
STATUTORY RULES OF NORTHERN IRELAND

1996 No. 389

ANIMALS

**Bovine Embryo Collection, Production and
Transplantation Regulations (Northern Ireland) 1996**

Made - - - - *21st August 1996*
Coming into operation *2nd October 1996*

The Department of Agriculture, in exercise of the powers conferred on it by Article 5(1) and (2) of the Artificial Reproduction of Animals (Northern Ireland) Order 1975⁽¹⁾ and section 2(1) of the Welfare of Animals Act (Northern Ireland) 1972⁽²⁾, and of every other power enabling it in that behalf and after consultation as to regulation 16 with such persons appearing to it to represent the interests concerned as it considers appropriate hereby makes the following Regulations:—

Part I

Introductory

Citation and commencement

1. These Regulations may be cited as the Bovine Embryo Collection, Production and Transplantation Regulations (Northern Ireland) 1996 and shall come into operation on 2nd October 1996.

Interpretation

2.—(1) In these Regulations—

“approved veterinary surgeon” means a veterinary surgeon approved by the Department for the purposes of these Regulations;

“bovine embryo collection team” means a group of technicians who collect, process and store embryos under the supervision of a team veterinarian;

“bovine embryo production team” means a group of technicians who produce and store embryos under the supervision of a team veterinarian;

(1) S.I.1975/1834 (N.I. 17) as amended by S.I. 1994/1891 (N.I. 6) Arts. 17 and 18
(2) 1972 c. 7 (N.I.) as amended by S.I. 1994/1891 (N.I. 6) Art. 10

“bovine embryo transplantation team” means a group of technicians who transplant embryos under the supervision of a team veterinarian;

“bull” means any male bovine animal which is capable of reproduction;

“collection” in relation to any embryo means the collection of that embryo from a donor cow;

“cow” means any female bovine animal which is capable of reproduction;

“the Directive” means Council Directive [89/556/EEC](#) on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species⁽³⁾;

“donor sire” in relation to any embryo means the bovine animal from which the semen used to conceive the embryo was collected;

“EEA State” means any state which is a contracting party to the Agreement on the European Economic Area⁽⁴⁾ signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993;

“embryo” has the same meaning as in the Directive;

“intra-Area trade” means export to any EEA State, other than the United Kingdom;

“processed semen” means semen which has been processed by means of—

- (a) dilution;
- (b) the addition of any substance which is calculated to prolong its natural life;
- (c) the addition of any antibiotic or any antimicrobial substance for the purpose of promoting and safeguarding animal health;
- (d) packaging it into straws;
- (e) freezing; and
- (f) storing it after freezing in a quarantine storage depot for 30 days, or such other period as the Department may direct in writing; or

by means of one or more of the processes listed at (a), (b), (c) and (d) of this definition;

“processing” in relation to any embryo means the examination, washing, treating and placing in identified and sterile containers of that embryo;

“raw semen” means semen which is not processed;

“team veterinarian” means a veterinary surgeon who is responsible for supervising the activities of a bovine embryo collection, a bovine embryo production or a bovine embryo transplantation team, as the case may be;

“transplantation” means the transplantation into a cow of an embryo which was collected from another cow, or produced in vitro, as the case may be;

“veterinary prohibition or quarantine measures” means measures imposed by the Department for the purpose of controlling or eradicating an outbreak of disease in bovine animals; and

“veterinary surgeon” means a veterinary surgeon (or veterinary practitioner) registered or recognised under the Veterinary Surgeons Act 1966⁽⁵⁾.

(2) In relation to any embryo “the donor cow” means the cow from which it is collected and “the recipient cow” means the cow into which it is transplanted.

(3) O.J. No. L302, 19.10.89, p. 1 as amended by Council Directive [90/425/EEC](#) (O.J. No. L224, 18.8.90, p. 29), Council Directive [93/52/EEC](#) (O.J. No. L175, 19.7.93, p. 21) and Commission Decision [94/113/EEC](#) (O.J. No. L53, 24.2.94, p. 23)

(4) O.J. No. L1, 3.1.94, p. 1

(5) 1966 c. 36

Licences

3.—(1) Any licence granted under these Regulations—

- (a) shall be in writing;
- (b) may be granted subject to conditions; and
- (c) may be modified or suspended by notice in writing given to the holder thereof at any time.

(2) Without prejudice to the generality of paragraph (1)(c) any licence granted under these Regulations may, in particular, be granted subject to the condition that any premises or equipment to which it relates may be subject to inspection by the Department of such frequency as may be specified in the licence.

(3) Where a bovine embryo collection team, production team or transplantation team is licensed for a particular purpose under these Regulations it shall be given a distinguishing number in respect of each such purpose for which it is licensed.

(4) An application for a licence for a bovine embryo collection team, production team or transplantation team, or for any facilities used by such a team, or, for the storage of embryos, shall be made in writing to the Department and shall be signed by the team veterinarian or, in the case of storage facilities, by the person in charge thereof.

Application

4.—(1) The provisions of these Regulations relating to the collection, production or storage of embryos shall not apply to embryos produced for the purposes of research carried out in accordance with the conditions of a licence issued under the Animals (Scientific Procedures) Act 1986(6).

(2) These Regulations (other than Regulations 15 and 16) shall not apply in relation to embryos derived by transfer of nuclei.

Part II

Collection, production and processing of embryos

Licensing of bovine embryo collection teams and their facilities

5.—(1) Upon the Department being satisfied that a bovine embryo collection team complies with Schedule 1, and has at its disposal—

- (a) permanent laboratory facilities as specified in Part I of Schedule 2; or
- (b) mobile laboratory facilities as specified in Part II of Schedule 2,

it may licence that team for the purposes of collecting and processing, and those permanent or mobile laboratory facilities, as the case may be, for the purposes of processing, any embryos.

(2) Upon the Department being satisfied that a bovine embryo collection team complies with Schedule 1 and has at its disposal mobile laboratory facilities as specified in Part II or Part III of Schedule 2 it may licence that team for the purposes of collecting and processing, and those mobile laboratory facilities for the purposes of processing, embryos which are not intended for intra-Area trade.

Collection of embryos

6.—(1) Subject to paragraphs (3) and (4), a person shall not collect or process any embryo unless—

- (a) he is a member of a bovine embryo collection team licensed for the purpose under regulation 5(1) or (2);
- (b) he is a bovine embryo collection team veterinarian or acting under his authority;
- (c) the embryo is collected and processed either in accordance with Schedule 3 or Schedule 4;
- (d) at the date of collection the donor cow is not subject to any veterinary prohibition or quarantine measures and shows no clinical sign of disease; and
- (e) the embryo was conceived either—
 - (i) by natural service where the donor sire was, at the date of that service, not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of disease;
 - (ii) by artificial insemination using processed semen which at the time of insemination could lawfully have been distributed or sold in Northern Ireland; or
 - (iii) by artificial insemination using raw semen obtained from a donor sire which at the time of semen collection was not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of disease.

(2) A person shall not collect or process any embryo for the purpose of intra-Area trade unless—

- (a) he is a member of a bovine embryo collection team licensed for the purpose under regulation 5(1);
- (b) he is a bovine embryo collection team veterinarian or acting under his authority;
- (c) the embryo is collected and processed in accordance with Schedule 4;
- (d) the donor cow complies with the requirements of Schedule 5; and
- (e) the embryo was conceived as a result of artificial insemination with semen from a donor sire which, at the time of collection, was standing at a semen collection centre as defined in Article 2.b of Council Directive [88/407/EEC](#) laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species⁽⁷⁾.

(3) An embryo may be collected by a veterinary surgeon, or a member of a bovine embryo collection team licensed under regulation 5(1) or (2) acting under the authority of the team veterinarian, for transplantation without being processed in accordance with Schedule 3 or Schedule 4 if—

- (a) it is intended for use in the United Kingdom without being frozen or stored;
- (b) the recipient cow is owned by the same person as the donor cow;
- (c) at the date of collection, the donor cow is not subject to any veterinary prohibition or quarantine measures and shows no clinical sign of disease;
- (d) the embryo was conceived using raw semen, at the date when the donor cow was served or inseminated with that semen the donor sire was not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of disease; or
- (e) the embryo was conceived using processed semen, at the date when the semen was obtained from the donor sire, that animal was not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of disease.

(7) O.J. No. L194, 22.7.88, p. 10 as amended by Council Directive [90/120/EEC](#) (O.J. No. L71, 17.3.90, p. 37), Council Directive [90/425/EEC](#) (O.J. No. L224, 18.8.90, p. 29) and Council Directive [93/60/EEC](#) (O.J. No. L186, 28.7.93, p. 28)

(4) Where the Department thinks fit, it may licence the collection, by a veterinary surgeon or a member of a bovine embryo collection team licensed under regulation 5(1) or (2) of an embryo not intended for intra-Area trade where the conditions specified in this regulation are not satisfied in relation thereto.

Licensing of bovine embryo production teams

7. Upon the Department being satisfied that a bovine embryo production team complies with Schedule 6 it may licence that team for the purposes of the production and processing of embryos in vitro.

Production of embryos in vitro

8. A person shall not produce or process an embryo in vitro unless—
- (a) he is a member of a bovine embryo production team licensed for the purpose under regulation 7;
 - (b) he is a bovine embryo production team veterinarian or acting under his authority;
 - (c) the embryo is produced and processed in accordance with Schedule 7 using semen from a donor sire which, at the time of semen collection, was standing at a semen collection centre as defined in Article 2.b of Council Directive [88/407/EEC](#) or, in the case of embryos not intended for intra-Area trade, using semen which could lawfully have been distributed or sold in Northern Ireland at the time of fertilisation; and
 - (d) the donor cow complies with the requirements of Schedule 5.

Part III

Storage and transport of embryos

Storage of embryos for use in intra-Area trade

9.—(1) The Department may, on application, licence a store for the storage of embryos intended for intra-Area trade if it complies with the conditions of this regulation.

(2) The store shall be under the supervision of an approved veterinary surgeon who is the team veterinarian for a team licensed either as a bovine embryo collection team or as a bovine embryo production team and who shall ensure that the conditions of this regulation and any other conditions attached to the licence are complied with.

(3) The store shall consist of a lockable room which shall be locked when not in use.

(4) Nothing shall be stored in the room other than embryos, or bovine semen, eligible for intra-Area trade.

(5) The store shall be easy to clean and disinfect.

(6) Embryos in the store shall be kept at a suitable temperature.

10. A person shall not store any embryo for use in intra-Area trade except in a store licensed under regulation 9(1) and in accordance with the conditions of such a licence.

Storage of embryos not intended for intra-Area trade

11.—(1) The Department may, on application, licence a store for the storage of embryos not intended for intra-Area trade if it complies with the conditions of this regulation.

(2) The store shall, subject to paragraph (7), be under the supervision of an approved veterinary surgeon who shall ensure that the conditions of this regulation and any other conditions attached to the licence granted in relation to that store under paragraph (1) are complied with.

(3) The store shall consist of a lockable room which shall be locked when not in use.

(4) Nothing shall be stored in the room other than embryos eligible to be transferred in Northern Ireland or bovine semen which could lawfully be distributed or sold in Northern Ireland.

(5) The store shall be easy to clean and disinfect.

(6) Embryos in the store shall be kept at a suitable temperature.

(7) In the case of a store used for embryos which will only be used on the same premises as the premises where the store is situated—

(a) the store may be supervised by a person who is not a veterinary surgeon; and

(b) the person to whom the licence is granted under paragraph (1) shall ensure that the conditions of this regulation and any other conditions attached to the licence are complied with and that the embryos in that store are not removed from the premises on which the store is situated.

12. A person shall not store any embryo for use other than in intra-Area trade except in a store licensed under Regulations 9(1) or 11(1) and in accordance with the conditions of such a licence.

Transport of embryos

13.—(1) A person shall not transport any embryo except under satisfactory hygienic conditions.

(2) A person shall not transport any embryo for the purpose of intra-Area trade except in a sealed container marked in such a way that the number on the seal is the same as the number on the accompanying animal health certificate issued in accordance with the Animals and Animal Products (Import and Export) Regulations (Northern Ireland) 1995⁽⁸⁾.

Part IV

Transplantation of embryos

Licensing of bovine embryo transplantation teams

14. Upon the Department being satisfied that a bovine embryo transplantation team—

(a) is supervised by a veterinary surgeon; and

(b) has at its disposal a room or area equipped for cleaning and sterilising instruments and equipment used in the transplantation of embryos,

it shall licence that team and those facilities for the purposes of the transplantation of embryos.

Transplantation of embryos

15.—(1) A person shall not carry out any transplantation unless he is—

(a) a member of a bovine embryo transplantation team licensed for the purpose under regulation 14; or

(b) a veterinary surgeon.

(2) A person who is not a veterinary surgeon shall only carry out a transplantation if—

(8) S.R. 1995 No. 52

- (a) he is competent to do so;
 - (b) he has been trained by the team veterinarian in methods and techniques of hygiene; and
 - (c) the transplantation is carried out under the authority of the team veterinarian.
- (3) A veterinary surgeon shall only carry out a transplantation if he clinically examines the recipient cow before doing so and satisfies himself that—
- (a) it is suitable to receive the embryo; and
 - (b) there is no reason at that time to believe that the cow would not be able to carry to term a normal calf of the breed and type of the embryo being transplanted and to calve naturally.
- (4) A person who is not a veterinary surgeon shall only carry out the transplantation of an embryo if the team veterinarian, or a veterinary surgeon nominated for the purpose by him, has clinically examined the recipient cow within 30 days preceding the transplantation and has certified, in the form specified in Schedule 8, that—
- (a) he has done so and that the cow is suitable to receive the embryo;
 - (b) shows no clinical sign of disease; and
 - (c) he knows of no reason existing at the time of his examination which would cause him to believe that the cow would not be able to carry to term a normal calf of the breed and type specified in the certificate and to calve naturally.
- (5) A person shall not transplant any embryo unless it has been either—
- (a) collected, processed, stored or transported in accordance with the provisions of these Regulations or the Bovine Embryo Collection and Transplantation Regulations (Northern Ireland) 1994⁽⁹⁾;
 - (b) imported into Northern Ireland in accordance with the provisions of the Animals and Animal Products (Import and Export) Regulations (Northern Ireland) 1995 or any Regulations which they supersede;
 - (c) imported into Northern Ireland in accordance with the provisions of the Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1993⁽¹⁰⁾;
 - (d) imported into Northern Ireland in accordance with the provisions of the Landing of Carcases and Animal Products Order (Northern Ireland) 1985⁽¹¹⁾ as amended;
 - (e) imported into Northern Ireland in accordance with the provisions of the Artificial Reproduction of Animals (Northern Ireland) Order 1975;
 - (f) collected in Northern Ireland before 7th March 1994; or
 - (g) derived by transfer of nuclei.

Part V

General

Requirements to use anaesthetics

16.—(1) A person shall not *per vaginam* collect any embryo from or transplant any embryo into, a cow for the time being situate on agricultural land unless a general or an epidural anaesthetic has first been administered to the cow.

⁽⁹⁾ S.R. 1994 No. 35

⁽¹⁰⁾ S.R. 1993 No. 304

⁽¹¹⁾ S.R. 1985 No. 161 as amended by S.R. 1995 No. 315

(2) A person who contravenes paragraph (1) shall be guilty of an offence under section 2 of the Welfare of Animals Act (Northern Ireland) 1972.

Records at stores

17.—(1) The person supervising a store for embryos shall keep a record in permanent form of the following—

- (a) the identification of each embryo entering the store;
- (b) the date of entry of each such embryo;
- (c) the place of origin of each such embryo or the place in which it was last stored, if different;
- (d) the date of removal of each such embryo from the store;
- (e) the destination of each such embryo,

and shall keep the record for the period during which the embryo remains in the store and for 12 months after the date of its removal from the store.

(2) In the case of embryos derived by in vitro fertilisation, the identification in the record kept under paragraph (1) may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries or oocytes and the identification of the herd of origin of the donor animals.

Records other than at stores

18.—(1) The team veterinarian of a bovine embryo collection or production team must keep a record of its activities in respect of embryo collection or production for 12 months after collection or production of each embryo, including in particular—

- (a) the breed, age and identification of the donor animals concerned;
- (b) the place of collection, processing and storage of embryos collected by the team;
- (c) the identification of the embryos together with details of their destination if known; and
- (d) details of any micro-manipulation techniques which involve penetration of the *zona pellucida* or other techniques such as in vitro fertilisation or in vitro culture which have been performed on the embryos.

(2) In the case of embryos derived by in vitro fertilisation, the identification in the record kept under paragraph (1) must be done on the basis of a batch, and must contain details of the date and place of collection of ovaries or oocytes and the identification of the herd of origin of the donor animals.

(3) The team veterinarian of a bovine embryo transplantation team or a veterinary surgeon transplanting embryos shall keep a record for 12 months of—

- (a) the breed, age and identification of the recipient cow;
- (b) the place of transplantation; and
- (c) the identification of the embryo together with details of its source, if known.

Transitional provisions

19.—(1) Subject to paragraph (2), after 31st January 1999 a person shall not use any embryo collected before 7th March 1994 except in accordance with a licence issued by the Department.

(2) Notwithstanding the provisions of paragraph (1), a person may use any embryo collected in the period between 31st December 1990 and 7th March 1994 if the embryo was collected in accordance with the provisions of the Directive.

(3) In the case of embryos collected before 7th March 1994, it shall be a defence for any person charged with failing to keep any records required under Regulations 17 or 18 to show that the information required thereunder to be recorded was not available.

Revocation

20. The Bovine Embryo Collection and Transplantation Regulations (Northern Ireland) 1994 are hereby revoked.

Sealed with the Official Seal of the Department of Agriculture on 21st August 1996.

L.S.

P. T. Toal
Assistant Secretary

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SCHEDULE 1

Regulation 5

Conditions for the licensing of bovine embryo collection teams for all purposes including for intra-Area trade

The collection, processing and storage of embryos must be carried out either by the collection team veterinarian or under his authority by one or more technicians who are competent and trained by the collection team veterinarian in methods and techniques of hygiene.

SCHEDULE 2

Regulation 5

Part I

Permanently sited laboratories for all purposes including for intra-Area trade

1. The permanently sited laboratory, must have—
 - (a) a work surface, a microscope and cryogenic equipment;
 - (b) a room where embryos can be manipulated which is adjacent to but physically separate from the area used to handle the donor animals during collection;
 - (c) a room or area equipped for cleansing and sterilising instruments and equipment used in embryo collection and manipulation; and
 - (d) where micro-manipulation of the embryo which involves penetration of the *zona pellucida* is to be carried out, suitable laminar-flow facilities.

Part II

Mobile laboratories for all purposes including for intra-Area trade

1. The mobile laboratory must have—
 - (a) a work surface, a microscope and cryogenic equipment; and
 - (b) two separate sections, one for the examination and manipulation of embryos which shall be a clean section, and the other for accommodating equipment and materials used in contact with the donor animals.
2. The mobile laboratory shall always have contact with a permanently sited laboratory to ensure the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and manipulation of embryos.

Part III

Mobile laboratories for the purposes of trade within Northern Ireland

1. The mobile laboratory shall—
 - (a) have separate parts so that there is no contact between used and unused equipment and materials;
 - (b) carry sufficient equipment to enable the examination and manipulation of embryos to be carried out without contaminating them; and

- (c) have contact with a permanently sited laboratory to ensure the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and manipulation of embryos.

SCHEDULE 3

Regulation 6(1) and 6(3)

Conditions relating to the collection, processing and storage of embryos *not intended* for intra-Area trade

1. Embryos shall be processed in either a permanent laboratory facility or a mobile laboratory facility licensed under regulation 5(1) or (2), which is not situated in a zone subject to prohibition or quarantine measures.
2. All implements which come into contact with the embryos or the donor animal during collection and processing shall be properly disinfected or sterilised before use.
3. Products of animal origin used during collection of the embryos and in the transport medium shall be obtained from sources which present no animal health risk or are treated before use in such a way that such risk is prevented.
4. Storage flasks and transport flasks shall be properly disinfected or sterilised before the commencement of the initial filling operation.
5. The cryogenic agent used shall not have been previously used for other products of animal origin.
6. Each embryo container and the containers in which they are stored and transported shall be clearly marked with—
 - (a) the appropriate distinguishing number of the collection team;
 - (b) the date of the collection of the embryo; and
 - (c) either—
 - (i) the breed and identification of the donor sire and donor cow, or
 - (ii) a code from which this information can be readily established.
7. Each embryo shall be washed at least 10 times in a special fluid for embryos which shall be changed each time. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.
8. After the last wash each embryo shall be subjected to microscopic examination over its entire surface to determine that the *zona pellucida* is intact and is free from any adherent material.
9. Each consignment of embryos that has successfully undergone the examination provided for in paragraph 8 shall be placed in sterile containers marked in accordance with paragraph 6 and which shall be sealed immediately; and in this paragraph “consignment of embryos” means a quantity of embryos removed in one operation from a single donor.

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SCHEDULE 4

Regulation 6(1) to (3)

Conditions relating to the collection, processing, storage and transport of embryos for the purposes of intra-Area trade

1. Embryos shall be collected, processed and packed without coming into contact with any other consignment of embryos not meeting the requirements of these Regulations relating to embryos intended for intra-Area trade.

2. Embryos shall be collected in a place which is isolated from other parts of the premises or holding and which must be in good repair and easy to cleanse and disinfect.

3. Embryos shall be processed in either a permanent laboratory facility or a mobile laboratory facility licensed under regulation 5(1), which is not situated in a zone subject to veterinary prohibition or quarantine measures.

4. All implements which come into contact with the embryos or the donor animal during collection and processing shall be disposable or shall be properly disinfected or sterilised prior to use.

5. Products of animal origin used during collection of the embryos and in the transport medium shall be obtained from sources which present no animal health risk or are to be so treated prior to use so that such risk is prevented. All media and solutions shall be sterilised by approved methods according to the recommendations of the manual of the International Embryo Transfer Society⁽¹²⁾. Antibiotics may be added to the media in accordance with that manual.

6. Storage flasks and transport flasks shall be properly disinfected or sterilised before the commencement of each filling operation.

7. The cryogenic agent used shall not have been previously used for other products of animal origin.

8. Each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor cow, as well as the distinguishing number of the team can be readily established.

9. Each embryo shall be washed at least 10 times in a special fluid for embryos which shall be changed each time and which shall contain trypsin, in accordance with internationally recognised procedures. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.

10. After the last wash each embryo shall be subjected to microscopic examination at a magnification of at least 50x over its entire surface to determine that the *zona pellucida* is intact and is free from any adherent material. Any micro-manipulation which involves penetration of the *zona pellucida* must be carried out after the last wash and examination in the facilities approved for the purpose. Such micro-manipulation may only be carried out on an embryo having an intact *zona pellucida*.

11. Each consignment of embryos that has successfully undergone the examination provided for in the preceding paragraph shall be placed in a sterile container marked in accordance with paragraph 8 and sealed immediately.

12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian and which is subject to regular inspection by a veterinary officer of the Department.

(12) Edited by D. A. Stringfellow and S. M. Siedel and published in November 1990 by the International Embryo Transfer Society. It is obtainable from their headquarters at 309 West Clark Street, Champaign, Illinois, USA

13. Each collection team must submit routine samples of flushing fluids, washing fluids, disintegrated embryos, non-fertilised ova etc, resulting from its activities to the Department for official examination for bacterial and viral contamination.

SCHEDULE 5

Regulation 6(2) and 8(d)

Conditions relating to donor animals for the purposes of Regulation 6 or 8

Part I

Collection from live animals

1. The donor cow must have spent at least the previous six months in an EEA State or, in the case of any other country, in the country of collection.
2. The donor cow must have been present in the herd of origin for at least 30 days prior to collection.
3. The donor cow must come from a herd which is—
 - (a) officially tuberculosis free;
 - (b) officially brucellosis free or brucellosis free; and
 - (c) either enzootic bovine leucosis free or for which certification has been obtained that there has not been any clinical case of enzootic bovine leucosis during the past three years.
4. During the year before collection of the embryo, the donor cow must not have been present in a herd (or herds) which have shown any clinical sign of infectious bovine rhinotracheitis or infectious pustular vulvovaginitis.
5. On the day of embryo collection the donor cow—
 - (a) shall be kept in a holding which is not subject to veterinary prohibition or quarantine measures;
 - (b) shall show no clinical sign of disease.

Part II

Collection after slaughter

1. The donor cow shall not have been designated for slaughter as part of a national disease eradication programme, nor shall it have come from a holding subject to veterinary prohibition or restriction.
2. The abattoir where the ovaries and other tissues are collected must not be situated in a zone subject to veterinary prohibition or quarantine measures.

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SCHEDULE 6

Regulation 7

Conditions for the licensing of bovine embryo production teams

1. The production, processing and storage of embryos must be carried out either by the team veterinarian or under his authority by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene.
2. The production team personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions.
3. The team must have at its disposal a permanently-sited processing laboratory which must—
 - (a) have adequate equipment and facilities, including a separate room for recovering oocytes from ovaries, and separate rooms or areas for processing oocytes and embryos, and storing embryos;
 - (b) have laminar-flow facilities.
4. Where oocytes and other tissues are to be collected in an abattoir, the production team must have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

SCHEDULE 7

Regulation 8(c)

Conditions relating to the production of embryos

1. Embryos shall be produced by a licensed bovine embryo production team, and, in the case of embryos intended for intra-Area trade, without coming into contact with any other consignment of embryos not meeting the requirements of these Regulations relating to embryos intended for intra-Area trade.
2. Ovaries, oocytes and other tissues intended to be used in embryo production shall be collected in a place which is isolated from other parts of the premises or holding and which must be in good repair and easy to cleanse and disinfect.
3. Each bovine embryo production team must submit routine samples of flushing fluids, washing fluids, disintegrated embryos, non-fertilised ova etc, resulting from its activities to the Department for official examination for bacterial and viral contamination.
4. When ovaries, oocytes, and other tissues are to be collected at an abattoir, the abattoir should be officially approved and under the control of a veterinary officer of the Department who shall carry out ante- and post-mortem inspection of donors.
5. Materials and equipment coming into direct contact with ovaries, oocytes and other tissues shall be sterilised before use, and after sterilisation, used exclusively for those purposes. Separate equipment shall be used to handle oocytes and embryos from different batches of donor animals. All laminar-flow facilities shall be properly cleansed and disinfected between batches.
6. Embryos shall be produced, processed and placed in identifiable and sterile containers in a permanent laboratory facility which is not situated in a zone subject to prohibition or quarantine measures.
7. Products of animal origin used during production of the embryos and in the transport medium shall be obtained from sources which present no animal health risk or are to be so treated prior to use so that such risk is prevented. All media and solutions shall be sterilised by approved methods according to the recommendations of the manual of the International Embryo Transfer Society. Antibiotics may be added to the media in accordance with that manual.

8. Storage flasks and transport flasks shall be properly disinfected or sterilised before the commencement of each filling operation.

9. The cryogenic agent used shall not have been previously used for other products of animal origin.

10. Oocytes, semen and embryos shall be processed using the laminar-flow facility. However, the centrifugation of semen may be carried out outside the laminar-flow facility, as long as full hygienic precautions are taken.

11. Once the embryo has been produced, each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor dam or batch, as well as the registration number of the team can be readily established.

12. After the culture procedure has been completed, each embryo shall be washed at least 10 times in a special fluid for embryos which shall be changed each time (and which shall, for embryos intended for intra-Area trade, contain trypsin, in accordance with internationally recognised procedures). Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.

13. After the last wash each embryo shall be subjected to microscopic examination at a magnification of at least 50x over its entire surface to determine that the *zona pellucida* is intact and is free from any adherent material. Any micro-manipulation which involves penetration of the *zona pellucida* must be carried out in the facilities approved for the purpose, and after the last wash and examination. Such micro-manipulation may only be carried out on an embryo having an intact *zona pellucida*.

14. Each consignment of embryos that has successfully undergone the examination provided for in the preceding paragraph shall be placed in a sterile container marked in accordance with this Schedule and which shall be sealed immediately.

15. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian and which is subject to regular inspection by a veterinary officer of the Department.

16. Ovaries, oocytes and other tissues shall not be allowed to enter the processing laboratory until completion of the post-mortem inspection of the batch of donors. If any disease that might be transmitted in the material and make it unsuitable for producing embryos is found in the batch of donors, or in any animals slaughtered in that abattoir on that day, all tissues from the batch must be traced and discarded.

17. Only embryos from the same batch of donors should be stored in the same ampoule or straw.

SCHEDULE 8

Regulation 15(4)

Bovine embryo transfer

FORM OF CERTIFICATE

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Serial No.....

- 1. Registration number of the nominated embryo transplantation team
- 2. Name and address of the owner of the animals identified in the attached Annex

- 3. I hereby certify that the animal(s) identified in the attached annex was/were examined by me on (date) at (address of premises)

and

- (a) showed no clinical sign of disease;
- (b) showed no significant abnormalities of the reproductive tract(s) or birth canal(s); and
- (c) were in appropriate bodily condition and of a suitable size and conformation to receive the intended embryo(s) as specified in the attached Annex.

4. On the basis of the above examination, I am of the opinion that the animal(s) is/are suitable to receive the embryo(s). I know of no reason existing at the time of my examination which would cause me to believe that the animal(s) would not be able to carry to term a normal calf of the breed and type specified and to calve naturally.

Signed RCVS

Name (Block Capitals)

Date

Name of Practice

Address of Practice

.....
.....

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ANNEX

	<i>Recipient Identification (Ear Tag No)</i>	<i>Recipient Breed and Type</i>	<i>Breed and Type of Intended Embryo(s)</i>
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			

This Annex is provided in respect of the certificate, Serial No as laid down in Schedule 8 to the Bovine Embryo Collection, Production and Transplantation Regulations (Northern Ireland) 1996.

Signed..... RCVS

Name..... (Block Capitals)

Date

NOTE: The examining Veterinary Surgeon is required to sign immediately beneath the last entry on the above Annex

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations implement as respects Northern Ireland—
Council Directive [89/556/EEC](#) on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (O.J. No. L302, 19.10.89, p. 1);

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Council Directive [93/52/EEC](#) (O.J. No. L175, 19.7.93, p. 21) which amended Directive [89/556/EEC](#); and

Commission Decision [94/113/EEC](#) (O.J. No. L53, 24.2.94, p. 23) which further amended Directive [89/556/EEC](#).

The Regulations—

- (a) provide for the licensing of bovine embryo collection teams, production teams and transplantation teams (Regulations 5, 7 and 14 and Schedules 1, 2 and 6);
- (b) specify conditions to be complied with for the collection and production of bovine embryos (Regulations 6 and 8 and Schedules 3, 4, 5 and 7);
- (c) provide for the approval of stores for bovine embryos and specify the conditions to be complied with in relation to their storage (Regulations 9 to 12);
- (d) specify the conditions to be complied with in relation to the transport and transplantation of bovine embryos (Regulations 13 and 15 and Schedule 8);
- (e) require the use of anaesthetics in relation to the collection or transplantation of bovine embryos (regulation 16);
- (f) require records to be kept in relation to bovine embryos (Regulations 17 and 18); and
- (g) make transitional provisions (regulation 19) and specify a revocation (regulation 20).

Any person who fails to comply with any condition subject to which a licence under these Regulations is granted, who contravenes any provision of these Regulations (other than regulation 16) or knowingly or recklessly makes a statement false in a material particular for the purposes of obtaining a licence under these Regulations shall be guilty of an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale (currently £5,000), or to imprisonment for a term not exceeding 3 months or to both. Any person who contravenes regulation 16 shall be guilty of an offence under section 2 of the Welfare of Animals Act (Northern Ireland) 1972 and shall be liable on summary conviction to imprisonment for a term not exceeding 3 months or to a fine not exceeding level 4 on the standard scale (currently £2,500) or to both.