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.

(**6**) 1986 c. 14

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.