
STATUTORY INSTRUMENTS

1993 No. 2921

AGRICULTURE
LIVESTOCK INDUSTRIES

The Bovine Embryo Collection and Transfer Regulations 1993

	<i>22nd November</i>
<i>Made</i> - - - -	<i>1993</i>
<i>Laid before Parliament</i>	<i>30th November 1993</i>
<i>Coming into force</i> - -	<i>21st December 1993</i>

The Minister of Agriculture, Fisheries and Food in relation to England, the Secretary of State for Scotland in relation to Scotland and the Secretary of State for Wales in relation to Wales, in exercise of the powers conferred on them by section 10(1) and (2) of the Animal Health and Welfare Act 1984⁽¹⁾ and of all other powers enabling them in that behalf, hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Bovine Embryo Collection and Transfer Regulations 1993 and shall come into force on 21st December 1993.

Interpretation

2.—(1) In these Regulations—

“collection” means removal from a donor cow;

“cow” includes heifer;

“intra-Community trade” means export to another member State of the Economic Community;

“team veterinarian” means a veterinary surgeon who is responsible for an embryo collection or an embryo transfer team;

“transfer” means transfer to a recipient cow;

“veterinary surgeon” means a veterinary surgeon (or veterinary practitioner) registered or recognised under the Veterinary Surgeons Act 1966⁽²⁾.

(2) A reference in these Regulations to a directive is to that directive as amended.

(1) 1984 c. 40; the “appropriate Minister” referred to in section 10 is defined in section 10(8).

(2) 1966 c. 36.

Approvals

3. Any approval granted under these Regulations shall be in writing and may be made subject to conditions and may be modified, suspended or revoked by notice in writing at any time.

Application

4.—(1) These Regulations apply to—

- (a) the collection, processing, storage and transport of bovine embryos produced by *in vivo* fertilisation, and
- (b) the transfer of bovine embryos.

(2) The Regulations do not apply to bovine 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⁽³⁾.

Approval of bovine embryo collection teams

5.—(1) If the appropriate Minister is satisfied that a bovine embryo collection team complies with paragraph (a) of Chapter 1 of Annex A to 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⁽⁴⁾ and has at its disposal either—

- (a) permanent laboratory facilities as specified in paragraphs (c) and (d) of that Chapter, or
- (b) a mobile laboratory as specified in paragraphs (c) and (e) of that Chapter which has contact with a permanently sited laboratory as specified in that Chapter,

he shall approve that team and those facilities for the purposes of these Regulations.

(2) If the appropriate Minister is satisfied that a bovine embryo collection team complies with paragraph (a) of Chapter 1 of Annex A to Council Directive 89/556/EEC, 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,

he shall approve that team and those facilities for the purposes of these Regulations subject to the condition that an embryo collected by such team is not intended for intra-Community trade.

(3) Each approved team shall be issued with a registration number.

Collection of bovine embryos

6.—(1) Subject to paragraph (3) below, no person shall collect any bovine embryo unless—

- (a) he is a member of an approved embryo collection team,
- (b) the donor cow is not subject to any veterinary prohibition or quarantine measures and shows no clinical sign of infectious disease at the date of collection,

⁽³⁾ 1986 c. 14.

⁽⁴⁾ OJ No.L 302, 19.10.89, p. 1 as amended by Council Directive 90/425/EEC (OJ No.L 224, 18.8.90.p. 29).

- (c) if the embryo was conceived by natural service or using raw semen, the donor sire was not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of infectious disease at the date of service, and
 - (d) the embryo is processed in accordance with Schedule 1 to these Regulations.
- (2) No person shall collect any bovine embryo for the purpose of intra-Community trade unless—
- (a) he is a member of a bovine embryo collection team approved in accordance with Regulation 5(1) above,
 - (b) the embryo was conceived as a result of artificial insemination with semen from a donor sire 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⁽⁵⁾ 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 Council Directive [89/556/EEC](#), and
 - (d) the embryo is collected and processed in accordance with paragraph 1(a) to (1) of Chapter II of Annex A to Council Directive [89/556/EEC](#).
- (3) An embryo may be collected by a member of an approved bovine embryo collection team or a veterinary surgeon for transfer without being processed in accordance with Schedule 1 to these Regulations if—
- (a) the embryo is intended for use in the United Kingdom without being frozen or stored and the recipient cow is in the same ownership as the donor cow,
 - (b) the donor cow is not subject to any veterinary prohibition or quarantine measures at the date of collection, and
 - (c) if the embryo was conceived by natural service or using raw semen, the donor sire was not subject to any veterinary prohibition or quarantine measures at the date of service.
- (4) Where the appropriate Minister thinks fit, he may approve the collection of a bovine embryo produced from a donor animal which does not comply with this regulation provided it is not intended for intra-Community trade.

Processing

7. No person shall subject a bovine embryo to any processing unless he is a member of an approved bovine embryo collection team.

Storage and transport

8.—(1) No person shall store any bovine embryo except in premises complying with paragraph 2 of Chapter II of Annex A to Council Directive [89/556/EEC](#), approved by the appropriate Minister and under the supervision of an approved veterinary surgeon who, in the case of embryos intended for intra-Community trade, shall be a team veterinarian.

(2) No person shall transport any bovine embryo except under satisfactory hygienic conditions.

(3) No person shall transport any bovine 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 Council Directive [89/556/EEC](#).

(5) OJ No.L 194, 22.7.1988, p. 10 as amended by Council Directive [90/120/EEC](#) (OJ No.L 71, 17.3.90, p. 37) and Council Directive [90/425/EEC](#) (OJ No.L 224, 18.8.90, p. 29).

(4) Where the appropriate Minister thinks fit, he may approve storage not complying with paragraph (1) above provided the embryos are not intended for intra-Community trade.

Approval for the purposes of bovine embryo transfer

9. If the appropriate Minister is satisfied that a bovine embryo transfer team—
- (a) is headed by a veterinary surgeon, and
 - (b) has at its disposal a room or area equipped for cleaning and sterilising instruments and equipment used in bovine embryo transfer,

he shall approve that team and those facilities for the purposes of carrying out bovine embryo transfers.

Transfer of bovine embryos

10.—(1) No person shall transfer any bovine embryo unless he is a member of an approved bovine embryo transfer team or a veterinary surgeon.

(2) If the person carrying out the transfer is not a veterinary surgeon, he shall only do so if he is competent and has been trained by a team veterinarian of a bovine embryo transfer team in methods and techniques of hygiene, and the transfer shall be carried out under the responsibility of the team veterinarian.

(3) If the person carrying out the transfer is a veterinary surgeon, he shall clinically examine the recipient cow before carrying out the transfer and shall satisfy himself—

- (a) that the recipient is suitable to receive the embryo, and
- (b) that there is no reason of which he knows existing at the time of his examination which would cause him to believe that the animal would not be able to carry to term a normal calf from the breed and type of embryo being transferred and to calve naturally,

and if he cannot so satisfy himself he shall not transfer the embryo.

(4) If the person carrying out the transfer is not a veterinary surgeon, he shall not carry out the transfer unless a veterinary surgeon nominated for this purpose by the team veterinarian has clinically examined the recipient cow within 30 days preceding the transfer and has certified in the form specified in Schedule 2 to these Regulations that—

- (a) he has clinically examined the recipient,
- (b) the recipient is suitable to receive the embryo, and
- (c) he knows of no reason existing at the time of his examination which would cause him to believe that the animal 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) No person shall transfer any bovine embryo which has been collected, processed or stored in breach of the provisions of these Regulations.

Requirement to use anaesthetics

11. No person shall collect or transfer any bovine embryo *per vaginam* unless a general or an epidural anaesthetic has first been administered to the cow.

Record keeping

12.—(1) The team veterinarian of a bovine embryo collection team shall keep a record of the team's activities in accordance with paragraph 1(o) of Chapter II of Annex A to Council Directive [89/556/EEC](#).

(2) A person supervising approved storage premises shall keep a record in accordance with paragraph 2(iii) of Chapter II of Annex A to Council Directive [89/556/EEC](#).

(3) The team veterinarian of a bovine embryo transfer team and a veterinary surgeon transferring embryos shall keep a record for twelve months of—

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

Transitional provisions

13.—(1) Subject to paragraph (2) below, after 20th December 1998 no person shall use any bovine embryo collected before the date these Regulations come into force, except with the approval of the appropriate Minister.

(2) Notwithstanding the provisions of paragraph (1) above, where a bovine embryo was collected in accordance with the provisions of Council Directive [89/556/EEC](#) in the period commencing on 1st January 1991 and ending when these Regulations come into force, a person may use such embryo without an approval.

(3) In the case of embryos collected before the coming into force of these Regulations, it shall be a defence for any person charged with an offence under Regulation 12 to show that the information required to be recorded was not available.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

22nd November 1993.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

17th November 1993

Hector Monro
Parliamentary Under Secretary of State, Scottish
Office

9th November 1993

John Redwood
Secretary of State for Wales

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

SCHEDULE 1

Regulations 6(1)(d) and (3)

CONDITIONS RELATING TO THE PROCESSING OF BOVINE EMBRYOS

1. Embryos shall be processed (that is, examined, washed, treated and placed in identified and sterile containers) in either a permanent laboratory facility or a mobile laboratory facility, 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 to be so treated prior to use so 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 registration 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 above shall be placed in sterile containers marked in accordance with paragraph 6 above 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.

SCHEDULE 2

Regulation 10(4)

BOVINE EMBRYO TRANSFER

FORM OF CERTIFICATE

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Breed and type of embryo(s)
 Registration number of collecting 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)
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) 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

	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.

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations regulate the collection, storage and use 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 (OJ No.L 302, 19.10.89, p. 1) which deal with these matters.

They enable the appropriate Minister to approve embryo collection teams (Regulation 5) and embryo transfer teams (Regulation 9). They regulate the collection, processing, storage and transport of bovine embryos (Regulations 6 to 8 and Schedule 1) and their transfer (Regulation 10 and Schedule 2), and include a requirement to use anaesthetics (Regulation 11). They make requirements for record keeping, and have transitional provisions (Regulations 12 and 13).

Breach of the Regulations is an offence under section 10(6) of the Animal Health and Welfare Act 1984 and is punishable by imprisonment not exceeding three months or a fine not exceeding level 3 on the standard scale or both.