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Self-declaration of freedom from Swine Vesicular Disease by Italy

Self-declaration submitted to the OIE on 08 August 2019 by Dr Silvio BORRELLO, Delegate of Italy to the OIE, Chief Veterinary Officer, Directorate General for Animal Health and Veterinary Medicinal Products, Ministry of Health.

I. Background

Swine vesicular disease (SVD) was observed in Italy for the first time in 1966 and it is among the diseases that must be compulsory reported to the Competent Authority, even in the case of simple suspicion, according to the article 1 and 2 of the Veterinary Police Regulations - Presidential Decree n. 320 of 8.2.1954¹. SVD outbreaks have been notified to the OIE on a six-monthly basis during the period the disease was present in certain regions of southern Italy. Considering that from June 2015 no SVD outbreaks have been registered on the national territory², the European Commission has recognized Italy as a territory free from SVD by Commission implementing decision (EU) 2019/470 of 20 March 2019³.

II. Surveillance and eradication programme : Contents

According to [article 2 of the National Veterinary Police Regulation 320/1954](#) every case, even a suspected case of infectious disease, listed in the article 1 must be notified to the Competent authority by both public and professional veterinarians, the owner or the responsible of the animals, etc. the notification can be done in writing or verbally to the Mayor that communicate it to the Local Veterinary Service (LVS). The LVS goes to the holding to confirm the suspect, perform the epidemiological enquiry and take all necessary measures to prevent the spread of the disease.

In the article 1 of the National Veterinary Police Regulation, all diseases are listed, for which notification is mandatory and the following articles provide the application of general rules regarding their control. The notification of outbreaks of animal diseases identified in the Italian territory is available on the website of the Veterinary Information System, the National Animal Disease Information System (SIMAN), which allows private access by the competent authorities, to enter data and information about the suspicion and confirmation of positive results that, once registered, can

¹ [Presidential Decree No. 320](#) – Decree to be repeal due to the application of 320 Reg. 429/2016

² [ADNS report - 2015](#)

³ [Commission implementing decision \(EU\) 2019/470](#)

either be transmitted to international bodies and it can be consulted and assessed as part of the epidemiological study of animal diseases.

Delay or the failure to notify an infectious disease is configured as a legally punishable offense under article 500 of the Penal Code that provides that whoever commits this offense is punishable by a fine from 103 to 2,065 Euros and a prison sentence of one to five years. If the one who fails to report the disease is a public official or a public servant, this also responds to the rejection of acts of office in accordance to the article 328 of the Penal Code, and depending on the mode of failure to report may be subject to other charges.

Given that in Italy the subclinical infection of SVD was by far the most frequently observed condition, starting from 1995 a national surveillance and eradication programme has been implemented according to the scheme described in Figure 2., with the objective to eradicate the disease, to be achieved through the sanitary accreditation of the holdings and, consequently, the entire Regions.

The Regions of northern Italy were recognized as SVD free since 1997⁴, while for the southern Regions, control has been more gradual, due to the peculiarity of the southern pig breeding, characterized mainly by small farms with low number of animals (Figure 1.).

- A national Order of the Ministry of Health was issued in 2008, containing reinforced health measures to control an increase of the outbreaks during 2006/2007 and to achieve eradication in the Regions not yet recognized as SVD-free. Moreover, the order included strengthening of the serological controls in the fattening farms and dealers' premises, as well as it sets out compulsory biosecurity requirements for the different type of pig holdings and specific ones for the dealers' premises ([Annex I and X of 2008 Ministerial Order](#)). The efforts put in place have led to the recognition of Sicily and Abruzzo as SVD free regions in 2009 (Commission Decision 2009/2/EC 5 and Commission decision 2009/620/EC 6).

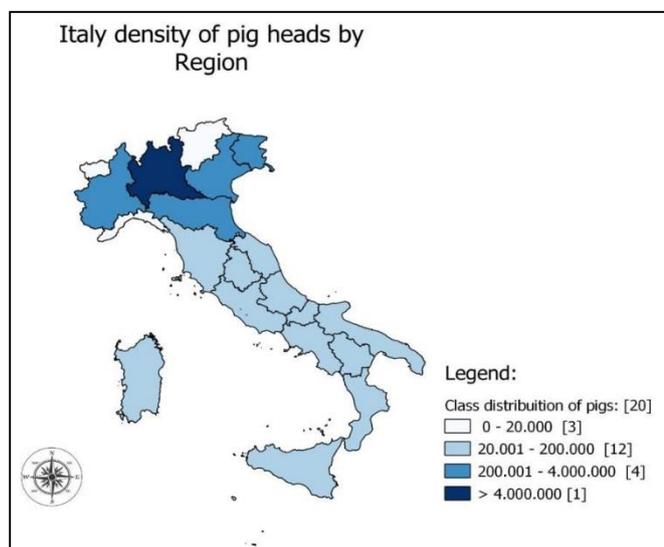


Figure 1. Density of pig heads by Region, Italy, 2019
[number of Regions included in this interval]
Data source: National Data Bank

In 2011, considering that only two regions (Campania and Calabria) were preventing the national territory from being totally free, the Ministry of Health in cooperation with CERVES (National reference laboratory for SVD) established a task force of experts. The group, working together with Regional and Local Veterinary Services, identified the main critical issues and laid down additional measures by specific regional laws ([Commissioner Decree n. 93 of 2011](#) and [n. 39 of 2012 for Campania](#) and [Commissioner Decree n. 139 of 2015 for Calabria region](#)) for the eradication of SVD such as:

- special serological control programme on backyard farms,
- checks for the compliance with the biosecurity requirements of all the commercial holdings,
- downgrading of the ones not complying with the biosecurity standards to backyard farms, and
- no compensation in case of seropositivity in holdings with non-compliance to biosecurity.

⁴ [Self-declaration from Italy of a zone free from swine vesicular disease – Published in the OIE Bulletin 2015 -1](#)

⁵ [Commission Decision of 18 December 2008](#)

⁶ [Commission Decision of 20 August 2009](#)

The implementation of the above-mentioned measures allowed significant improvement of the epidemiological situation in the two Regions (Campania and Calabria) that respectively reached the SVD free status in 2017 by Commission execution decision (EU) 2017/19107, and in 2019 by Commission implementing decision (EU) 2019/4708. By the last-mentioned legislative act of the European Commission, Italy was recognized as free from SVD. The following Figure 2. shows the serological control plan by type of pig holdings adopted in Italy from 2008 to date.

The official diagnostic activities are carried out by the ‘Istituti Zooprofilattici Sperimentali’ (IZSS). They act under the coordination of CERVES within the IZS of Lombardia and Emilia Romagna based in Brescia. The IZSS are evenly distributed across the country, with 10 headquarters covering one or more Regions and 90 local diagnostic sections (Figure 3.).

All the official diagnostic tests used in Italy for the diagnosis of SVD are carried out in accordance with the provisions of Chapter 3.8.8. of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

The serological tests are:

- competitive ELISA (screening tests performed by IZS competent for the area where the holding is located);
- ELISA for IgM and IgG (carried out by CERVES);
- VN – virus neutralization (confirmatory test by CERVES).

		Fattening	Breeding (Farrow-to-feeder: Open Cycle)	Breeding (Farrow-to-finish: Closed Cycle)	Dealers' premises and high turnover farms (HTO)
SVD free regions	Farms under the program	Representative sample based on the number of fattening farms in the Region (prev.3%)	All	All	All
	N° of samples in selected farms	Prev=5% CI=95%	Prev=10% CI=95%	Prev=10% CI=95%	Prev=5% CI=95%
	Sampling frequency	Twice a year	Twice a year	Yearly	Monthly
SVD not free regions	Farms under the program	All	All	All	All
	N° of samples in selected farms	Prev=5% CI=95%	Prev=10% CI=95%	Prev=10% CI=95%	Prev=5% CI=95%
	Sampling frequency	Twice a year	Twice a year	Yearly	Monthly blood and faeces

Figure 2. SVD National Surveillance scheme, Italy

The virological tests are carried out on faeces samples in case of serological positivity in a farm or on a dealer's premise/High turnover farm (HTO) by CERVES are PCR and virus isolation by cell culture.

The laboratory tests and the sampling methods as well as criteria for the evaluation of the results of the laboratory tests for the confirmation and differential diagnosis of SVD are set out in the Decision 2000/428/ EC⁹.

⁷[Commission execution decision \(EU\) 2017/1910](#)

⁸[Commission implementing decision \(EU\) 2019/470](#)

⁹[Decision 2000/428/ EC](#)

III. Epidemiological evolution of the disease

From June 2015 to date, no outbreaks of SVD have been registered on the national territory. The last one occurred in Calabria on 7 May 2015 in a small fattening farm with 20 pigs (Figure 6). In 2014, five outbreaks have been detected: two in Basilicata region (one primary and one secondary), one in Campania region (primary) and two in Calabria region (one primary and one secondary). The outbreaks involved holdings with a low number of pigs (842 animals in total). In 2013, only one outbreak was detected in Calabria in a small backyard farm with four fattening pigs. In all the outbreaks, the control measures have been implemented as required by current legislation; these measures were removed only after the cleaning and disinfection operations of the affected farms and negative results of the serological controls in the surrounding pig holdings within the restriction areas and in those epidemiologically linked.

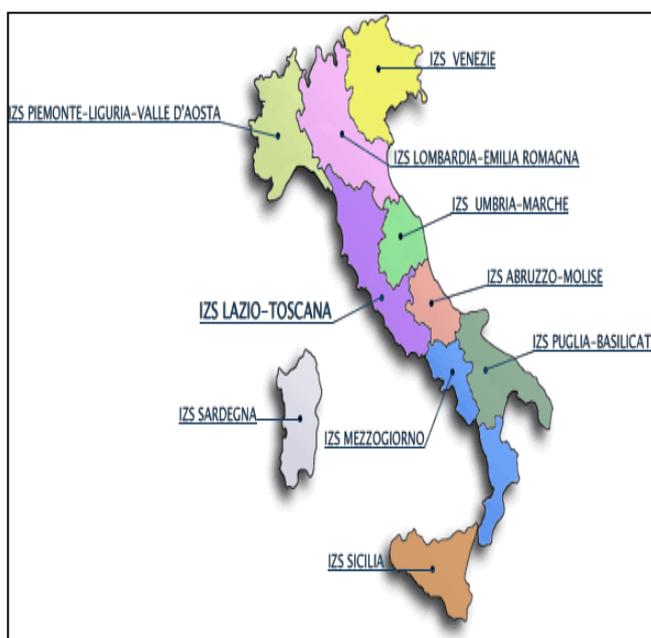


Figure 3. Headquarters of the Istituti Zooprofilattici Sperimentali (IZS), Italy, 201

Year	Total number of animal under the program	Number of animals checked	Number of animals individually sampled (competitive Elisa carried out)	% annual animals coverage
2011	5.355.458	5.977.542	379.216	111,62%
2012	5.222.027	5.834.350	411.806	111,73%
2013	4.529.434	5.357.856	435.629	118,29%
2014	6.029.725	5.982.167	419.385	99,21%
2015	6.181.432	6.145.170	402.549	99,41%
2016	5.965.981	5.870.854	377.854	98,41%
2017	5.457.090	5.370.388	349.137	98,41%
2018	5.477.175	5.474.902	329.338	99,96%
2019 (1 st semester)	5.107.606	2.112.323	127.195	44,46%

Figure 4. National SVD surveillance programme from 2011 to 2019 (first semester)
Data source: National Data Bank

YEAR	Antibody detection				Virus detection	
	Competitive ELISA (SCREENING test)	VNT (CONFIRMATORY test)	Isotyping ELISA IgG	Isotyping ELISA IgM	PCR	Virus Isolation test
2011	379.216	1.157	1.118	1.118	2.527	99
2012	411.806	895	917	917	2.463	11
2013	435.629	370	356	356	2.398	12
2014	419.385	431	367	367	2.438	0
2015	402.549	587	552	552	2.532	0
2016	377.854	449	486	487	2.139	0
2017	349.137	637	636	636	2.209	0
2018	329.338	683	704	704	2.519	0
2019(1 st sem.)	127.195	264	261	261	759	0

Figure 5. Laboratory tests performed for antibody and virus detection from 2011 to 2019 (first semester)
Data source: CERVES

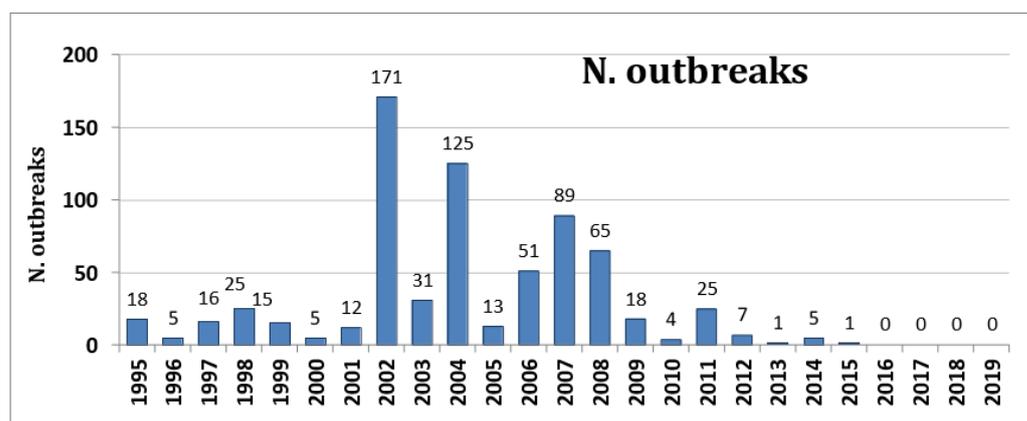


Figure 6. Trend of SVD outbreaks from 1995 to 2019 (first semester).
Data source: CERVES

Figure 6. shows the positive trend of the number of SVD outbreaks from 1995 to 2019, in particular following the application of the measures laid down in the [Order of the Ministry of Health of 2008](#).

IV. Official control and eradication measures

In case of an outbreak, the Local authority promptly shall adopt the measures according to the Presidential Decree February 8, 1954 "Regulation of veterinary police" and Measures established in Council Directive 92/119/EEC transposed by Presidential Decree N.362/1996 and Commission Directive 2007/10/CE transposed by Ministerial Decree 28/3/2007 (i.e. killing and destruction of all pigs in the outbreak, sanitary measures in the protection and surveillance zone, transport management, epidemiological enquiry, serological tests in the epidemiologically linked holding etc.).

Moreover, after confirmation of an outbreak, the SVD free status of the affected Province was immediately suspended and the movements of pigs were allowed only under authorization of the Ministry of Health. All holdings were tested twice, 28–40 days apart (P: 5%, I.C.:95%) to regain their individual free status. When no further cases were confirmed and the results of the epidemiological enquiry demonstrated the absence of risk for further spread of the disease, the official status could be considered regained for the whole province.

V. Measures to maintain disease freedom

To ensure the maintenance of national SVD free status the surveillance activities implemented in the previous years on the national territory (Figure 2.) remain in force. In addition, in case of a suspicion of an emergency disease resembles characteristics of SVD, all the measures laid down by the national contingency plan and the [operational manual](#) for vesicular diseases are applied. When SVD is confirmed, the sanitary measures established by the Presidential Decree N.362/1996 and Ministerial Decree 28/3/2007 are adopted.

Italian innovation systems

In addition to the activities included in the SVD national surveillance programme, the Directorate General for Animal Health and Veterinary Medicines of the Ministry of Health has implemented some new tools related to the national information system (www.vetinfo.sanita.it), such as the computerized document for animal transport (model N. 4) and Classyfarm ([click](#) for more information). The latter system allows to categorize the farms according to the risk, using harmonized and scientifically validated methods that allow to collect and process data relating to the following assessment areas: biosafety, animal welfare, health and production parameters, animal feeding, antimicrobial consumption and lesions found at the slaughterhouse. The integrated use of this data by the Competent Authority will create an increasingly efficient system of surveillance and prevention of animal diseases on the entire Italian territory.

VI. Conclusions

Therefore, considering all the information reported and in particular that:

- no outbreaks of SVD have been detected since 2015;
- Italy applies the stamping out policy in case of confirmation of a SVD outbreaks;
- the surveillance programme has not shown evidence of SVD virus circulation in the national territory;

The Delegate of Italy to the OIE declares the freedom of Italy from SVD in accordance with Chapter 1.6 and Article 1.4.6. points 2.a and 2c. of the OIE *Terrestrial Animal Health Code* and Chapter 3.8.8. of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

I, the undersigned, Dr Silvio BORRELLO, Delegate of Italy to the World Organisation for Animal Health (OIE), takes responsibility for the self-declaration of freedom from Swine Vesicular Disease.

Drawn up on 8 August 2019

Signature of the Delegate: _____

A handwritten signature in black ink, appearing to read 'S. Borrello', is written over a horizontal line. The signature is cursive and somewhat stylized.