1994 No. 35

ANIMALS

Bovine Embryo Collection and Transplantation Regulations (Northern Ireland) 1994

Made . . . . . *31st January 1994*

Coming into operation . . *7th March 1994*

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(**a**) and section 2(1) of the Welfare of Animals Act (Northern Ireland) 1972(**b**), and of every other power enabling it in that behalf and after consultation as to regulation 11 with such persons appearing to it to represent the interests concerned as it considers appropriate hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Bovine Embryo Collection and Transplantation Regulations (Northern Ireland) 1994 and shall come into operation on 7th March 1994.

Interpretation

2.—(1) In 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 transplantation team" means a group of technicians who transplant embryos under the supervision of a team veterinarian;

"collection" in relation to any embryo means the collection of that embryo from a cow;

"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(**c**);

"embryo" has the same meaning as in the Directive;

"intra-Community trade" means export to any Member State of the Economic Community other than the United Kingdom;

(a) S.I. 1975/1834 (N.I. 17)
(b) 1972 c. 7 (N.I.)
(c) 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)

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

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

"transplantation" means the transplantation into a cow of an embryo collected from another cow;

"veterinary prohibition or quarantine measures" means measures imposed by the Department of Agriculture 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(**a**).

(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.

Licences

3. 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.

Application

4.—(1) Subject to paragraph (2) these Regulations apply to—

(*a*) the collection, processing, storage and transport of embryos produced by *in vivo* fertilisation; and

(*b*) the transplantation of embryos.

(2) These Regulations do not apply in relation to embryos produced for the purposes of research carried out in accordance with the conditions of a valid licence issued under the Animals (Scientific Procedures) Act 1986(**b**).

Licensing of bovine embryo collection teams and their facilities

5.—(1) Upon the Department being satisfied that a bovine embryo collection team complies with paragraph (*a*) of Chapter I of Annex A to the Directive, and has at its disposal—

(*a*) permanent laboratory facilities as specified in paragraphs (*c*) and (*d*) of that Chapter; or

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(**a**) 1966 c. 36
(**b**) 1986 c. 14

(*b*) mobile laboratory facilities as specified in paragraphs (*c*) and (*e*) of that Chapter and which have contact with such permanent laboratory facilities,

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

(2) Upon the Department being satisfied that a bovine embryo collection team complies with paragraph (*a*) of Chapter I of Annex A to the Directive and has at its disposal a mobile laboratory which—

(*a*) has separate parts so that there is no contact between used and unused equipment and materials;

(*b*) carries sufficient equipment to enable the examination and manipulation of embryos to be carried out without contaminating them; and

(*c*) has 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,

it shall licence that team for the purposes of collecting and processing, and that mobile laboratory for the purposes of processing, embryos which are not intended for intra-Community trade.

(3) The Department shall issue to each bovine embryo collection team licensed under this regulation a distinguishing registration number.

Collection of bovine embryos

6.—(1) Subject to paragraphs (3) and (4), a person shall not collect 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*) at the date of collection, the donor cow is not subject to any veterinary prohibition or quarantine measures and shows no clinical sign of infectious disease;

(*c*) if the embryo was conceived using raw semen, at the date the donor cow was inseminated with that semen the bovine animal from which the semen came was not subject to any veterinary prohibition or quarantine measures and showed no sign of infectious disease; and

(*d*) the embryo is collected and processed in accordance with Schedule 1 in laboratory facilities licensed for the purpose under regulation 5(1) or (2).

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

(*a*) he is a member of a bovine embryo collection team licensed for the purpose under regulation 5(1);

(*b*) the embryo was conceived as a result of artificial insemination with semen from a bovine animal 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(**a**) or as a result of natural service by bulls whose health status complies with Annex B to that Directive if authorised under Article 3(*a*), second indent, of Council Directive 89/556/EEC;

(*c*) the donor cow complies with the requirements of Annex B to the Directive; and

(*d*) the embryo is collected and processed in accordance with paragraph 1(*a*) to (*l*) of Chapter II of Annex A to the Directive in laboratory facilities licensed for the purpose under regulation 5(1).

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

(*d*) if the embryo was conceived using raw semen, at the date when the donor cow was inseminated with that semen the bovine animal from which the semen came was not subject to any veterinary prohibition or quarantine measures.

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

Processing

7. A person shall not process any embryo under these Regulations unless he is a member of a bovine embryo collection team licensed for the purpose under regulation 5(1) or (2).

Storage and transport

8.—(1) A person shall not store any embryo except in premises which—

(*a*) comply with paragraph 2 of Chapter II of Annex A to the Directive;

(*b*) are licensed by the Department for the purpose; and

(*c*) subject to paragraph (4), are under the supervision of a veterinary surgeon approved in writing by the Department who, in the case of embryos intended for intra-Community trade, shall be a team veterinarian.

(a) O.J. No. L194, 22.7.1988, p. 10 as amended by Council Directive 90/120/EEC (O.J. No. L71, 17.3.90, p. 37) and Council Directive 90/425/EEC (O.J. No. L224, 18.8.90, p. 29)

(2) A person shall not transport any embryo except under satisfactory hygienic conditions.

(3) A person shall not transport any embryo for the purposes of intra-Community trade except in a sealed container marked in accordance with paragraph (3) of Chapter II of Annex A to the Directive.

(4) Notwithstanding paragraph (1) a person may store an embryo other than under the supervision of a veterinary surgeon approved under that paragraph if he is licensed for the purpose by the Department and the embryo is not intended for intra-Community trade.

Licensing of bovine embryo transplantation teams

9. 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 bovine embryos

10.—(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 9; or

(*b*) a veterinary surgeon.

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

(*a*) he is competent to do so;

(*b*) he has been trained by a team veterinarian in methods and techniques of hygiene; and

(*c*) the transplantation is carried out under the supervision 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 2, that—

(*a*) he has done so and that the cow is suitable to receive the embryo; and

(*b*) 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 which has been collected, processed or stored in contravention of the provisions of these Regulations.

Requirements to use anaesthetics

11.—(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.

(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(**a**).

Record keeping

12.—(1) A team veterinarian responsible for supervising the activities of a bovine embryo collection team shall keep a record of those activities in accordance with paragraph 1(*o*) of Chapter II to Annex A of the Directive.

(2) A person (whether a veterinary surgeon or not) supervising any storage premises licensed under regulation 8(1) shall keep such records as may be necessary to comply with paragraph 2(iii) of Chapter II of Annex A to the Directive.

(3) A team veterinarian responsible for the supervision of the activities of a bovine embryo transplantation team shall keep a record, in relation to each transplantation carried out by a member of that team, of—

(*a*) the breed, age and identification of the recipient cow;

(*b*) the place where the transplantation was carried out; and

(*c*) the identification of the embryo together with details of its donor cow, if known.

Transitional provisions

13.—(1) Subject to paragraph (2), after 31st January 1999 a person shall not use any embryo collected before the date these Regulations come into operation, 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 from 31st December 1990 until the date these Regulations come into operation if the embryo was collected in accordance with the provisions of the Directive.

(3) In the case of embryos collected before the coming into operation of these Regulations, it shall be a defence for any person charged with failing to keep any records required under regulation 12 to show that the information required thereunder to be recorded was not available.

(**a**) 1972 Ch. 7

Sealed with the Official Seal of the Department of Agriculture on 31st January 1994.

(L.S.) *D. A. J. Hirrell*
Assistant Secretary

SCHEDULE 1 Regulation 6(1)(*d*) and (3)

Conditions relating to the collection and processing of bovine embryos

1. The embryo 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 veterinary prohibition or quarantine measures.

2. All implements which come into contact with the embryo or donor cow during the collection and processing of the embryo shall not have been used previously or shall have been properly disinfected or sterilised prior to use.

3. Products of animal origin used during collection of an embryo and in the medium used to transport it shall be obtained from sources which present no animal health risk or shall have been so treated prior to such use so that such risk is prevented.

4. Storage and transportation flasks shall be properly disinfected or sterilised before the commencement of the initial filling operation.

5. The cryogenic agents used in the storage and transportation flasks 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 registration number issued to the relevant bovine embryo collection team under regulation 5(3);
   (*b*) the date of the collection of the embryo; and
   (*c*) either—
      (i) the breed and identification of the donor cow and the bovine animal from which the semen used to conceive the embryo was collected;
      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 micro-pipette shall be used to transfer the embryo between washes.

8. After the last wash carried out under paragraph 7, 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 is to say a quantity of embryos removed in one operation from a single donor cow) that has successfully undergone the examination provided for in paragraph 8 shall be placed in a sterile container marked in accordance with paragraph 6 and which shall be sealed immediately.

SCHEDULE 2 Regulation 10(4)

CERTIFICATE

Bovine Embryo Transplantation

Breed and type of embryo(s) .....

Registration number of collection team .....

1. I hereby certify that the animal(s) identified in the Schedule overleaf was/were clinically examined by me on (date) ..... at (address of premises)

   .....

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   .....

2. I found the animal(s) to be in good health.

3. I was unable to detect any significant abnormalities of the reproductive tract(s) or birth canal(s).

4. I found the animal(s) to be in appropriate bodily condition and of a suitable size and conformation to receive the intended embryo(s).

5. On the basis of the above examination, I am of the opinion that the animal(s) specified in the second column of the Annex to this certificate is/are suitable to receive the embryo(s) specified opposite thereto. 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 so specified in relation to it/them and to calve naturally.

Signed ..... RCVS

Name (Block Capitals) .....

Date .....

Name of Practice .....

Address of Practice .....

.....

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ANNEX

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

The examining Veterinary Surgeon is required to sign immediately beneath the last entry on the above Schedule.

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations regulate the collection, processing, storage, transportation and transplantation of bovine embryos. They implement the parts of 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) which deal with these matters.

They enable the Department to licence teams of technicians which carry out the collection of bovine embryos from donor cows (regulation 5) and their transplantation into recipient cows (regulation 9) together with the laboratory and other facilities used for those purposes. They regulate the collection, processing, storage and transportation of bovine embryos (regulations 6 to 8 and Schedule 1). They also regulate their transplantation (regulation 10 and Schedule 2) and include a requirement to use anaesthetics during collection and transplantation (regulation 11). They also impose requirements for record keeping (regulation 12). Regulation 13 makes certain transitional provisions.

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 11) 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 shall be liable on summary conviction to a fine not exceeding £2,000 and to imprisonment for a term not exceeding 3 months. Any person who contravenes regulation 11 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 £1,000) or both.

1994 No. 36

This Order has been exempted from printing by the Statutory Rules (Northern Ireland) Order 1979. A summary is given in the List of Statutory Rules of a Local Character under the heading ROADS.