho 1). Two swine also lived on the farm.

**April 9**—*First suspect FMD case reported to prefectural veterinary services*—A private veterinarian reported a possible case of FMD in cattle on a farm in Tsuno-cho to the prefectural veterinary services (case: Tsuno-cho 2). A prefectural veterinarian visited the farm and observed that the cow had fever, anorexia, salivation, and erosions in the oral cavity but that other animals exhibited no clinical signs. No further action was taken at the time.

**April 16**—Two more animals on the Tsuno-cho 2 farm exhibited the same clinical signs. The prefectural veterinary services submitted laboratory samples to test for bluetongue, bovine viral diarrhea, infectious bovine rhinotracheitis, and Ibaraki disease.

**April 19**—*First samples for FMD testing submitted to laboratory*—Negative laboratory results were returned for the above diseases. The prefectural veterinary services submitted samples to the National Institute for Animal Health (NIAH) to test for FMD.

**April 20**—*Laboratory confirmation of FMD infection*—The NIAH confirmed FMD virus in the samples from the Tsuno-cho 2 farm, using RT-PCR. The prefectural veterinary services implemented a movement restriction zone (MRZ) around the affected farm, started an epidemiological investigation, depopulated and buried all susceptible animals on the farm (16 head of cattle), began cleaning and disinfection procedures.

Also on April 20—*First involvement of national veterinary services*—MAFF set up an FMD Control and Prevention Department in Tokyo to direct the eradication efforts. MAFF also notified the OIE of the outbreak and suspended all export certificates for ruminants and derived products.

**April 21-23**—MAFF reported 4 case farms in Kawaminami-cho (cases: Kawaminami-cho 1-4) and 1 in Tsuno-cho (case: Tsuno-cho 1); all cases occurred within the established MRZ. The NIAH later confirmed FMD virus antigen in a sample taken from the sick water buffalo on the Tsuno-cho 1 farm on March 31. Depopulation and burial of susceptible animals on these farms occurred April 22-25.

**April 22**—*Virus serotype identified*—The NIAH confirmed FMD virus serotype O from the first reported case (case: Tsuno-cho 2), using antigen detection ELISA.

**April 24-28**—MAFF reported 3 case farms in Kawaminami-cho (cases: Kawaminami-cho 5-7) and 1 in Ebino city (case: Ebino city 1), which is located some 60 kilometers west. The prefectural government placed an MRZ around the Ebino city 1 farm, which affected parts of neighboring Kumamoto and Kagoshima prefectures. All susceptible livestock on the affected farms were depopulated and buried April 28 to May 4.

April 26—*First laboratory-confirmed case in swine*—One of the newly-detected Kawaminami-cho farms (case: Kawaminami-cho 6) housed 486 swine, five of which were confirmed infected on April 26; all of the animals were destroyed on April 28.

**April 29-May 5**—MAFF reported a second case farm in Ebino city (case: Ebino city 2) and 12 additional cases in Kawaminami-cho (cases: Kawaminami-cho 8-19). All affected farms were located in one of the previously established MRZs. Depopulation and burial of susceptible animals occurred between April 30 and May 13.

May 1—The Japanese government dispatched a contingent of the Japan Self Defense Force Miyazaki prefecture to help with FMD control measures.

**May 6-12**—MAFF reported 53 additional cases in Ebino city (case: Ebino city 3), Tsuno-cho (cases: Tsuno-cho 3 and 4), and Kawaminami-cho (cases: Kawaminami-cho 20-69), bringing the total number of case farms to 76. All affected farms were located within the existing MRZs. Depopulation of susceptible animals occurred May 8 to June 5.

**May 13-19**—MAFF reported 55 more cases, primarily in Kawaminami-cho (cases: Kawaminami-cho 70-116). However, infected animals were also found on farms in Shintomi-cho (cases: Shintomi-cho 1 and 2), Takanabe-cho (cases: Takanabe-cho 1-4), Tsuno-cho (case: Tsuno-cho 5), and Ebino city (case: Ebino city 4). All affected farms were located within the established MRZs. Depopulation occurred from May 16 to June 16.

May 13—*Evacuation of MLIA bulls*—With special clearance from MAFF, six valuable Wagyu breeding bulls were moved from the Miyazaki Livestock Improvement Association (MLIA) farm in Takanabe-cho to a vacant farm in Saito city; the bulls tested negative just before departure.

May 16—FMD was diagnosed at the MLIA farm in Takanabe-cho (Takanabe-cho 4); the 6 bulls evacuated to Saito city remained under observation.

May 17—The Japanese government assigned 20 officials to the task force at the prefectural office, including a MAFF deputy minister and an assistant to the Prime Minister; their primary duties were providing financial support to farmers and making arrangements with related ministries.

May 18—The Governor of Miyazaki Prefecture declared a state of emergency.

May 19—Culling of susceptible animals on affected farms had stalled at approximately 67 percent.

**May 20-26**—MAFF reported 87 more cases, bringing the total number to 218. The majority of cases occurred in Kawaminami-cho (cases: Kawaminami-cho 117-169), Tsuno-cho (cases: Tsuno-cho 6-13), Takanabe-cho (cases: Takanabe-cho 5-16), and Shintomi-cho (cases: Shintomi-cho 3-12). However, affected farms were also detected in neighboring Kijo-cho (cases: Kijo-cho 1-3) and Saito city (cases: Saito city 1-3). Three of the outbreaks occurred on vaccinated farms. The elapsed time between vaccination and clinical signs of infection ranged from 1 to 3 days. Depopulation of susceptible animals on affected farms occurred from May 21 to June 23.

May 21—*FMD confirmed in evacuated MLIA bull in Saito city*—One of the 6 breeding bulls evacuated from the MLIA farm in Takanabe-cho to Saito city was confirmed infected with FMD virus (case: Saito



city 2). The infected bull was destroyed on May 22, but the other 5 breeding bulls were spared. Veterinary officials considered these bulls to have a different epidemiologic status because they were kept strictly separated on the Saito city farm.

Also on May 21—*Only laboratory-confirmed case in goats*—One of 2 pet goats on a farm in Kawaminami-cho (case: Kawaminami-cho 147) exhibited clinical signs of FMD and tested positive using RT-PCR. Both goats were destroyed on May 26; there were no other susceptible animals on the farm.

May 22—*Vaccination against FMD begun*—The official veterinary services started emergency vaccination against FMD, targeting all domestic susceptible animals on unaffected farms within the Kawaminami area. Vaccination outside of this area remained prohibited. Vaccination occurred from the perimeter of the MRZ towards the center, with higher priority for given to swine than cattle.

Also on May 22—*Only involvement of sheep in 2010 outbreak*—FMD infection was detected cattle on a farm in Saito city that also had 8 sheep (case: Saito city 3). None of the sheep showed clinical signs and all were depopulated without laboratory testing.

May 24—Surveillance testing started to confirm FMD-free status of the MRZ around Ebino city.

As of May 25, approximately 120,000 animals had been vaccinated in 2 cities and 5 towns (95 percent of target). Some farmers had not yet agreed to vaccination.

**May 27-June 2**—MAFF reported 35 additional cases (cases: Kawaminami-cho 170-183; Tsuno-cho 14-24; Takanabe-cho 17-22; Shintom-cho 13 and 14; and Saito city 4 and 5); all case farms were located within the existing MRZs. Vaccination of swine was completed with 79,603 animals vaccinated; the number of vaccinated cattle reached 45,612. Thirty-three of the new case occurred on farms that had been vaccinated. The elapsed time between vaccination and clinical signs of infection ranged from 2 to 7 days. All susceptible livestock on the affected farm were depopulated between May 29 and June 24.

June 2—The prefectural veterinary authorities started classifying animals showing typical clinical signs of FMD on farms located in the MRZ around Kawaminami-cho as FMD cases without PCR testing, based on previously high correlation between clinical signs of FMD and positive PCR results. PCR testing of suspicious animals without clinical signs or kept in other areas continued.

**June 3-10**—MAFF reported 26 more cases (cases: Kawaminami-cho 184-196; Tsuno-cho 25-30; Takanabe-cho 23-25; Shintomi-cho 15-17; Kijo-cho 4). All were on vaccinated farms; the elapsed time between vaccination and clinical signs of infection ranged from 4 to 15 days. Depopulation and burial of susceptible animals on affected farms occurred June 5-21.

June 4—The MRZ around Ebino city 1-4 was lifted, following active clinical and serological surveillance of all susceptible domestic animals in the area.

June 5—*Destruction of vaccinated animals begun.*

**June 11-15**—MAFF reported 7 additional cases within existing MRZs (cases: Kawaminami-cho 197 and 198; Saito city 6-8; Kijo-cho 5; and Shintomi-cho 18). Five were vaccinated farms. Elapsed time between vaccination and detection exceeded 14 days on 4 of the 5 farms (range 16 to 19 days). MAFF also reported single cases in the new areas of Hyuga city, Miyakonojo city, and Miyazaki city. The official

veterinary services established MRZs around the each of the new areas. Depopulation of susceptible animals on affected farms occurred June 10-20; depopulation of vaccinated, presumably uninfected animals was ongoing.

**June 13—*Quarantine released on MLIA bulls***—The MRZ around the case farm in Saito city where the remaining MLIA bulls resided (case: Saito city 2), 21 days after the outbreak occurred. Laboratory testing found no evidence of FMD virus in the 5 remaining bulls on the premises; susceptible animals on 2 farms within 10km of the affected farm were also checked.

**June 16-23**—MAFF reported 2 more case farms, 1 in Miyazaki city (case: Miyazaki city 2) and the other in the new area of Kunitomi-cho (case: Kunitomi-cho 1); neither farm had been vaccinated.

**June 30—*Destruction of vaccinated animals completed***—Destruction of all susceptible animals in the vaccination area was completed.

**July 2**—The MRZ around the Miyakonojo city case (case: Miyakonojo city 1) was lifted. The absence of infection was demonstrated by serological surveillance targeted at all susceptible animals kept within 3 kilometers around infected farms and on epidemiologically-related farms, as well as by clinical surveillance targeted at all susceptible animals in the area.

**July 3**— The MRZ around the Hyuga city case (case: Hyuga city 1) was lifted; same surveillance plan as above.

**July 6**—The MRZ around the other Saito city cases was lifted; same surveillance plan as above.

**July 4**—One new outbreak was detected on an unvaccinated farm in Miyazaki city (case: Miyazaki-3), within the MRZ around Miyazaki city. The farm was located approximately 800 meters from the last case detected June 18. All susceptible animals on the farm were destroyed on July 5.

**July 8**—The MRZ around the Kunitomi-cho case farm (case: Kunitomi-cho 1) was lifted after serological surveillance targeted at all susceptible animals within a 3-kilometer radius and in epidemiologically-related farms, as well as clinical surveillance targeted at all susceptible animals in the area.

**July 16**—The MRZ around the Kawaminami area was lifted except for 1 unaffected farm in Takanabe-cho, which had refused vaccination and depopulation; same surveillance plan as above.

**July 17**—The hold-out farm in Takanabe-cho was depopulated.

**July 18**—The MRZ around the hold-out farm in Takanabe-cho was lifted; no additional surveillance since there were no susceptible animals remaining in the area.

**July 22-August 9**—Clinical inspections of 946,424 livestock on 8, 076 farms in the prefecture for FMD.

**July 27—*Last MRZ lifted***—The MRZ around Miyazaki city was lifted; same surveillance plan as above.

**August 20-October 25**—Targeted serologic testing of wildlife in Miyazaki prefecture.

**August 26**—All affected farms completed cleaning and disinfection procedures.

**August 31-October 22**—Sentinel cattle introduced onto 175 previously affected and depopulated farms; serum samples collected 3-4 weeks after introduction were negative for FMD.

**September 6-13**—Random sample of 150 farms within Miyazaki prefecture were surveyed at a level sufficient to detect 2 percent affected farms with at least 95 percent confidence.

**October 6**—MAFF declared Japan free of FMD.

**February 4, 2011**—The OIE reinstates Japan's status as FMD free without vaccination.

## References

MAFF. 2010. Recovery of FMD country free status: Japan's report to the World Organization for Animal Health (OIE) to recover country freedom from FMD without vaccination. Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau; Tokyo. Dated October 6, 2010.

OIE. 2011. World Animal Health Information Database: Japan foot and mouth disease—immediate notification and follow-up reports 1-16. World Organization for Animal Health. Available at: <http://web.oie.int/wahis/public.php?page=home>.

International Society for Infectious Diseases. 2011. ProMED reports: Foot and mouth disease—Japan (01-39). Available at: <http://www.promedmail.com/pls/apex/f?p=2400:1000>.