

**PROTOCOL BETWEEN
THE MINISTRY OF HEALTH OF THE ITALIAN REPUBLIC AND THE
GENERAL ADMINISTRATION OF CUSTOMS OF THE PEOPLE'S
REPUBLIC OF CHINA ON HEALTH REQUIREMENTS FOR BOVINE
SEMEN TO BE EXPORTED FROM ITALY TO CHINA**

The Ministry of Health of the Italian Republic (hereinafter referred to as «the Italian Party») and the General Administration of Customs of the People's Republic of China (hereinafter referred to as «the Chinese Party») have reached the following understanding on health requirements for bovine semen to be imported from Italy to China.

Article 1

The Italian Party will be responsible for the quarantine and inspection of the donor bulls, the teaser animals and the bovine semen to be exported to China and for the issuing of the health certificates:

1.1. After having received the import permit for each consignment of bovine semen to be exported to China issued by the Chinese Party, the Italian Party may start to implement the quarantine and inspection of the donor bulls, the teaser animals and the conditions of semen collection in compliance with this Protocol.

1.1.1 Each import permit can only allow the importation of one consignment of bovine semen.

1.1.2 The Italian Party is responsible for the quarantine and inspection and the issuance of health certificates according to this Protocol.

1.2. The Italian Party will provide in advance to the Chinese Party a model of health certificate for the Chinese Party's approval before it is adopted.

1.2.1 The health certificate will include the following:

1.2.1.1 Statement that all the requirements of quarantine and sanitary controls provided for in this Protocol have been met;

1.2.1.2 Name, approval number and address of the semen center (hereinafter referred to as SC) including collection and/or storage;

1.2.1.3 Name and address of consignor and consignee;

1.2.1.4 Name and identification number of the donor bull;

1.2.1.5 Number of straws;

1.2.1.6 Identification marks of the straws with the date of collection and the identification number of the donor bulls;

- 1.2.1.7 Methods of dilution and final concentration of active spermatozoa;
- 1.2.1.8 Components of the diluting liquid, relative proportions of antibiotics added (not less than 500 µg streptomycin per ml final dilution, 500 IU penicillin per ml final dilution, 150 µg lincomycin per ml final dilution, 300 µg spectinomycin per ml final dilution or any alternative combination of antibiotics with an equivalent effect against campylobacters, leptospire and mycoplasma) and the list of other ingredients;
- 1.2.1.9 Results of clinical examinations, methods and results of the tests;
- 1.2.1.10 Seals and marks on the containers for the transportation of the semen;
- 1.2.1.11 Date of issuance of the health certificate, name [typewritten] and signature of the official veterinarian;
- 1.2.1.12 The official stamp of the competent Italian Authority responsible for the release of the certificate.
- 1.2.1.13 Each consignment of the semen for export will be collected, processed, stored, packed, sealed and transported under the supervision of the official veterinarian.
- 1.2.2 There will be one original and at least two copies of the health certificate.
- 1.2.3 The health certificate will be typed in the Italian, Chinese and English language. Handwritten or altered versions are invalid.
- 1.2.4 The original health certificate will accompany the semen batches and will arrive in China at the same time.
- 1.2.5 Should a semen batch arrive at the port of entry into the People's Republic of China with invalid health certificate or without a health certificate, the semen batch will be returned or destroyed.

Article 2

2.1. The Italian Party confirms that Italy is free from Foot-and-mouth Disease, Rinderpest, Lumpy Skin Disease, Contagious Bovine Pleuropneumonia and Peste des Petits Ruminants.

2.2. Should one of the diseases mentioned in article 2.1. occurs in Italy, the Italian Party will inform the Chinese Party in a timely manner about the disease name, the geographic coordinates and address of infected farm(s), the species and number of infected animal(s), and the measures taken to control the disease spreading. Moreover, without any delay, the Italian Party will stop the exporting of semen from Italy to China.

2.3 According to the EU and OIE rules, the Italian Party should have control program for Bluetongue and the Italian Party will provide a zoning map available on the following website: https://bluetongue.izs.it/j6_bluetongue/list_territoriRestrizione.

Article 3

3.1. The Italian Party confirms that:

3.1.1 The SC is located in a province free from native rabies.

3.1.2 The SC has been free from Rift Valley Fever, Vesicular Stomatitis, Epizootic Haemorrhagic Disease of Deer, Bluetongue, Bovine Tuberculosis, Bovine Brucellosis and Enzootic Bovine Leukosis for at least three (3) years, and no clinical case of Infectious Bovine Rhinotracheitis, campylobacteriosis, trichomoniasis, anaplasmosis, mucosal disease (BVD/MD), paratuberculosis and leptospirosis, has occurred during the last two (2) years (or the last year in case of implementation of a procedure of test/slaughter/disinfection) ;

3.1.3 During a period of five (5) years prior to the first collection of semen for export to China up till six (6) weeks after the last collection of the semen for export to China, all animals in the SC for export of semen have been free of rabies.

3.2. All resident animals of the SC, including donor bulls and teasers, are regularly tested in accordance with the Italy and EU legislations.

3.3. All resident animals of the SC, including donor bulls and teasers, have been tested with negative results, at least thirty (30) days before the first semen collection, according to the requirements of this Protocol.

3.4. In case of occurrence of one of the diseases mentioned in articles 3.1.1. and 3.1.2. in a SC exporting to China and registered by both Parties, the Italian Party will inform the Chinese Party and stop all issuance of health certificate for bovine semen from this center.

Article 4

4.1. The Italian Party will transmit to the Chinese Party a list of the SCs that produce frozen bovine semen to be exported to China, and comply with the requirements of this Protocol.

4.2. The Chinese Party will send official veterinarian to carry out audits for the approval of the SC. The semen to be exported to China will originate from a SC approved by the Chinese Party.

4.3. The SCs exporting semen to China are:

- 4.3.1 Approved by the Italian Party, according to the Italian and EU legislations and to the requirements of this Protocol;
- 4.3.2 Supervised by the Italian Party;
- 4.3.3 located in areas included in a national surveillance program conducted in accordance with OIE guidelines for prevention, control and eradication of bovine spongiform encephalopathy (BSE) and blue tongue; and
- 4.3.4 Complying with OIE standards for the production and processing of semen.

Article 5

5.1. The donor bulls:

5.1.1 Have unique and permanent identification marks, have been registered by the Italian Party and are traceable;

5.1.2 Have never been used for natural mating and are at least one (1) year old;

5.1.3 Were born in Italy or legally imported into Italy in accordance with the Italian and EU regulations in order to preclude the entry of Bluetongue, and before the semen collection, have been continuously resident in a SC for at least six (6) months, including the quarantine period;

5.1.4 Were born after the implementation of the ruminant feed ban (i.e. after January the 1st 2001) and hence have not been fed with ruminant proteins or feeds containing ruminant proteins prohibited under feed ban in Italy during their lifetime. If imported, they originated from countries with a controlled BSE risk status or with a negligible BSE risk status;

5.1.5 Have been confirmed free from the following genetic diseases: Bovine Leukocyte Adhesion Deficiency (for Holstein), Complex Vertebral Malformation (for Holstein), SHGC (Montbéliarde), Brachyspina (for Holstein), Zinc Deficiency (for Pezzatarossa Italiana), Acromegaly (for Pezzatarossa Italiana), Haplotype of the Bruna 2 (for Pezzatarossa Italiana), Haplotype of the Fleckvieh 5 (for Pezzatarossa Italiana).

5.2. Both the donor bulls and the teasers will have been free from any evidence of contagious or infectious diseases mentioned in Article 2.1, 3.1.1 and 3.1.2 of this Protocol, neither 30 days before the time of semen collection nor the shipment of the semen;

5.3. The semen does not come from donor bulls dead of a disease or BSE positive donor bulls.

Article 6

6.1 All resident animals of the SCs, including donor bulls and teasers, are tested for diseases listed in Annex with negative results.

6.2 If one donor bull is tested positive for one of the diseases mentioned in article 5, no semen collected from this donor bull will be exported to China, and positive animals should immediately be removed and isolated from the herd.

Article 7

7.1 Each consignment of semen will be put in straws, sealed and marked under the supervision of the veterinarian authorized by the Italian Party.

7.2 Only clean and disinfected containers and nitrogen not previously used for any purpose will be used for the storage.

Article 8

8.1. This Protocol and its Annex can be amended in writing by mutual consent between the Parties.

8.2. The Annex to this Protocol form an integral part of it.

Article 9

9.1 Either Party may terminate this Protocol at any time by giving the other Party a six (6) months written notice.

9.2. This Protocol takes effect on the date of signature, it will remain valid for five (5) years and will be automatically renewed for further periods of five (5) years, unless one of the Parties notifies the other of its intention to terminate it as provided for in the previous paragraph.

Article 10

This Protocol also applies to buffalo semen.

Article 11

Any costs regarding the implementation of the present Protocol will be borne by the

Parties in conformity with their respective national legislations and without any additional costs for the ordinary State budgets of the Italian Republic and the People's Republic of China.

Article 12

This Protocol will be implemented in accordance with the Italian and Chinese legislations, as well as applicable international law and, as for the Italian Party, the obligations arising from Italy's membership of the European Union.

Article 13

Any difference in the interpretation and/or implementation of this Protocol will be settled amicably by means of direct consultations and negotiations between the Parties.

Done in Rome on 23 march 2019 in two originals each in Italian, Chinese, and English, all texts being equally authentic. In case of divergence, the text in English will prevail.

On behalf of
the Ministry of Health of Health
of the Italian Republic

Giulia Grillo

On behalf of
the General Administration of Customs
of the People's Republic of China

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**ANNEX:
TESTS REQUIRED FOR THE EXPORTATION OF BOVINE SEMEN
FROM ITALY TO CHINA**

Disease		Methods and results
1	Bovine Tuberculosis	Intradermaltuberculation test twice a year as Italy producers with negative result (OIE method).
2	Bovine Brucellosis	Within 30 days before the first semen collection and 21-60 days after the last semen collection, ELISA or BBAT (OIE method) with negative results.
3	Bovine Leukosis	Within 30 days before the first semen collection and 21-60 days after the last semen collection, lymphonodes are not swollen, and AGID or ELISA test with negative results.
4	Infectious Bovine Rhinotracheitis	Within 30 days before the first semen collection and 21-60 days after the last semen collection, Serum neutralization (SN) test (dilution 1:2) or ELISA test with negative results, Or Three straws of semen from each ejaculation are submitted for IBR virus isolation or RT-PCR with negative results.
5	Campylobacter foetus	Isolation and culture or PCR test twice a year as Italy producers with negative results.
6	Trichomonose	Culture and direct microscopic examination or PCR test twice a year as Italy producers with negative results.
7	Leptospirosis	Within 30 days before the first semen collection and 21-60 days after the last semen collection, Micro-agglutination test for sejroe, ballum, hardjo, Pomona, canicola, grippotyphosa, icterohemmorrhagiae, Bratislava and Tarassovi with negative results
8	Bovine Viral Diarrhea (BVD)	Before being admitted to the SC, the donor bulls have been subjected to: <ul style="list-style-type: none"> · a virus isolation test or a test for virus antigen · and a serological test (serum neutralization SN or ELISA) to determine the absence of antibodies.

		<p>Within 30 days before the first semen collection and 21-60 days after the last semen collection the donor bulls have been subject to serological test (serum neutralization SN or ELISA) to determine the absence of antibodies.</p>
9	<p>Bluetongue (Semen collected after May 1st 2006)</p>	<p>The donor bulls have been subjected to a serological test (AGID or serum neutralization SN or ELISA), with negative results:</p> <ul style="list-style-type: none"> · at least every sixty (60) days throughout the collection period, and · a test performed between twenty-one (21) and sixty (60) days after the final collection for this consignment; <p>or</p> <p>have been subjected to an agent identification test (virus isolation or PCR test) with negative results, on blood samples collected:</p> <ul style="list-style-type: none"> · at the commencement and conclusion of the collection of the semen to be exported, · and at least every 7 days (virus isolation test) or at least twenty-eight (28) days (PCR test) during semen collection for this consignment.
10	<p>Schmallenberg disease (Semen collected after June 1st 2011)</p>	<p>The donor bulls have been subjected to one (1) serological test (serum neutralization SN or ELISA) performed between twenty-one (21) and sixty (60) days after the conclusion of the collection of the semen to be exported with negative results</p> <p>And each consignment of semen to be exported has been individually tested for detecting the presence of the Schmallenberg virus genome after an RNA extraction and a RT-PCR test, with negative results.</p>
11	<p>Paratuberculosis</p>	<p>Within 30 days before the first semen collection and 21-60 days after the last semen collection, subjected to ELISA test with negative result.</p>
12	<p>Q fever</p>	<p>Within 30 days before the first semen collection and 21-60 days after the last semen collection, complement fixation test with negative result.</p>