Normative Instruction nº 19, February 15, 2002

THE SECRETARY OF ANIMAL AND PLANT HEALTH AND INSPECTION – SUBSTITUTE, OF THE BRAZILIAN MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, proceeding from his attributions established by Article 83, Item IV, of the Internal Regulation Manual of the Secretariat, approved by Ministerial Decree No. 574 of 8 December 1998, pursuant to the Animal Health Defense Regulation, approved by Decree No. 24548, 3 July of 1934,

Whereas the economic importance of swine farming and the need to maintain an appropriate health level in farms that sell, distribute or keep swine breeders for animal breeding purposes, in order to prevent the spread of diseases and provide desirable levels of productivity, and the contents of Process No. 21000.005128/2001-29, decides:

Article 1 – Approve standards for the accreditation of swine breeder farms, as the APPENDIX.

Article 2 – The marketing and distribution within Brazilian territory of swine intended for breeding, as well as its participation in exhibitions, fairs and auctions, shall only be allowed if it comes from Accredited Swine Breeder Farms. (GRSC – *Granjas de Reprodutores Suídeos Certificadas*).

(1) Institutions keeping livestock for animal breeding purposes shall comply with the standards of Accredited Swine Breeder Farms.

Article 3 – Delegate powers to the Director of the Department of Animal Defense (DDA – *Departamento de Defesa Animal*), to publish additional standards for accreditation of swine breeder farms, from proposals submitted by the Coordination for Surveillance and Health Programs.

Article 4 – Recommend that Secretaries of Agriculture and animal health defense authorities of the States and Federal District, to support the development of activities under this Normative Instruction.

Article 5 – This Normative Instruction shall come into effect on the date of its publication.

Article 6 – It is abrogated Normative Instruction No. 12, 23 June 1999.

RUI EDUARDO SALDANHA VARGAS

APPENDIX

STANDARDS FOR ACCREDITATION OF SWINE BREEDER FARMS

1. DEFINITIONS

1.1. For the purpose of this Instruction:

1.1.1. Swine: any animal of the gender *Sus sp.*;

1.1.2. Swine breeder: swine kept on a farm and used for animal breeding purposes;

1.1.3. Institutions keeping swine breeding material: central units of artificial insemination and disseminators of genes;

1.1.4. Breeder farm: establishment or property where swine are raised or kept for sale or distribution purposes, whose final product is intended for reproduction;

1.1.5. Accredited Swine Breeder Farms (GRSC – *Granja de Reprodutores Suídeos Certificada*): farm which fully comply with basic and specific standards for accreditation. Farm's accreditation shall be based on serological monitoring and health classification pursuant to this Normative Instruction;

1.1.6. Owner: any person or company who hold under its responsibility swine whose final product is intended for reproduction;

1.1.7. Official service: federal, state or municipal animal health defense body;

1.1.8. Veterinarian official: veterinarian of the official service;

1.1.9. Accredited veterinarian: professional accredited by the official service in accordance with Decree-Law No. 818, dated 5 September 1969;

1.1.10. Technician in charge: veterinarian, appointed by the owner, responsible for compliance with the standards set by this Instruction;

1.1.11. Official laboratory: animal laboratory belonging to the network of the Ministry of Agriculture, Livestock and Food Supply;

1.1.12. Accredited laboratory: laboratory belonging to a public institution that receives, by delegation of powers of the Ministry of Agriculture, Livestock and Food Supply, act of accreditation;

1.1.13. Production of breeders: activity whose main purpose is producing male and female breeders;

1.1.14. Full cycle production of breeders: complete swine breeder farm, involving all stages in facilities in the same geographical area;

1.1.15. Site 1: producing unit of piglets, involving the stages of insemination, pregnancy, maternity, weaning and, depending on the establishment, nursery and central of insemination for exclusive use;

1.1.16. Site 2: unit that receives piglets from Site 1 to foster them at the nursery, nursery and growth or growth only until the reproduction phase;

1.1.17. Site 3: unit that receives pigs from Site 2 to foster them until the reproduction phase;

1.1.18. Health surveillance: periodic and systematic procedures aimed to test, qualify and quantify the level of health in breeder farms for a specific disease or infection;

1.1.19. Degree of vulnerability: set of rules aimed to prevent the ingress of pathogens at breeder farms;

1.1.20. Biosafety: Development and implementation of strict rules to protect the herd of swine against the ingress and spread of infectious agents in breeder farms;

1.1.21. Zootechnical data: set of parameters of productivity of a breeding farm, intended to characterize and evaluate its performance;

1.1.22. Quarantine area: a zone aimed to keep newly admitted animals, apparently healthy, isolated and under observation, to perform diagnostic tests and prophylactic measures to prevent the ingress of pathogens in breeder farms.

2. BASIC STANDARDS

2.1. Swine breeder farms shall comply with the following basic standards, in order to be accredited:

2.1.1. Be registered in the proper body of the Ministry of Agriculture, Livestock and Food Supply and keep a record system that allows the identification of animals and their genetic ancestry.

2.1.2. Be registered in the official service with jurisdiction in the area, as well as a complete animal health record (birth, death, diagnosis of diseases, treatments, and vaccination program for health monitoring of swine breeders), with information covering all swine of the establishment, available to the official service;

2.1.3. Adopt biosafety procedures against the ingress of pathogens and to prevent the spread or exacerbation of diseases in breeder farms;

2.1.4. Keep veterinary assistance and a technician in charge, which shall represent the establishment before the official service, notifying sanitary related events and zootechnical data through the quarterly technical report submitted to the official service, or immediately in case of diseases of immediate notification. The technician shall collect material for laboratory tests, to perform examinations of the herd, and also implement a program of cleaning and disinfection and vaccination, keeping record of such measures and other activities of health control, according to this Instruction, supervised by the official service;

2.1.5. The collection of material for laboratory tests, inoculation of tuberculin and its interpretation for the purpose of health surveillance of farms to be accredited and reaccredited shall be performed under direct supervision of the official service, and the cost of examinations shall be paid by the owner;

2.1.6. The ingress of swine for animal replacement and breeding material collection in accredited breeder farm shall only occur if the animals come from Accredited Swine Breeder Farms (GRSC), and accredited at least to the same optional diseases.

2.1.7. Accreditation is valid for six months. It shall be printed in a specific form by the official service, based on clinical test results of the herd, performed by official or accredited laboratories and, in the case of tuberculosis, based on results of diagnostic tests performed by the technician in charge of the farm and proof of compliance with other requirements of these Instruction;

2.1.8 Swine in transit shall be accompanied by official transit permit and copy of the GRSC accreditation, attested by official agent;

2.1.9. Accreditation may be suspended at any time by the official service, in case of non-compliance with this Instruction or upon request of the establishment.

3. SPECIFIC STANDARDS

3.1. Sanitary and biosafety standards that shall be met by swine breeder farms to be accredited are:

3.1.1. Have a surrounding fence with single entry and disinfection system for people or vehicles at the entrance;

3.1.2. Have loading and unloading station close to the fence;

3.1.3. Have a guest book, identifying the last date and place of visits to other swine farms, laboratories, slaughterhouses or other places with the presence of swine, with a minimum fallow period of 24 hours;

3.1.4. Have a disinfection system for the ingress of materials and equipment into the farm;

3.1.5. Have wardrobe with impervious walls and floors, with bath, shower and clothing for the visitors and staff of the breeder farm;

3.1.6. Have known source of water, which is not a natural course, to supply the farm with tanks protected, cleaned and disinfected at least every six months;

3.1.7. Hold state environmental agency permission, covering the treatment and disposal of manure;

3.1.8. Have an adequate system, accredited by the official body, to manage corpses and remains of births (stillbirths, mummified, placentas);

3.1.9. Breeder farms with two sites of production shall comply, in both sites, with all standards for accreditation, regardless whether the sites are located in the same property or not;

3.1.10. Farms with three sites of production shall comply with all standards for accreditation in sites 1 and 3, whereas the site 2 shall only comply with conditions of biosafety, regardless whether the sites are located in the same property or not.

3.1.11. In breeder farms with 2 or 3 sites, in case of suspicion of any of the diseases described in this Instruction, in any of the sites of production, at the discretion of the Ministry of Agriculture, Livestock and Food Supply, tests shall be performed at all sites, according to sampling standards of this Instruction, even beyond the date of reaccreditation, and the accreditation of production sites may be suspended until the outcome of tests.

3.2. Accredited Swine Breeder Farms, satisfied the items above, shall be evaluated for an initial classification to be reviewed annually, about their degree of vulnerability to pathogens ingress, as Table 1.

Table 1 – Evaluation of the Degree of Vulnerability of GRSC to the ingress of External Pathogens

Variable	**Criteria**	**Points**	**Score of the farm**
1. Distance to a non-accredited swine farm or swine slaughterhouse.	more than 3.5 Km	0	
	1 - 3.5 Km	1	
	from 500 m to 1 Km	2	
	less than 500 m	3	
2. Density of swine herds in a radius of 3.5 Km	1 herd	0	
	2-3 herds	1	
	4 or more herds	2	
3. Farms supplying swine for herd replacement	own replacement or by hysterectomy	0	
	1 farm	1	
	2 farms	2	
	3 or more farms	3	
4. Distance from highway where swine are transported	more than 500 m	0	
	from 300 m to 500 m	1	
	less than 300 m	2	
5.1. Quality of the isolation of the farm - fence	*excellent* – double fence interspersed with green belt	0	
	very good – fence screen at least 50 m away from sheds	1	
	good – fence screen less than 50 m away from sheds	2	
	reasonable – non-screened fence only	3	
5.2. Quality of the isolation of the farm - green belt	outside line of the green belt at least 50 m away from farm's facilities	0	
	outside line of the green belt less than 50 m away from farm's facilities	1	
	no green belt	2	
6. Control of visits in the farm	occasional visits, with 72h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	0	
	occasional visits, with 48h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	1	
	occasional visits, with 24h of fallowing. Regime of bath with exchange of clothes and shoes. Bathroom with clean and dirty area.	2	
7. Quarantine area	yes, at least 500 m away from the herd, with green bell; or no external swine admissions.	0	
	yes, less than 500 m away from the herd or without green belt.	1	
	no quarantine for admitted swine.	2	
	no use feeding flour of animal origin	0	

8. Ration given to animals	use of feeding flour of animal origin	2	
9. Source of the feed given to animals	own factory inside the establishment	0	
	third factory	1	
10. Transport of feed used in the farm	bulk trucks or vehicles that don't carry swine	0	
	the same trucks that carry swine	2	
Farm total score:			

3.2.1. Classification of farms in the degree of vulnerability to external pathogens:

a) farm "A": well-protected - from 0 to 5.0 points, since that has no criteria with a score 2 or 3;

b) farm "B": low vulnerability - up to 8.0 points, since that has no criteria with score 3 and is not included as farm "A";

c) farm "C": moderate vulnerability – from 8.0 to 12.0 points, since that is not included as farm "B";

d) farm "D": highly vulnerable - with 13.0 or more points.

3.2.2. Evaluating the degree of vulnerability of Artificial Insemination Centers (CIA – *Centrais de Inseminação Artificial*), Item 3 of the Table 1 shall not be applied. However, all breeders admitted to CIA shall be tested for the basic diseases of accreditation.

3.3. Health Levels of GRSC

3.3.1. All accredited swine farm shall be free from classical swine fever, Aujeszky's disease, brucellosis, tuberculosis, scabies and free or controlled from leptospirosis.

3.3.2. GRSC shall comply with the following standards for classical swine fever - CSF:

3.3.3. Perform serological tests, every six months, by means of ELISA, using kits registered in the Ministry of Agriculture, Livestock and Food Supply, and the sera that tested positive or is suspected shall undergo additional differential tests, by testing of neutralization, including the differentials ones for the Bovine Virus Diarrhea.

3.3.4. Breeder farm shall achieve compliance with CSF only if all tests are negative. In the case of positive test, standard prophylaxis measures for classical swine fever shall be implemented, pursuant to current regulations.

3.3.5. GRSC shall comply with the following standards for Aujeszky's disease:

3.3.5.1. Not to perform vaccination of swine housed in the breeder farm.

3.3.5.2. Perform serological tests, every six months by means of ELISA, using kits registered in the Ministry of Agriculture, Livestock and Food Supply, and the sera that tested positive shall undergo neutralization testing;

3.3.5.3. Breeder farm shall achieve compliance with serological standards for Aujeszky's disease only if all tests are negative. In the case of positive test, accreditation shall be suspended and serology tests shall be performed to 100% of the herd of breeders, with an interval of 30 and 60 days. Remaining positive, the farm will lose accreditation.

3.3.6. For brucellosis, serologic tests shall be performed every six months, using the buffered acidified antigen or another one approved by the Ministry of Agriculture, Livestock and Food Supply and indicated for the case, and the seroreactive shall be submitted to additional tests for the 2-mercaptoethanol or fixation of complement;

3.3.6.1. Breeder farm shall achieve compliance with serologic conditions for brucellosis only if all tests are negative. In the case of positive test, accreditation shall be suspended. Positive tests shall be eliminated and the herd completely retested within 30 days. Remaining positive, the farm will lose accreditation.

3.3.7. For tuberculosis, male and female breeders shall be tested, by sampling, as the table of Item 3.3.11.1, every 6 (six) months in the comparative test with bovine PPD and avian PPD tuberculin.

3.3.7.1. The reading shall occur after 48 hours, using millimetric ruler, measuring the largest diameter of the reaction. The interpretation of the test will be based on the herd, whereas the arithmetic mean of reactions greater than 0.5 cm.

3.3.7.2. The farm shall achieve compliance with standards for tuberculosis if all animals are negative for bovine PPD or in case of a positive reaction, the average diameter of reactions to bovine PPD is lower than the average diameter of PPD reactions to influenza.

3.3.7.3. The farm shall be considered positive for tuberculosis if the average diameter of reactions to bovine PPD is greater than the mean diameter of PPD reactions to influenza. In this case, accreditation shall be suspended and sanitation measures implemented.

3.3.7.4. If the average diameter of tuberculin reactions to PPD influenza is higher than the average of the reactions to bovine tuberculin PPD, the farm shall be considered infected with Mycobacterium Avium Complex (MAC). In this case, the farm does not lose accreditation and a program of control shall be implemented.

3.3.7.5. In case of suspicious interpretation of reactions to tuberculin, the farm shall temporarily lose accreditation, until diagnosis is completed, based on laboratory testing for identification of the mycobacteria involved.

3.3.8. For Leptospirosis, farms shall have two options:

3.3.8.1. Breeder farms considered free from Leptospirosis will be subject to serologic control. Serological tests of microagglutination shall be performed every six months. Sera shall be tested against the serovars L. canicola, L. grippothyphosa, L. hardjo, L. icterohaemorrhagiae, L. pomona and L. bratislava, showing negative results.

3.3.8.2. At the discretion of the sanitary authority, additional serovars may be included.

3.3.8.3. Breeder farms considered controlled for Leptospirosis (with vaccination), the accreditation shall contain the words “farm vaccinated for Leptospirosis”. The vaccine shall contain all serovars contained in Section 3.3.8.1.

3.3.9. For scabies, two tests of scraping of the skin shall be performed, every 2 or 3 months, including 5 breeders and 5 pigs for slaughter, identified by the official veterinarian, using clinical examination as potential carriers of scabies. Everyone shall present negative results.

3.3.9.1. If positive, accreditation shall be suspended and eradication performed through drug treatment, developed and implemented by the technician in charge.

3.3.10. Farms that do not fully comply with standards mentioned in this Instruction shall lose the condition of Accredited Swine Breeder Farms (GRSC).

3.3.11. Farms will be accredited after the completion of two consecutive negative tests at intervals of two to three months for all diseases described in this Instruction, except for scabies. In this particular case, it will be according to item 3.3.9.

3.3.11.1. In the first test, 100% of the breeder herd shall be tested. Table 2 shall be used in the sampling for the second test and subsequent monitoring. In the case of new farms, populated with the surveillance of the official service, with animals proceeding from already accredited farms, there shall be no need for testing 100% of the herd. In this case, prescriptions of Table 2 are enough.

Table 2 - Sampling of Accredited Swine Breeder Farms

Number of animals for blood collection and completion of comparative tuberculin test, according to the number of swine breeders in the herd, considering an estimated prevalence at 5% and a confidence level of 95%.

No. of breeders in the herd	**No. of animals to be sampled**	**No. of breeders in the herd**	**No. of animals to be sampled**
10	10	350	54
20	19	400	55
30	26	450	55
40	31	500	56
50	35	600	56
60	38	700	57
70	40	800	57
80	42	900	57
90	43	1000	57
100	45	1200	57
120	47	1400	58
140	48	1600	58
160	49	1800	58
180	50	2000	58
200	51	3000	58
250	53	4000	58
300	54	> 5000	59

4. DISEASES FOR OPTIONAL ACCREDITATION

At the discretion of the owner of the breeder farm, the Ministry of Agriculture, Livestock and Food Supply, from June 2002 on, can issue optional accreditation free from any of the diseases listed below:

4.1. Progressive Atrophic Rhinitis (PAR):

4.1.1. Breeder farm shall be considered free from PAR if:

- No Toxigenic type D Pasteurella multocida is detected in 3 starting consecutive tests with an interval of 30 days. It shall be collected nasal and tonsil swabs of 30 piglets with 8 weeks of age that are not being treated with antibiotics. The swabs shall be placed in a transport medium (0.5 ml) and kept at 4 Celsius degrees. In the laboratory, the swabs shall be cultured on selective medium Agar 8HPG, blood agar and placed back in the transport medium. Then it is shaken in vortex, and with the suspensions obtained, a pool of five animals is selected (0.10 ml x 5> 0.50 ml), which shall be inoculated in mice. After 7 days, the mice will be sacrificed, an attempt to isolate *P. multocida*. Samples of *P. multocida* will be tested to identify their toxigenicity by ELISA, Seroneutralization Assay or PCR.

- No damage is found in nasal turbinate superior than 1 by the method of visual assessment (the scale is 0> no lesion, 1> slight deviation from normality; 2> moderate damaged and 3> serious damaged), 3 starting consecutive tests, with an interval of 30 days. Tests shall be performed in a group of at least 30 pigs aged five to six months.

4.1.2. To maintain the accreditation, tests shall be repeated every 6 months, all with negative results.

4.2. Mycoplasma pneumonia (MP)

4.2.1. Breeder farm shall be considered free from Enzootic Pneumonia if:

- *Mycoplasma hyopneumoniae* is not detected in 3 starting consecutive serological tests, with an interval of 30 days, 30 pigs aged over 10 weeks. If there is positive serology and absence of damage at slaughter, live animals with positive serology shall be submitted to bronchial washing and collection of material for Nested-PCR and/or cultivation of *Mycoplasma hyopneumoniae*.

- No pulmonary damage caused by MP is found in 3 starting consecutive tests at the slaughterhouse, with an interval of 30 days, 30 pigs aged 5 to 6 months. If damages caused by MP are found, they shall be submitted to histopathology, followed by immunofluorescence or immunoperoxidase test for *Mycoplasma hyopneumoniae*.

4.2.2. To remain accredited these tests shall be repeated, once, every 6 months, all with negative results.

4.3. Porcine Pleuropneumonia

4.3.1. Breeder farm shall be considered free from Porcine Pleuropneumonia if:

- No pathogenic serovars of *Actinobacillus pleuropneumoniae* is detected in 3 starting consecutive tests, with an interval of 30 days, by the polyvalent ELISA test on 30 piglets with 13 or more weeks of age. If damages caused by Porcine Pleuropneumonia are detected at the slaughterhouse, secretions and fragments of tonsil shall be collected from positive animals and submitted to direct bacteriological tests in selective medium, applying the immunomagnetic separation for isolation of *Actinobacillus pleuropneumonia*, or PCR test.

- No damages caused by Porcine Pleuropneumonia is detected in 3 starting consecutive tests with an interval of at least 30 days, 30 pigs aged 5 to 6 months. If any damage consistent with PPS is observed, it shall be used in serotyping test and to perform tests intended to isolate *Actinobacillus pleuropneumoniae*.

4.3.2. To remain accredited, tests shall be repeated, once, every 6 months, with all results negative.

4.4. Swine Disenteria (SD)

4.4.1. Breeder farm shall be considered free from SD if:

- *Brachyspira hyodysenteriae* is not detected in 3 starting consecutive tests with an interval of 30 days, by laboratory tests of a pool of feces from 6 pigs per pen, taken from 6 different pens of pigs on growth. The feces shall be tested by direct immunofluorescence and confirmed by PCR. To remain accredited tests shall be performed every six months, of a pool of feces from 6 pigs, from 6 different pens of pigs on growth.

4.4.2. To remain accredited, tests shall be repeated, once, every 6 months, with all results negative.

4.5. Concerning diseases described in items 4.1, 4.2, 4.3, 4.4, the GRSC shall be classified into four levels, as follow:

a) Level 1: free from four optional diseases;

b) Level 2: free from at least two optional diseases;

c) Level 3: free from one optional disease;

d) Level 4: no accredited for optional diseases.

5. FINAL DECISIONS

5.1. At the discretion of the Department of Animal Defense (DDA – *Departamento de Defesa Animal*) additional diseases can be required for accreditation.

5.2. Penalties resulting from non-compliance with standards of this Normative Instruction are described in the legislation of Animal Health Defense, regardless of the loss of accreditation.

5.3. Cases not covered by this Normative Instruction shall be addressed by the Department of Animal Defense (DDA).

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