

Agribusiness | Animal Pharm

# African Swine Fever 2020

Characteristics; Epidemiology; History and Geography; Control Methods; Disease Impact; Vaccines; Diagnostics; Patents; Future Scenarios Please find the contents and sample pages below. If you have any questions, or would like to speak to a member of our team about this report please use our <u>contact us</u> page.

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# **Executive Summary**

African swine fever (ASF), is a highly contagious viral disease of domestic and wild pigs that has become a serious global threat to the pig industry and related sectors. Its existence and rampant spread has made a significant impact on protein availability, consumption and trade. It also poses a blockbuster opportunity for those involved in the science of the disease and deployment of interventions to combat its spread. This report presents the current status of ASF, including understanding of the virus, epidemiology, history and geographical control, prevention and control methods, state-of-the-art in terms of technological interventions, and the impact of ASF on the commercial pig industry in the absence of a vaccine.

The African swine fever virus (ASFV) affects all members of the pig family including domesticated swine, European wild boars, warthogs, bush pigs and the giant forest hogs. ASF does not pose a risk to public health as it cannot be transmitted to human beings.

ASF is endemic in many African countries, where it was limited prior to 2007 when the ASFV entered Georgia. It has since gone on to rapidly spread across Asia, leaving a devastating trail in China. In 2018, China reported the first case of ASF. China has the world's largest pig population, has since seen its pig population reduced by half. This has led to supply and demand shortages not only in China but globally. The ASFV can be transmitted directly, indirectly via contaminated feed and fomites, or can be vector-borne and transmitted through tick vectors. Once the ASFV has been introduced, infected swine develop high viral loads which are easily shed and lead to further direct transmission or indirect transmission via fomites on items such as contaminated clothing, shoes, equipment and vehicles. Wild boar has played an important role in spreading the disease; however, larger geographical leaps in the spread of the disease have been the result of human activity and the international transportation of domestic pigs.

Presently there is no vaccine or treatment available for ASF; the best control methods are prevention through biosecurity and early detection. The implementation of control methods varies among countries and regions depending on the epidemiological status of the disease, and the predominant type of pig production (traditional or backyard vs commercial). There are some countries which have managed to effectively control ASF post introduction. This has usually depended on a systematic and holistic biosecurity and awareness measures promoted by government authorities. Financial incentives to pig farmers also appears to help control the disease, however it is noted that these incentives do not appear to be as effective in low-middle income countries where the disease is ravaging local pig populations.

An analysis of the global pig production landscape helps in appreciating the present and future impact of ASF across the world. The presence of ASF has led to a dramatic decrease in the pig populations leading to shortened supplies of pork, breeding stock, and in some cases notable price increases. Traditional or backyard operations are more susceptible to ASF due to low implementation of adequate biosecurity measures and the use of swill for feed which remains an important mode of transmission of the disease. For example, China has lost an estimated 50% of its pig population since the first reported case of ASF. 85% of the herd population loss has occurred among small scale and backyard producers. This has led to unprecedented shortages in the

country's pork supply which has subsequently altered global trade flows and will continue to do so for the foreseeable future. In order to cater for the increasing demand in the wake of production loss, global exports of pork are predicted to increase by 10 % (at 10.4 million tons) in 2020- a record high.

Pigs surviving ASF infection develop a strong and protective immunity. They are protected against reinfection or challenge with related viruses. There is currently no published Target Product Profile (TPP). The Vaccine Review section summarises current approaches of ASF vaccine development, analysing the main characteristics and limitations of replicating (or live) vaccines and non-replicating (or replication redistricted) vaccines. A suggested TPP is also presented for contemplation by readers. Despite all the efforts to produce a safe and efficacious ASF vaccine, no vaccine is currently available. It seems unlikely that any type of ASF vaccine will be available in the near future. In the short-term, the live attenuated vaccines (LAVs) are the most promising candidates, but further research is needed to confirm their safety and efficacy in long-term controlled experiments.

The clinical signs of infection with ASFV and the post-mortem signs are highly variable. Moreover, ASFV clinical signs can be similar to other diseases. Thus, laboratory confirmation plays a critical role. A prompt diagnosis is critical to restrain and control the disease. The Diagnostics Review section provides a summary of virus detection tests and antibody detection tests.

Patenting activity of ASF-related technologies has increased globally in the last 10 years. This is evidenced by an average of 13% increase in patent filings. Based on this trend, it is expected that patent filings and R&D funding will continue to grow over the next few years. A mixture of both public and private-sector organisations appears to be applicants/assignees (the owners) on ASF-related patents. Some notable top-10 applicants/assignees include the University of Yangzhou (China), Qingdao Agricultural University (China), US Department of Agriculture and Boehringer Ingelheim Vetmedica (DE). Some notable patent filings and related transactions are discussed in further detail within this chapter.

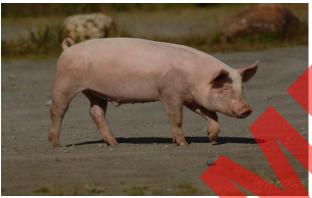
The market for an ASF vaccine should be considered under different scenarios and is heavily dependent on the (i) type of the vaccine developed, (ii) volume requirements, (iii) target demographic. The market assessment in this report analyses three possible scenarios; 1) vaccines for endemic countries, 2) wild boar vaccine and 3) commercial vaccines. It also provides a discounted cash flow-based valuation of a potential vaccine appropriate for the Asian market.

# Chapter 3: Epidemiology

### 3.1 Species affected

ASFV affects all members of the pig family (Suidae) including domesticated swine (*Sus scrofa domesticus*), European wild boars (*Sus scrofa scrofa*), warthogs (*Phacochoerus spp.*), bush pigs (*Potamochoerus larvatus and Potamochoerus porcus*) and the giant forest hogs (*Hylochoerus meinertzhageni*). Peccaries (family *Tayassuidae*), are not believed to become infected.

Figure 4: Domesticated swine and warthogs





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African wild suids do not show obvious clinical signs of the disease. Warthogs, which are considered the original vertebrate host for ASFV, usually have only subclinical or mild infections. They are considered the most

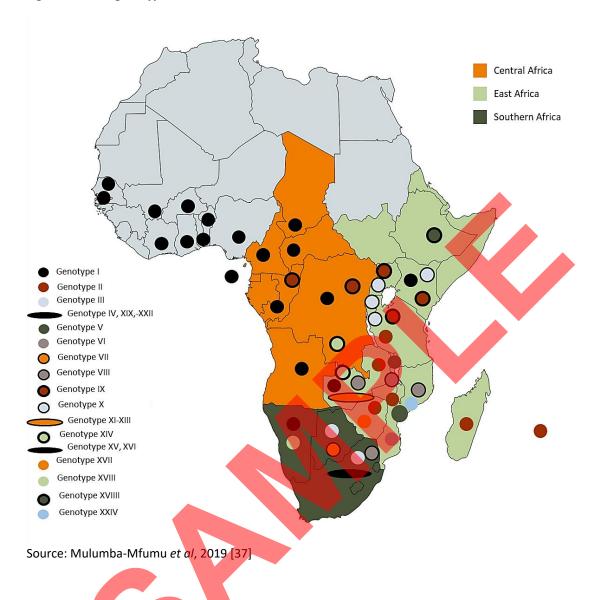


Figure 7: ASFV genotypes identified in Africa

#### 4.2 Africa

ASF is endemic and causes sporadic outbreaks in many sub-Saharan Africa countries, causing a high socio-economic impact amongst both rural backyard livestock keepers and commercial farmers (see section 6.4 *Socio-economic Impact*). It is the most important constraint for pig production in Africa. The history of ASF in Africa has been well described by Penrith et al. [18, 38] and recently reviewed by Mulumba-Mfumu et al. [37]. Below is a summary of its evolution and spread in Africa; the details and original references can be found in those reviews.

ASF was first observed in settlers' pigs in Kenya in 1909, but it has been suggested that the sylvatic cycle between warthogs and ticks might have been present at least since the early 1700s. Studies conducted between 1910 and 1917 demonstrated that the disease was caused by a virus that produced high mortality in pigs but was different from classical swine fever as reported by Montgomery in 1921 [36]. Similar disease cases had been reported in Zambia in 1912 and 1914. It was then first described in South Africa in 1928. There are

Table 3: Number of outbreaks of ASFV in Asia and the Pacific reported to the OIE since 2018 (up to 19th December 2019)

Country	Total outbreaks	Ongoing outbreaks	% administrative divisions affected (affected/total)	Total animal losses
Cambodia	13	0	20 (5/25)	3,673
China (People's Rep of)	165	36	100 (31/31)	378,806
Hong Kong (SAR-PRC)	3	0	100 (1/1)	4,163
Indonesia	392	392	3(1/35)	28,136
Korea (Dem People's Rep. of)	1	1	9 (1/11)	99
Korea (Rep. of)	58	58	17 (3/18)	26,999
Laos	141	141	94 (17/18)	38,773
Mongolia	11	0	29 (6/21)	2,855
Myanmar	4	4	7 (1/15)	72
Philippines	40	40	7 (6/83)	53,611
Russia (Asian continent)	74	17	5 (4/81)	2,853
Timor Leste	100	100	100 (1/1)	405
Vietnam	8,429	8,273	100 (63/63)	5,828,136
TOTAL	9,431	9,0162	-	6,368,581

Source: OIE - Situational updates of ASF in Asia and the Pacific, https://rr-asia.oie.int/en/projects/asf/situational-updates-of-asf-in-asia-and-the-pacific/, accessed on 4<sup>th</sup> January 2020.

Note: the losses are calculated based on the sum of dead and culled animals in the infected premises notified within the outbreaks. It does not include information on additional control measures such as preventative culling around the outbreak. This explains the differences with other number of animal losses reported by other sources.

#### 4.5 Americas

ASF has only been reported in a very limited number of countries in the Americas: Brazil, Cuba, Dominican Republic and Haiti. The disease was eliminated in the early 1980s [4, 40].

Cuba was the first country in the Caribbean to report ASF in 1971, and it is believed the virus came from Spain. The last outbreak in Cuba was in 1980. Dominican Republic had its first outbreak in 1978, and Haiti in 1979. Dominican Republic notified the last outbreak in 1981, and the last occurrence in Haiti was in 1984 [40].

ASF was introduced in Brazil in 1978, probably from Spain or Portugal through food waste in flights or products imported by tourists. The last report of ASF in Brazil was in 1981.

#### 4.6 Oceania

ASF has never been reported in Oceania, but its appearance in Timor Leste in September 2019 has generated considerable concern.

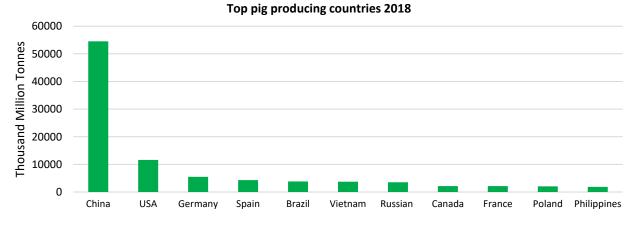
# Chapter 6: Disease impact

In order to fully appreciate the impact ASF is likely to have across the world, it is important to understand the global pig production landscape, including the demand for pork. An analysis of the global pig production landscape helps in appreciating the present and future impact of ASF across the world. The presence of ASF has led to a dramatic decrease in the pig populations leading to shortened supplies of pork, breeding stock, and in some cases notable price increases. Unprecedented shortages in the China's pork supply, the world's largest consumer and producer of pigs, has subsequently altered global trade flows.

Figures 15-17, below, provide a snapshot and overview of pig production globally, top pig producers, pork consumption rates and pork consumption relative to other types of mainstream animal protein sources.

Figure 15: Global pig production snapshot by region, company and country (2018)





CANADA EU - #1 Global pork exporter #3 Global pork exporter -Net importer - Valued at ~USD 171 million (2019) (2019) - Forecast ↑13% in 2020 J-1% in 2018/19 (2018) Forecast ↓1% in 2020 Rising export levels Main contributions from Germany (~USD 4.4 billion) and Spain ((~USD 4 #1 Global pork importer (2019) Valued at ~USD 2 trillion (2018) billion- 2018 Forecast ↑35% in 2020 USA #2 Global pork exporter (2019) - Valued at ~USD 4.6 billion in Forecast ↑11 % in 2020 #2 Global pork importer (2019) ~ USD 4.4 trillion #3 Global pork importer (2019) Valued at ~USD 1.4 trillion (2018) SOUTH AFRICA #4 Global pork exporter (2019) AUSTRALIA Valued at ~USD 73 million -Valued at ~USD 1 trillion -Net importer - Valued at ~USD 461.6 (USD 24 million in 2018) ↑20% between 2018 and 2019 Source: USDA, Comtrade (2019)

Figure 32: Global pork trade (selected countries)

The above man /Figure 22) focuses as a number of

The above map (Figure 32) focuses on a number of significant countries in the global pork trade. The top three exporters of pork are the Germany, Spain (represented under the European Union) the USA and Canada. Current forecasts indicate that the EU will remain the top global exporter of pork throughout 2020, although Brazil is predicted to see the largest growth (20 %) [80]. The top three importers are listed as China, Japan and Mexico, with China forecast to experience a 35 % rise in imports in 2020. Australia and South Africa, whilst being net importers, make significant contribution to the meat trade in their respective regions.

#### 6.3.1. Asia

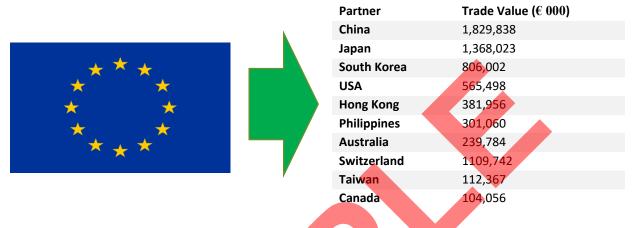
#### China

The decline in production in China, which produces and consumes half of the world's pork [96], will cause an estimated USD 10-20 million pork production deficit in the country and aggravate the pork shortage throughout Asia well into 2020 and beyond [96]. As a direct result of ASF in the country, from 2018 onwards, China has imported increasing amounts of pork, seen in Figure 33 below. As at August 2019 the country's pork imports were 67 % higher than the same time the previous year [80]. As mentioned previously, production deficit in China is likely to decrease pork availability elsewhere, including domestically in Europe and the US, where producers are likely to take advantage of rising pork prices in China, as well as in price-sensitive markets.

Brazil is also reportedly increasing exports to other ASF-affected countries, including South Korea. It is reported that in February 2019, South Korea's Animal and Plant Quarantine Agency announced that it had granted an additional 9 Brazilian packers (5 of which deal in pork) licence to import meat into the country [114].

#### 6.3.3. Europe

Figure 41: Leading Markets for EU pork exports 2018 (Euros)



Source: Europa (2018)

Figure 42: Pig Prices in continental Europe and the UK (2018-2019)



Source: AHDB Pork (2019)

On the quest for an ASF vaccine, it is important to consider the requirements for such a vaccine. There is currently no published Target Product Profile (TPP) and the requirements might vary depending on the target population or use-case. A TPP sets out the properties of a vaccine and is often expressed as the characteristics of the ideal vaccine and also what the minimum characteristics would be. For example:

- In an endemic country, where there is a majority of traditional backyard pig production, a vaccine with an efficacy that might be considered "low" for commercial producers might be acceptable, as it would be 'better than nothing'. It could be expected that traditional backyard pig farmers that depend on pigs for their livelihoods, would be happy to have a vaccine to protect at least some of their pigs. The same acceptance could be expected if some minor side effects were present that were not acceptable for commercial pig farmers, such as injection site reactions. For those farmers, a small "lump" might be seen as a small inconvenience compared to saving the pigs' lives and having the pigs' value accessible, for example to pay for children's school fees.
- Before the recent outbreaks in Eurasia, a vaccine for wild boar might not have been considered a priority. However, taking into account the role they are playing in the current outbreaks, a vaccine for wild boar, which might require a different form/presentation than for commercial pigs e.g. formulated in a bait, could be very valuable, and many governments, pig associations and other organization would be happy to have access to such a vaccine if it had the right characteristics.
- For countries wanting to eliminate the disease, the possibility to differentiate infected animals from vaccinated animals (DIVA) vaccines will be a key requirement. For endemic countries, this is not a limiting factor as any realistic ability to eliminate the disease would be many years ahead.

Keeping in mind the different requirements of a vaccine, a TPP for ASF may have the attributes set out in Table 4. Some of the attributes are interrelated, for example the use case and the DIVA capability. This TPP might be used as a starting point, but TPPs are dynamic tools that need to be reviewed as knowledge progresses.

Table 4: Suggested Target Product Profile for an ASF vaccine for pigs					
	Attribute	Minimum	Ideal		
1	Antigen	Immunogen with ASF virus protective antigens	Immunogen with ASFV protective antigen		
2	Use case	Protection of pigs to at least 1 genotype of ASF virus or predominant ASFV circulating in a specific geographic region	Protection of pigs against all genotypes of ASFV		
3	Recommended species	Domestic pigs	Domestic and wild pigs		
4	Recommended dose	2 ml	1 ml		
5	Pharmaceutical form	Reconstituted injectable solution/suspension	Ready to use solution/suspension		
6	Route of administration	Intramuscular	Intramuscular or needle-free (including oral baits or IN)		
7	Regimen - primary vaccination	Two doses given 4 weeks apart	Single lifetime dose		
8	Regimen - booster	First booster 6 months after primary vaccination followed by single annual booster	Lifelong immunity after primary vaccination		
9	Epidemiological relevance	For use in settings that are not aiming at ASF elimination	For possible use in settings aiming at ASF elimination		

# Chapter 8: Diagnostics review

#### 8.1 Relevance and reference laboratories

The clinical signs of infection with ASFV and the post-mortem signs are highly variable, and clinical signs can be similar to other diseases. Therefore, laboratory confirmation plays a critical role. A prompt diagnosis is critical to restrain and control the disease. ASF diagnostics are usually conducted by the official national or reference laboratories. The OIE and FAO ASF reference laboratories are listed in Table 5. Some national ASF laboratories are presented in Table 6.

The OIE sets the standards for diagnostics and international trade. <u>Chapter 3.8.1 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</u> [9] deals with infections with ASFV. FAO has produced a comprehensive <u>Manual on AFS detection and diagnosis</u> [153] which includes differential diagnosis, sampling, packaging and transport of samples, and laboratory diagnosis.

In the European Union, the <u>Commission Decision 2003/422/EC of 26 May 2003</u>, approves the African swine fever diagnostic manual included in the annex of that document. However, one of the gaps identified in Europe, is the need for a list of validated tests [139]. In the USA, the USDA disease response strategy to ASF mentioned in section 5.2, defines which tests are to be conducted when there is a suspicion of ASF, and the samples to be sent.

Table 5: International ASF reference laboratories				
	Laboratory	Country	Contact person	
	Onderstepoort Veterinary Institute	South Africa	Dr Livio Heath <u>HeathL@arc.agric.za</u>	
OIE	Centro de Vigilancia Sanitaria Veterinaria (VISAVET)	Spain	Dr José Manuel Sánchez-Vizcaíno jmvizcaino@visavet.ucm.es	
	The Pirbright Institute	UK	Dr Linda Dixon linda.dixon@pirbright.ac.uk	
FAO and EU	Animal Health Research Centre - Centro de Investigación en Sanidad Animal (CISA)	Spain	Dr Marisa Arias arias@inia.es	

animal feed. Patenting of technologies pertaining to modified cell lines, and/or DNA or RNA based technologies as it relates to genetic engineering, vectors and so forth have remained steady. These trends have been measured based on the frequency of International Patent Classification ("IPC") codes assigned to ASF related patent filings in the past five years. Figure 49 provides a snapshot of the key technology areas claimed by patents filed in the last 10 years.

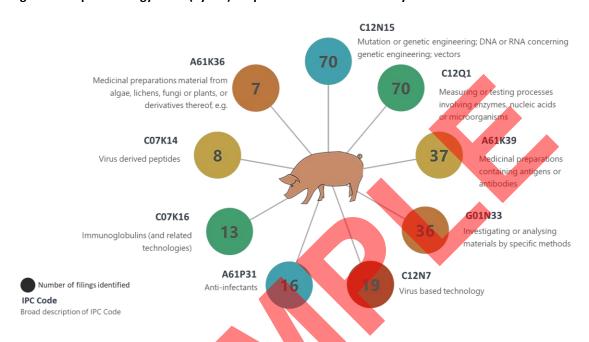


Figure 49: Top technology areas (by IPC) for patents filed in the last 10 years

A priority country is a term used to identify the first jurisdiction in which a patent application is filed. Applicants generally file in their home country first and then extend protection (via family filings) to other jurisdictions. Priority countries are quite telling, as they often point out where a lot of R&D is taking place and, in the case of public institutions, where national investment exists for a particular line of research. Looking at the current patent landscape, most ASF-related filings made in the past 10 years appear to be in China, far surpassing filings made in the United States (second in terms of ASF-related filings), Europe (third, including filings originating in the UK) and Russia (fourth).

A mixture of both public and private organisations appear to be applicants/assignees (the owner) on ASF related patents. Some notable top-10 applicants/assignees include the University of Yangzhou (China), Harvard University (US), Massachusetts Institute of Technology (US), Broad Institute (US), Qingdao Agricultural University (China), US Department of Agriculture and Boehringer Ingelheim Vetmedica (DE). A considerable number of ASF-related patent filings appear to name more than one organisation as an applicant/assignee – therefore, suggesting that cross-organisational collaboration is common with regards to ASF R&D.

If you would like to find out more about this report, please use our <u>contact us</u> page, and a member of our team will be in touch.