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Agency: Ministry of Agriculture, Livestock and Food Supply/Office of the Minister

NORMATIVE INSTRUCTION 36, DATED JULY 25, 2018

THE ACTING MINISTER OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, using the powers conferred upon him by Article 87, sole paragraph, item II of the Constitution, and pursuant to Legislative Decree no. 188, enacted December 15, 1995, Decree no. 1901 enacted May 9, 1996, and Case File nº 21000.019496/2018-01, resolves that:

Article 1. The “Zoosanitary Requirements for the Party-States of the Mercosur to Import Frozen Porcine Semen” approved by the GMC - MERCOSUR Resolution no. 07/17, which is appended to this Normative Instruction, is hereby added to Brazil’s legal framework.

Article 2. Revokes SDA Normative Instruction No. 54 dated September 17, 2002.

Article. 3 This Normative Instruction shall come into force as of the date of its publication.

EUMAR ROBERTO NOVACKI

APPENDIX

MERCOSUR/GMC/RES. No. 07/17

ZOOSANITARY REQUIREMENTS FOR THE PARTY-STATES TO IMPORT FROZEN PORCINE SEMEN

WHEREAS: The Treaty of Asunción, the Protocol of Ouro Preto, and Decision no. 06/96 of the Common Market Council.

WHEREAS: It is necessary to have zoosanitary requirements and a template for the International Veterinary Certificate to export frozen porcine semen to the Party-States.

THE COMMON MARKET GROUP RESOLVES:

Article 1. To approve the “Zoosanitary Requirements for the Party-States of the Mercosur to Import Frozen Porcine Semen” and the “Template for International Veterinary Certificate” in the Appendices I and II, respectively, and which are part of this Resolution.

Article 2. The Party-States will indicate the national competent agencies that will implement this Resolution, according to Work Subgroup no. 8 "Agriculture" (SGT no. 8).

Article 3. This Resolution must be incorporated to the legal regulation of the Party-States before 06/10/2017.

CIII GMC - Buenos Aires, 06/04/17.

APPENDIX I

ZOOSANITARY REQUIREMENTS FOR THE PARTY-STATES TO IMPORT FROZEN PORCINE SEMEN

CHAPTER I - GENERAL PROVISIONS

Article 1. All the imports of frozen porcine semen shall be accompanied by the International Veterinary Certificate issued by the Veterinary Authority of the exporting country.

The exporting country must draft the certificate template that will be used to export frozen porcine semen to the Party-States of MERCOSUR, including the sanitary guarantees that are stated in this Resolution to be previously approved by the importing Party-State.

Article 2. The importing Party-State will grant the International Veterinary Certificate an expiry of thirty (30) consecutive days counted as of its date of issuance.

Article 3. Diagnostic testing must be performed in official laboratories, or in laboratories approved or recognized by the Veterinary Authority of the semen exporting country. These tests must be performed according to the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals” of the World Animal Health Organization (OIE), henceforth called “Terrestrial Manual”.

Article 4. Sampling for the diagnostic tests established in this Resolution must be supervised by an Official Veterinarian, or a by a Veterinarian authorized by the Veterinary Authority of the exporting country.

Article 5. The Official Veterinarian of the exporting country at the exit point must certify the integrity of the semen containers and their seals.

Article 6. The country that exports semen, which the OIE declares its territory or zone in the country, that complies with the provisions in the Sanitary Code for Terrestrial Animals by the OIE (OIE Terrestrial Code) in order to be considered officially free of any disease for which assays or vaccination are required, and obtain the recognition of the importing Party-State, may be exempted from performing them. In both cases, it must have the recognition of this condition by the importing Party-State, and the certification of a free country or zone must be included in the International Veterinary Certificate.

Article 7. The importing Party-State that has an official program to prevent, control or eradicate any disease not included in this Resolution have the right to require additional measures with the purpose to prevent the disease from entering the country.

Article 8. The importing Party-State and the Veterinary Authority of the exporting country may agree about other equivalent health procedures or diagnostic tests to import frozen porcine semen.

CHAPTER II

EXPORTING COUNTRY

Article 9. Since the first date of semen collection, and at least up to thirty (30) days after the last semen collection, the exporting country must comply with the provisions in the corresponding chapters of the OIE Terrestrial Code to be considered free of African Swine Fever, and this condition must be recognized by the importing Party-State.

Article 10. The exporting country or zone must be officially recognized by the OIE or comply with the provisions in the corresponding chapters of the OIE Terrestrial Code to be considered free of Classical Swine Fever, and this condition must be recognized by the importing Party-State. Furthermore, semen donors must have remained in said country or zone for at least three (3) months before semen collection.

Article 11. Cases of Japanese Encephalitis in susceptible species shall not have been reported in the exporting country in at least the last twelve (12) months before collection.

Article 12. The exporting country, or zone in the exporting country, shall be recognized by the OIE as free of foot-and-mouth disease with or without vaccination.

12.1. Donors should not have shown any clinical sign of foot-and-mouth disease during semen collection, or during the thirty (30) days after this collection, and

12.2. Semen donors must have remained in a country or zone free of foot-and-mouth disease with or without vaccination for at least three (3) months before semen collection.

CHAPTER III

CENTERS FOR SEMEN COLLECTION AND PROCESSING

Article 13. Semen must be collected and processed in a Center for Semen Collection and Processing (CCPS) that complies with the following conditions:

13.1. The CCPS must be registered and supervised by the Veterinary Authority of the exporting country and comply with the conditions established in the corresponding chapter of the OIE Terrestrial Code applicable to the Artificial Insemination Centers, semen collection facilities and semen treatment laboratories.

13.2. It must be declared free of Brucellosis and Aujeszky's disease by the Veterinary Authority of the exporting country.

13.3. In order to enter the CCPS, all males must undergo quarantine for a minimum period of thirty (30) days, to be clinically healthy and test negative in the diagnostic testing established in Chapter V.

13.4. In order to enter the CCPS, and while the animals remain in the Center, they must be vaccinated against Porcine Reproductive and Respiratory Syndrome (PRRS).

Article 14. Semen must be collected and processed under the supervision of the Veterinarian who is technically responsible for the CCPS.

Article 15. At the CCPS, controls must be performed every six months using multivalent ELISA to detect PRRS in all animals, or in a sample that presents 99% confidence to detect at least one infected animal and a 10% expected prevalence.

Article 16. The CCPS shall not have notified cases of PRSS, Vesicular Stomatitis, Swine Vesicular Disease, and Transmissible Gastroenteritis in the last one hundred and eighty (180) days before the first collection of the semen to be exported.

CHAPTER IV

SEMEN DONORS

Article 17. Semen donors must have been born and remained continuously, since their birth, in the Exporting Country or have been imported from a country with an equal or superior sanitary status indicated in Chapter II of this Resolution.

Article 18. While remaining in the CCPS, the animals must not be used for natural breeding.

Article 19. During the period for collection of semen to be exported, and during the thirty days after the collection, the donors cannot have presented clinical signs of infectious diseases.

CHAPTER V

DIAGNOSTIC TESTS AND TREATMENT

Article 20. All animals, including the exciters, during the quarantine period before entering the CCPS, must be subjected and test negative for the following diagnostic tests:

PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME (PRRS):

The animals must be subjected to two (2) multivalent ELISA tests performed at a 21-day interval between them.

AUJESZKY'S DISEASE: Serological test to detect antibodies against the complete virus, performed after the 21st day from the beginning of the quarantine period.

SWINE BRUCELLOSIS (Brucella suis): Buffered Acidified Antigen (AAT) Test. If testing positive, they can undergo a Complement Fixation assay after the 21st day from starting the quarantine period or subjected to a Competitive ELISA test or to a polarized fluorescence assay.

Article 21. Donors of semen to be exported must be subjected and test negative for the following diagnostic tests:

SWINE VESICULAR DISEASE

Within the thirty (30) days before the first collection, shall be subjected and test negative for a viral neutralization test.

SWINE BRUCELLOSIS (*Brucella suis*):

Within the thirty (30) days before the first collection, the animals must be subjected to a Buffered Acidified Antigen (AAT) Test. If testing positive, they can undergo a Complement Fixation Assay, a Competitive ELISA test or to a polarized fluorescence assay.

PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME (PRRS):

At the beginning of the collection, or at least every thirty (30) days, the animals must test negative for a serum PCR test and, between 21 and 60 days after the last collection of semen to be exported, testing negative for a multivalent ELISA assay; and

One sample of collected sample in each batch to the exported (collection from a donor on the same date) must be subjected and test negative for an RT-PCR to detect PRRS.

AUJESZKY'S DISEASE:

Every one hundred and twenty (120) days, the animals must be subjected to a serological test to detect antibodies against the complete virus.

If the CCPS is located in a country free of the disease, the serological test may be performed every twelve (12) months.

FOOT AND MOUTH DISEASE:

When porcine semen is intended to go to an FMD-free zone where vaccination is not practiced, additional specific conditions may be established, including the performance of diagnostic tests, previously agreed between the exporting country and the importing Party-State.

CHAPTER VI

SAMPLING, PROCESSING AND STORAGE OF SEMEN

Article 22. Semen diluents may contain effective antibiotics against *Leptospira* spp., which must be stated in the International Veterinary Certificate.

Article 23. The semen must be collected, processed and stored according to the general hygiene recommendations applicable to collection, treatment, handling and preparation of doses of semen in the laboratory, as described in the corresponding chapter of the OIE Terrestrial Code.

Article 24. The egg-based products used as semen diluents must come from a country, zone or compartment free of notifiable Avian Influenza and Newcastle Disease, or come from specific-pathogen free (SPF) farms with official certification.

Article 25. The semen must be stored in enough quantity of first-use liquid nitrogen, in clean and disinfected, or first-use containers. The sheaths must be individually identified and kept supervised by the Veterinarian who is technically responsible for the CCPS until the moment of shipping.

Article 26. Semen cannot be exported before the thirty (30) days after the last collection date and, during this period, no case of the diseases mentioned in Chapters II and III can be reported in the CCPS. Furthermore, semen cannot be stored with a lower-health condition semen from the CCPS.

Article 27. Each sheath must have the donor identification, collection date and identification

CHAPTER VII - SEAL

Article 28. The cryogenic tank with semen to be exported must be sealed before leaving the CCPS, under the supervision of the official veterinarian or authorized by him/her, and the seal number must be written on the corresponding International Veterinary Certificate.

APPENDIX II**INTERNATIONAL VETERINARY CERTIFICATE TO EXPORT FROZEN PORCINE SEMEN TO THE PARTY-STATES OF THE MERCOSUR**

Certificate Number	(repeat on all pages of the certificate)
Date of issuance	
Validity	thirty (30) days
Number of the Import Permit	

I. ORIGIN

Semen exporting country	
Name and address of the exporter	
Name and address of the Center for Semen Collection and Processing (CCPS)	
Registration number of the Center for Semen Collection and Processing (CCPS)	
Number of containers (figures and letters)	
Number of the container seal(s)	

II. DESTINATION

Country of Destination	
Name of the importer	
Address of the importer	

III. TRANSPORTATION

Means of Transportation	
Exit Border Inspection Post	

IV. SEMEN IDENTIFICATION

Identification of the donor	Identification of the sheaths	Data of sampling	Breed	Number of sheaths

The undersigned Official Veterinarian certifies that

V. HEALTH INFORMATION

Data required in Chapters II, III, IV and V herein shall be included in detail.

VI. SAMPLING, PROCESSING AND STORAGE OF SEMEN

Data required in Chapter VI herein shall be included in detail.

VII. SEAL

Data required in Chapter VII herein shall be included in detail.

Place and date issued:

Name and Signature of the Official

Veterinarian: Official Stamp:

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