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STATUTORY INSTRUMENTS

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**1995 No. 2478**

**AGRICULTURE**  
**LIVESTOCK INDUSTRIES**

**The Bovine Embryo (Collection,  
Production and Transfer) Regulations 1995**

*Made* - - - - *21st September 1995*  
*22nd September*  
*Laid before Parliament* *1995*  
*Coming into force* - - *13th October 1995*

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<sup>(1)</sup> and of all other powers enabling them in that behalf, hereby make the following Regulations:

**Citation and commencement**

**1.** These Regulations, which implement:

- (a) 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<sup>(2)</sup>;
- (b) Council Directive [93/52/EEC](#) amending 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<sup>(3)</sup>; and
- (c) Commission Decision [94/113/EC](#) amending 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 (text with EEA relevance)<sup>(4)</sup>,

may be cited as the Bovine Embryo (Collection, Production and Transfer) Regulations 1995 and shall come into force on 13th October 1995.

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(1) [1984 c. 40](#); see section 10(8) for a definition of “appropriate Minister”.  
(2) OJ No. L302, 19.10.89, p. 1.  
(3) OJ No. L175, 19.7.93, p. 21.  
(4) OJ No. L53, 24.2.94, p. 23.

## Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“approved” means approved by the appropriate Minister for the purposes of these Regulations;

“collect” means remove from a donor cow;

“cow” includes heifer;

“the International Embryo Transfer Society” means the Society of that name founded in Denver, Colorado, United States of America in 1974, incorporated in the State of Nebraska on 7 April 1975 and currently having its headquarters at 309 West Clark Street, Champaign, Illinois 61820, United States of America;

“intra-Area trade” means trade between the United Kingdom and another state of the European Economic Area;

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

“transfer” means transfer to a recipient cow;

“veterinary surgeon” means a veterinary surgeon (or veterinary practitioner) registered under the Veterinary Surgeons Act 1966<sup>(5)</sup>.

(2) Subject to paragraph (1) above, any expressions used in these Regulations have the meaning they bear in Council Directive [89/556/EEC](#);

(3) A reference in these Regulations to a directive is to that directive as amended at the date of coming into force of these Regulations.

(4) Unless the context otherwise requires, any reference in these Regulations to a numbered regulation is to a regulation so numbered in these Regulations, and any reference to a Schedule is a reference to a Schedule to these Regulations.

## Exemptions from the Regulations

3.—(1) The provisions of these Regulations relating to the collection, production or storage of bovine embryos shall not apply to bovine 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<sup>(6)</sup>.

(2) Other than regulations 21 and 22, these Regulations shall not apply in relation to embryos derived by transfer of nuclei.

## Approvals

4.—(1) An application for approval as a bovine embryo collection team, production team or transfer team, or for any facilities used by such team shall be made in writing to the appropriate Minister and signed by the proposed team veterinarian.

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

(3) In particular, any approval of premises and equipment granted under these Regulations may specify that such premises and equipment may be inspected, and may specify the frequency of such inspection.

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<sup>(5)</sup> 1966 c. 36.

<sup>(6)</sup> 1986 c. 14.

### **Approval of bovine embryo collection teams for all purposes including intra-Area trade**

5. The appropriate Minister may, on application, approve a bovine embryo collection team for the purposes of collecting bovine embryos for all purposes, including intra-Area trade, if it complies with Schedule 1.

### **Approval of bovine embryo collection teams for purposes other than intra-Area trade**

6. The appropriate Minister may, on application, approve a bovine embryo collection team for the purposes of collecting bovine embryos other than for the purposes of intra-Area trade if it complies with Schedule 2.

### **Approval of bovine embryo production teams**

7. The appropriate Minister may, on application, approve a bovine embryo production team for the purposes of artificial production of bovine embryos if it complies with Schedule 3.

### **Approval of bovine embryo transfer teams**

8. The appropriate Minister may, on application, approve a bovine embryo transfer team for the purposes of transfer of bovine embryos if it—

- (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.

### **Registration numbers**

9. Each team approved under regulation 5, 6, 7 or 8 above shall be given a registration number by the appropriate Minister, and if a team is approved for more than one activity shall be given a different number for each activity.

### **Collection of bovine embryos intended for intra-Area trade**

10. No person shall collect or process any bovine embryo intended for intra-Area trade unless—

- (a) he is a member of a collection team approved under regulation 5;
- (b) he is the collection team veterinarian or acting under his authority;
- (c) the bovine embryo is collected and processed in accordance with Schedule 4;
- (d) the donor cow complies with the requirements of Schedule 5; and
- (e) the bovine embryo was conceived as a result of artificial insemination with 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](#) 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<sup>(7)</sup>.

### **Collection of bovine embryos not intended for intra-Area trade**

11.—(1) No person shall collect or process any bovine embryo not intended for intra-Area trade unless—

- (a) he is a member of a collection team approved under regulation 5 or regulation 6;

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(7) OJ No. L194, 22.7.1988, p. 10 as amended by Council Directive [90/120/EEC](#) (OJ No. L71, 17.3.90, p. 37), Council Directive [90/425/EEC](#) (OJ No. L224, 18.8.1990, p. 29) and Council Directive [93/60/EEC](#) (OJ No. L186, 28.7.93, p. 28).

- (b) he is the collection team veterinarian or acting under his authority;
- (c) the bovine embryo is collected and processed in accordance with Schedule 4 or Schedule 6;
- (d) 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; and
- (e) the bovine embryo was conceived either—
  - (i) from a donor sire (either by natural service or by using raw semen) which, at the date of service, was not subject to any veterinary prohibition or quarantine measures and showed no clinical sign of infectious disease, or
  - (ii) by artificial insemination using semen which was eligible for distribution or sale in Great Britain at the time of insemination.

(2) A bovine embryo may be collected by either a veterinary surgeon or a member of an approved bovine embryo collection team acting under the authority of the team veterinarian for transfer without being processed in accordance with Schedule 4 or Schedule 6 if—

- (a) the bovine 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) in a case where the bovine 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.

(3) 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-Area trade.

#### **Production of bovine embryos in vitro**

**12.** No person shall produce or process a bovine embryo in vitro unless—

- (a) he is a member of a production team approved under regulation 7;
- (b) he is the production team veterinarian or acting under his authority;
- (c) the bovine embryo is produced 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 bovine embryos not intended for intra-Area trade, using semen which was eligible for distribution or sale in Great Britain at the time of fertilisation;
- (d) the donor cow complies with the requirements of Schedule 5.

#### **Approval of stores for bovine embryos for use in intra-Area trade**

**13.—**(1) The appropriate Minister may, on application, approve a store for the storage of bovine embryos intended for intra-Area trade if it complies with the conditions of this regulation.

(2) The store shall consist of a lockable room under the supervision of an approved veterinary surgeon who is the team veterinarian for a team approved either as a bovine embryo collection team or as a bovine embryo production team.

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

#### **Storage of bovine embryos for use in intra-Area trade**

14.—(1) The person supervising a store approved for the storage of bovine embryos intended for use in intra-Area trade shall ensure that the conditions of this regulation and any other conditions attached to the approval are complied with.

(2) The store shall be locked when not in use.

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

(4) The bovine embryos shall be stored at a suitable temperature.

#### **Prohibition on the storage of bovine embryos for use in intra-Area trade other than at an approved store**

15. No person shall store any bovine embryo for use in intra-Area trade except in a store approved under regulation 13 and in accordance with the conditions of the approval.

#### **Approval of stores for bovine embryos not intended for use in intra-Area trade**

16.—(1) The appropriate Minister may, on application, approve a store for the storage of bovine embryos not intended for intra-Area trade if it complies with the conditions of this regulation.

(2) The store shall consist of a lockable room under the supervision, subject to regulation 19, of a veterinary surgeon.

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

#### **Storage of bovine embryos not intended for use in intra-Area trade**

17.—(1) The person supervising a store approved under regulation 16 shall ensure that the conditions of this regulation and any other conditions attached to the approval are complied with.

(2) The store shall be locked when not in use.

(3) Nothing shall be stored in the room other than bovine embryos eligible for transfer in Great Britain or bovine semen eligible for use in Great Britain.

(4) The bovine embryos shall be stored at a suitable temperature.

#### **Prohibition on the storage of bovine embryos not intended for intra-Area trade other than at an approved store**

18. No person shall store any bovine embryo for use other than in intra-Area trade except in a store approved under regulation 13 or regulation 16 and in accordance with the conditions of that approval.

#### **Storage of bovine embryos for use on the same premises as the store**

19. In the case of a store used for bovine embryos which will only be used on the same premises as the premises where the store is situate, the store may be supervised by a person who is not a veterinary surgeon, but in this case all the duties placed on the veterinary surgeon shall be placed on the person to whom the approval is granted, and it shall be the duty of the person to whom the approval is granted to ensure that bovine embryos in that store are not removed from the premises on which the store is situate.

### Transport of bovine embryos

**20.**—(1) No person shall transport any bovine embryo except under satisfactory hygienic conditions.

(2) No person shall transport any bovine embryo for the purposes of intra-Area trade except under satisfactory hygienic conditions in a sealed container marked in such a way that the number on the seal is the same as the number on the animal health certificate provided by the competent authority of the exporting member State for the purposes of intra-Area trade.

### Transfer of bovine embryos

**21.**—(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 in methods and techniques of hygiene by a team veterinarian of a bovine embryo transfer team, 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 bovine 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 bovine 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 8 to these Regulations that—

- (a) he has clinically examined the recipient;
- (b) the recipient is suitable to receive the bovine 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 unless it has been—

- (a) collected, processed and stored in accordance with the provisions of these Regulations or of the Bovine Embryo Collection and Transfer Regulations 1993<sup>(8)</sup>;
- (b) imported into Great Britain in accordance with the provisions of the Animals and Animal Products (Import and Export) Regulations 1995<sup>(9)</sup>, or any Regulations which they supersede;
- (c) imported into Great Britain in accordance with the provisions of the Products of Animal Origin (Import and Export) Regulations 1992<sup>(10)</sup> or any Regulations which they supersede;
- (d) imported into Great Britain in accordance with the provisions of the Importation of Embryos, Ova and Semen Order 1980<sup>(11)</sup>;

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<sup>(8)</sup> S.I. 1993/2921.

<sup>(9)</sup> S.I. 1995/.

<sup>(10)</sup> S.I. 1992/3298 to which there were amendments not relevant to these Regulations.

<sup>(11)</sup> S.I. 1980/12 to which there are amendments not relevant to these Regulations.

- (e) subject to regulation 25, collected in Great Britain before 21 December 1993; or
- (f) derived by transfer of nuclei.

(6) In the case of imported bovine embryos, or bovine embryos collected in Great Britain before 21 December 1993, no person shall transfer such embryo unless it has been transported and stored in accordance with these Regulations or any earlier legislation then applicable.

### **Requirement to use anaesthetics**

**22.** 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.

### **Records at stores**

**23.—**(1) The person supervising a store for bovine 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 embryo;
- (c) the place of origin of each embryo or the place in which it was last stored, if different;
- (d) the date of removal of each embryo from the store; and
- (e) the destination of each embryo,

and shall keep the record for the period the embryo remains in the store and for twelve months after the date of removal of the embryo from the store.

(2) In the case of bovine embryos derived by in vitro fertilisation, the identification in the record may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries or oocytes. It must also be possible to identify the herd of origin of the donor animals.

### **Records other than at stores**

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

- (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 micromanipulation 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 bovine embryos derived by in vitro fertilisation, the identification in the record may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries or oocytes. It must also be possible to identify the herd of origin of the donor animals.

(3) The team veterinarian of a bovine embryo transfer team or a veterinary surgeon transferring bovine 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 bovine embryo together with details of its source if known.

### **Transitional provisions**

**25.**—(1) Subject to paragraph (2) below, after 20 December 1998 no person shall transfer any bovine embryo collected before 21 December 1993, 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 between 1 January 1991 and 21 December 1993, a person may use such embryo without an approval.

(3) In the case of bovine embryos collected before 21 December 1993, it shall be a defence for any person charged with an offence relating to record keeping concerning that bovine embryo to show that the information required to be recorded was not available.

### **Revocation**

**26.**—(1) The Bovine Embryo Collection and Transfer Regulations 1993(**12**) are hereby revoked.

(2) Any approval granted to a bovine embryo collection or transfer team under those Regulations shall be deemed to be an approval for the same purposes under these Regulations.

(3) Any requirement under those Regulations to keep records shall continue in existence notwithstanding the revocation of those Regulations.

21st September 1995

*Tony Baldry*  
Minister of State, Ministry of Agriculture,  
Fisheries and Food

19th September 1995

*Lindsay*  
Parliamentary Under Secretary of State, Scottish  
Office

Signed by authority of the Secretary of State for Wales

21st September 1995

*Gwilym Jones*  
Parliamentary Under Secretary of State, Welsh  
Office



## SCHEDULE 1

Regulation 5

### CONDITIONS FOR THE APPROVAL OF BOVINE EMBRYO COLLECTION TEAMS FOR ALL PURPOSES INCLUDING INTRA-AREA TRADE

1. In order to be given approval under regulation 5, each bovine embryo collection team must fulfil the requirements of this Schedule.

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

3. The team must have at its disposal either a permanently sited laboratory or a mobile laboratory where bovine embryos can be examined, processed and packed, and which complies with paragraph 4 below in the case of a permanently sited laboratory or paragraph 5 below in the case of a mobile laboratory.

4. In the case of a permanently sited laboratory, the team must have at its disposal—

- (a) a work surface, a microscope and cryogenic equipment;
- (b) a room where bovine 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 bovine embryo collection and manipulation; and
- (d) where micromanipulation of the bovine embryo which involves penetration of the *zona pellucida* is to be carried out, suitable laminar-flow facilities.

5.—(1) In the case of a mobile laboratory the team must have at its disposal—

- (a) a work surface, a microscope and cryogenic equipment; and
- (b) a specially equipped part of the vehicle consisting of two separate sections, one for the examination and manipulation of bovine embryos which shall be a clean section, and the other for accommodating equipment and materials used in contact with the donor animals.

(2) A 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 bovine embryos.

## SCHEDULE 2

Regulation 6

### CONDITIONS FOR THE APPROVAL OF BOVINE EMBRYO COLLECTION TEAMS FOR PURPOSES OTHER THAN FOR INTRA-AREA TRADE

1. In order to be given approval under regulation 6 each bovine embryo collection team must fulfil the requirements of this Schedule.

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

3. The team must have at its disposal either—

- (a) a permanent laboratory facility as specified in Schedule 1; or
- (b) a mobile laboratory facility as specified in Schedule 1; or
- (c) a mobile laboratory which:

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- (i) has separate parts so that there is no contact between used and unused equipment and materials, and
- (ii) carries sufficient equipment to enable the examination and manipulation of bovine embryos to be carried out without contaminating them, and
- (iii) 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 bovine embryos.

### SCHEDULE 3

Regulation 7

#### CONDITIONS FOR THE APPROVAL OF BOVINE EMBRYO PRODUCTION TEAMS

1. To be approved as a team for the production and processing of bovine embryos derived by in vitro fertilisation and/or in vitro culture, a bovine embryo production team must fulfil the following requirements.
2. The production, processing and storage of bovine embryos must be carried out either by a team veterinarian or under his responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene.
3. The production team personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions.
4. 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 bovine embryos, and storing bovine embryos; and
  - (b) have laminar-flow facilities.
5. 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 4

Regulations 10 and 11

#### CONDITIONS RELATING TO THE COLLECTION, PROCESSING STORAGE AND TRANSPORT OF BOVINE EMBRYOS FOR THE PURPOSES OF INTRA-AREA TRADE

1. Bovine embryos shall be collected and processed by an approved collection team, without coming into contact with any other consignment of bovine embryos not meeting the requirements of these Regulations relating to bovine embryos intended for intra-Area trade.
2. Bovine 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. Bovine embryos shall be processed (that is, examined, washed, treated and placed in identifiable 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.
4. All implements which come into contact with the bovine 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 bovine embryos and in the transport medium shall be obtained from sources which present no animal health risk or are treated prior to use in such a way 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(13). 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 bovine 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 bovine embryos and the breed and identification of the donor sire and donor dam, as well as the registration number of the team can be readily established.

9. Each bovine embryo shall be washed at least 10 times in a special fluid for bovine 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 bovine embryo on each occasion.

10. After the last wash each bovine embryo shall be subjected to microscopic examination at a magnification of at least 50× over its entire surface to determine that the *zona pellucida* is intact and is free from any adherent material. Any micromanipulation 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 micromanipulation may only be carried out on a bovine embryo having an intact *zona pellucida*.

11. Each consignment of bovine 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 of this Schedule and sealed immediately.

12. Each bovine 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 an official veterinarian.

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

## SCHEDULE 5

Regulations 10 and 12

### CONDITIONS RELATING TO DONOR ANIMALS FOR THE PURPOSES OF REGULATION 10 or 12

#### PART I

#### COLLECTION FROM LIVE ANIMALS

1. For the purposes of collection from live animals of bovine embryos or oocytes for the purposes of regulation 10 or 12, donor animals must meet the requirements of this Part of this Schedule.

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(13) 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, U.S.A.

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2. The donor animals must have spent at least the previous six months within the territory of the European Economic Area or, in the case of a country outside that Area, in the country of collection.
3. The donor animals must have been present in the herd of origin for at least 30 days prior to collection.
4. The donor animals must come from herds which are—
  - (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.
5. During the previous year, the donor animals must not have been present in a herd (or herds) which have shown any clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.
6. 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, and
  - (b) shall show no clinical signs of disease.

## PART II

### COLLECTION AFTER SLAUGHTER

7. For the purposes of collection of ovaries, oocytes and other tissues to be collected after slaughter in an abattoir, donor animals must comply with the requirements of this Part of this Schedule.
8. The donor animals should not have been designated for slaughter as part of a national disease eradication programme, nor should they have come from a holding subject to restrictions because of animal disease.
9. The abattoir where the ovaries and other tissues are collected must not be situated in a zone subject to prohibition or quarantine measures.

### SCHEDULE 6

Regulation 11

#### CONDITIONS RELATING TO THE COLLECTION, PROCESSING AND STORAGE OF BOVINE EMBRYOS NOT INTENDED FOR INTRA-AREA TRADE

1. Bovine embryos shall be processed (that is, examined, washed, treated and placed in identifiable 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 bovine embryos or the donor animal during collection and processing shall either be disposable and unused, or shall be properly disinfected or sterilised before use.
3. Products of animal origin used during collection of the bovine 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 bovine 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 bovine 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 bovine embryo shall be washed at least 10 times in a special fluid for bovine 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 bovine embryo on each occasion.

8. After the last wash each bovine 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 bovine 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 bovine embryos” means a quantity of bovine embryos removed in one operation from a single donor.

## SCHEDULE 7

Regulation 12

### CONDITIONS RELATING TO THE PRODUCTION OF BOVINE EMBRYOS

1. The production of bovine embryos shall be in accordance with this Schedule.

2. Bovine embryos shall be produced by an approved production team, and, in the case of bovine embryos intended for intra-Area trade, without coming into contact with any other consignment of bovine embryos not meeting the requirements of these Regulations relating to bovine embryos intended for intra-Area trade.

3. Ovaries, oocytes and other tissues intended to be used in bovine 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.

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

5. When ovaries and other tissues are to be collected at an abattoir, the abattoir should be officially approved and under the control of an official veterinarian whose responsibility it is to carry out ante- and post-mortem inspection of donors.

6. 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 bovine embryos from different batches of donor animals. All laminar-flow facilities shall be properly cleaned and disinfected between batches.

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7. Bovine 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.

8. Products of animal origin used during production of the bovine 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.

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

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

11. 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.

12. Once the bovine embryo has been produced, each bovine 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 bovine 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.

13. After the culture procedure has been completed, each bovine embryo shall be washed at least 10 times in a special fluid for bovine embryos which shall be changed each time (and which shall, for bovine 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 bovine embryo on each occasion.

14. After the last wash each bovine embryo shall be subjected to microscopic examination at a magnification of at least 50× over its entire surface to determine that the *zona pellucida* is intact and is free from any adherent material. Any micromanipulation 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 micromanipulation may only be carried out on an bovine embryo having an intact *zona pellucida*.

15. Each consignment of bovine 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.

16. Each bovine 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 an official veterinarian.

17. 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 bovine embryos is found in the batch of donors, or in any animals slaughtered in that abattoir on that day, all tissues from that batch must be traced and discarded.

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

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SCHEDULE 8

Regulation 21

FORM OF CERTIFICATE BOVINE EMBRYO TRANSFER

Breed and type of bovine 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) .....

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 .....

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<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		

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

**EXPLANATORY NOTE**

*(This note does not form part of the Regulations)*

These Regulations (which apply to England, Scotland and Wales) give effect to the provisions of Council Directive [89/556/EEC](#) (OJNo. L302, 19.10.89, p.1) as amended by Council Directive [93/52/EEC](#) (OJ No. L175, 19.7.93, p.21) and Commission Decision [94/113/EC](#) (OJ No. L53, 24.2.94, p.23), as regards the export for European Economic Area trade of bovine embryos and the approval of collection, production and transfer teams and storage conditions for bovine embryos. They also provide for domestic trade in bovine embryos.

They revoke and replace the Bovine Embryo Collection and Transfer Regulations 1993 (S.I.1993/2921).

The Regulations—

- (a) provide for the approval of bovine embryo collection teams, production teams and transfer teams (regulations 4 to 8 and Schedules 1 to 3);
- (b) provide for the allocation of a registration number for each registered team (regulation 9);



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- (c) specify conditions to be complied with for the collection and production of bovine embryos (regulations 10 to 12 and Schedules 4 to 7);
- (d) provide for the approval of stores for bovine embryos and specify the conditions to be complied with in relation to their storage (regulations 13—19);
- (e) specify the conditions to be complied with in relation to the transport and transfer of bovine embryos (regulations 20 and 21 and Schedule 8);
- (f) require the use of anaesthetics in relation to the collection or transfer of bovine embryos (regulation 22);
- (g) require records to be kept in relation to bovine embryos (regulations 23 and 24); and
- (h) make transitional provisions (regulation 25) and specify revocations (regulation 26).

The manual of the International Embryo Transfer Society referred to in Schedules 4 and 7 of these Regulations was published by the International Embryo Transfer Society in November 1990. Copies can be obtained by post from their headquarters at 309 West Clark Street, Champaign, Illinois, U.S.A.

Contravention of the Regulations or of an approval issued under them 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.

A Compliance Cost Assessment in relation to these Regulations, has been placed in the libraries of each House of Parliament. Copies may be obtained from:

Animal Health (International Trade) Division

Ministry of Agriculture, Fisheries and Food

Room C33

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Hook Rise South

Tolworth

Surbiton

Surrey

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