

STATES OF JERSEY



DRAFT COMMUNITY PROVISIONS (BOVINE EMBRYOS) (JERSEY) REGULATIONS 201-

**Lodged au Greffe on 17th August 2010
by the Minister for Planning and Environment**

STATES GREFFE



Jersey

DRAFT COMMUNITY PROVISIONS (BOVINE EMBRYOS) (JERSEY) REGULATIONS 201-

REPORT

Purpose of the Regulations

To assist business growth in the dairy industry and underpin Jersey's international reputation for integrity and to introduce legislation enabling development of trade in bovine embryos compliant with EU standards.

Background

Export of pedigree Jersey cattle from the Island to many countries worldwide was an important trade between the mid-nineteenth and twentieth centuries.

Trade dwindled from the 1970s as improvements to breed productivity achieved in the recipient countries could not be matched locally because insufficient numbers from which to select only allowed relatively limited progress.

Additionally, advances in techniques for artificial breeding has changed the world trade pattern and very few live cattle are now transported over long distances because genetic material, semen and embryos, can be traded more safely and more efficiently.

To enable Jersey's dairy farmers to benefit from improvements in both productivity and conformation, the States voted for legislative change in 2008 to permit the import of bovine semen, subject to internationally agreed disease control measures. With approximately 80% of cow inseminations in the Island by artificial insemination, and approximately 80% of these using imported semen, the industry's uptake is significant.

Legislative changes permitting import and export of genetic material is part of a suite of measures, agreed by the dairy industry, to be put in place to achieve increased efficiency and profitability enabling a move away from the historic levels of taxpayer support.

Trade opportunities

In May 2008, the World Jersey Cattle Bureau Conference was held in the Island and attended by delegates from all major dairying countries in the world. The conference included visits to farms where local cattle were appraised by world-class breeders and particular cow families were identified for embryo collection and export.

Following the Conference and subsequently the import of bovine semen, the Royal Jersey Agriculture and Horticulture Society has received enquiries for bovine embryos from several countries, including Argentina and New Zealand. As Jersey does not have the legal framework to enable export, some of the prospective buyers are known to be considering the option of buying embryos from Island cows which have been exported to the UK.

Legislative requirements

Jersey is obliged to implement animal health and veterinary legislation for trade in animals and animal products with EU Member States, as set out in Protocol 3 to the Act of Accession of the United Kingdom to the European Communities 1972.

In order to trade bovine embryos in EU Member States, compliance with the requisite Directive must be implemented and enforced. This is equivalent to the Directive governing trade in bovine semen.

Council Directive 89/556/EEC lays down the standards for collection, processing and storing bovine embryos, including –

- personnel carrying out the procedures;
- health status of donors and semen;
- laboratory facilities;
- disinfection of equipment including storage and transport flasks;
- source or treatment of products of animal origin and media;
- cryogenic agent;
- washing, identifying, examining and freezing embryos;
- premises in which procedures are carried out,

to achieve and maintain specified health requirements. The requirements are subject to official approval and control and verified by veterinary certification when trade takes place.

The standards are applicable to imports and exports between Member States and for imports from third countries. Imports from third countries can only take place through specific entry points and are subject to veterinary checks to verify compliance with the standards, before release for trade in the Community. Embryos which do not meet the requirements are not imported. The entry points themselves are subject to official approval and control.

Complying with the Directive to enable trade with EU Member States will also enable trade with many third countries which have adopted Directive compliance as the condition for import to their territories. To enable export of bovine embryos from Jersey to third countries, the standards described above and laid down in the Directive must be achieved.

Financial and manpower implications

Any business wishing to operate an embryo collection and storage will be required to pay full cost recovery for official inspections and approvals or employ a suitably qualified and approved individual for a private assessment. No additional States staffing requirement is identified.

Explanatory Note

These Regulations regulate trade in bovine embryos with Member States and the importation of bovine embryos from other countries (“third countries”). If these Regulations are adopted, separate provision will be made by Order to enable trade in bovine embryos with the remainder of the British Islands and exports to third countries.

Part 1 – Introductory

Regulation 1 is the interpretation provision. In order to trade with Member States, bovine embryos produced in Jersey must satisfy the health requirements laid down by Council Directive 89/556, defined in these Regulations as the “Community Provision”.

Regulation 2 makes it clear that the Regulations do not apply to embryos produced by cell nuclear replacement therapy.

Part 2 – Trade with European Community

Regulation 3 sets out the requirements for export of bovine embryos to Member States. The embryos must have been conceived using semen collected in Jersey at a collection centre licensed under the Artificial Insemination of Domestic Animals (Bovine Semen) (Jersey) Order 2008 (the “Bovine Semen Order”) or imported and stored in accordance with that Order. The donor animals must satisfy the health requirements in *Schedule 1*. The embryos must be collected, processed and stored, in accordance with *Schedule 2*, by an embryo collection team approved under *Part 3* and complying with *Schedule 3*. The embryos must be despatched with an animal health certificate.

Regulation 4 sets out the requirements for import of bovine embryos from a Member State. In essence, the embryos must comply with the requirements of the Community Provision, as implemented in the Member State of despatch.

Part 3 – Approvals and Certification

Regulation 5 sets out the process for approval of an embryo collection team by the Minister for Planning and Environment (the “Minister”) and specifies mandatory conditions of approval. Each approved team will be assigned a unique registration number and *Regulation 6* requires the Minister to maintain a public register of approved embryo collection teams.

Regulation 7 empowers the Minister to vary the conditions of approval of a team. The Minister is required to withdraw approval if a team no longer satisfies the requirements in *Schedule 3* or does not comply with the conditions of its approval. Ordinarily, a variation or withdrawal of approval will not take effect for 21 days. However, the Minister may require the variation or withdrawal to take effect immediately or in a shorter period if a delay would constitute an unacceptable risk to animal health.

Regulation 8 sets out the procedures for, and mandatory conditions applicable to, approval of an embryo production team. Such a team must comply with the same requirements as an embryo collection team and, in addition, the requirements in *Schedule 4*. Each approved team will be assigned a unique registration number and

Regulation 9 requires the Minister to maintain a public register of approved embryo production teams.

Regulation 10 provides for the variation or withdrawal of approval of embryo production teams on terms that equate to those applicable to embryo collection teams by virtue of *Regulation 7*.

Regulation 11 sets out the arrangements for approval of embryo storage facilities by the Minister. As for embryo collection and embryo production teams, *Regulation 12* empowers the Minister to vary or withdraw approval of storage facilities.

Regulation 13 entitles a person to apply to the Royal Court for a review of a decision of the Minister under any of the preceding Regulations in this Part.

Regulation 14 empowers an official veterinarian to issue animal health certificates required for the export of bovine embryos.

Part 4 – Third Country Imports

Regulation 15 imposes restrictions on the importation of bovine embryos from third countries. Embryos may only be imported from third countries listed by the Commission. The embryos must be produced and collected by a regulated team and satisfy the animal health standards imposed by the Commission or agreed with the third country.

Regulation 16 describes the regulatory checks that are required for the importation of bovine embryos from a third country. In practice, such embryos would be transported through a border inspection post in the Community and then onwards to Jersey. At the border inspection post, they will be subject to the checks required to permit their entry into the territory of the Community. By way of example, Heathrow Airport is the border inspection post in England for cattle.

Part 5 – Control Measures and Enforcement

Regulation 17 empowers an official veterinarian and any other person authorized by the Minister to inspect premises occupied by embryo collection or production teams and storage facilities. An official veterinarian can inspect equipment, animals and embryos on the premises, take samples and conduct tests.

Regulation 18 empowers the Minister to require embryo collection and production teams to make returns of information.

Regulation 19 makes it an offence to contravene any requirement of these Regulations or of an approval given under them. It is also made an offence to provide false information for any of the purposes of the Regulations; to fail to provide information when required to do so; to alter or use fraudulently an approval or animal health certificate or to obstruct a person exercising powers under the Regulations.

Regulation 20 provides for the liability of officers when an offence is committed by a company or limited liability partnership.

Part 6 – Closing Provisions

Regulation 21 empowers the Minister to amend various references to Community instruments, having regard to subsequent amendments to, or substitutions of, those instruments. The Minister is also empowered to amend the Schedules. The Schedules contain detailed, technical conditions, liable to require amendment so as to keep in

step with rules laid down by the Commission's Standing Committee on the Food Chain and Animal Health.

Regulation 22 empowers the Minister, by Order, to set fees for certificates and approvals issued, and inspections conducted, under the Regulations.

Regulation 23 provides for the citation and commencement of the Regulations.

Schedule 1 sets out the health requirements for donor animals.

Schedule 2 sets out conditions applicable to the collection, processing, storage and transport of bovine embryos.

Schedule 3 sets out the conditions for approval of embryo collection teams.

Schedule 4 sets out the conditions for approval of embryo production teams, which are in addition to the conditions in *Schedule 3*.



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Made [date to be inserted]

Coming into force [date to be inserted]

THE STATES, in pursuance of Article 2 of the European Communities Legislation (Implementation) (Jersey) Law 1996¹, have made the following Regulations –

PART 1

INTRODUCTORY

1 Interpretation

In these Regulations, unless the context otherwise requires –

“animal health certificate” means a certificate issued under Regulation 14;

“border inspection post” means an inspection post designated and approved in accordance with Article 6 of the Council Directive of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (91/496/EEC, OJ L 268, 24.9.1991, p.56²) as amended up to 3rd September 2008;

“bovine embryo storage facility” means a facility approved under Regulation 11;

“Bovine Semen Order” means the Artificial Insemination of Domestic Animals (Bovine Semen) (Jersey) Order 2008³;

“Community Provision” means the Council Directive of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (89/556/EEC, OJ L 302, 19.10.1989, p.1⁴) as amended up to 3rd September 2008;

“consignment of embryos” means a quantity of embryos removed in one operation from a single donor and covered by a single animal health certificate;

“country of collection” means the Member State or third country in which embryos are produced, collected, processed and, where necessary, stored, and from which they are sent to Jersey;

“embryo” means the initial stage of development of a domestic animal of the bovine species while it is capable of being transferred to a recipient dam;

“embryo collection team” means a team for the time being approved under Regulation 5;

“embryo production team” means a team for the time being approved under Regulation 8;

“herd” means an animal or group of animals kept on a holding as an epidemiological unit and, if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status;

“Member State” means a Member State of the European Community;

“Minister” means the Minister for Planning and Environment;

“official veterinarian” means –

- (a) the Veterinary Officer appointed in accordance with Article 2 of the Diseases of Animals (Jersey) Law 1956⁵; and
- (b) any other veterinary surgeon appointed by the Minister as such for the purposes of these Regulations;

“premises” includes land or any means of transport;

“public slaughterhouse” means the slaughterhouse provided by the States and administered by a Minister;

“semen collection centre” means premises licensed under Article 3(2) of the Bovine Semen Order;

“team veterinarian” means a veterinary surgeon who is responsible for the supervision of an embryo collection team or an embryo production team;

“third country” means a country or territory that is not a Member State or another place in the British Islands;

“veterinary surgeon” means a recognized veterinary surgeon, within the meaning of the Veterinary Surgeons (Jersey) Law 1999⁶.

2 Application

These Regulations do not apply to embryos derived by transfer of nuclei.

PART 2

TRADE WITH EUROPEAN COMMUNITY

3 Conditions for export of bovine embryos to a Member State

- (1) A person shall not export, or consign for export, embryos to another Member State unless the conditions set out in paragraphs (2) and (3) are complied with.
- (2) The embryos –
 - (a) must have been conceived as a result of artificial insemination or in vitro fertilization with semen –
 - (i) from a donor sire standing at a semen collection centre, or
 - (ii) imported and stored after importation in accordance with the Bovine Semen Order;
 - (b) must have been collected from domestic animals of the bovine species whose health status complies with Schedule 1;
 - (c) must have been collected, processed and stored –
 - (i) by an embryo collection team,
 - (ii) in accordance with Schedule 2.
- (3) The consignment of embryos must be accompanied, during its transport from its place of despatch to the Member State of destination, by an animal health certificate.

4 Conditions for import of bovine embryos from a Member State

- (1) A person shall not import embryos from a Member State (either for entry into Jersey or by way of transit to a Member State) unless the embryos meet the conditions imposed by Article 3 of the Community Provision (subject to any derogations permitted or additional requirements imposed in accordance with the Community Provision).
- (2) Where embryos are imported from a Member State (either for entry into Jersey or by way of transit to a Member State) the importer and, if different, the person in charge of the embryos, shall comply with all the relevant provisions of the Community Provision until the embryos arrive at their place of destination in Jersey or leave Jersey, as the case may be.

PART 3

APPROVALS AND CERTIFICATION

5 Embryo collection teams

- (1) An application for approval as an embryo collection team shall be made to the Minister.

- (2) An application shall be in writing and contain or be accompanied by such information as the Minister reasonably requires in order to be satisfied that the team fulfils the requirements in Schedule 3.
- (3) The Minister shall only give an approval if the Minister is satisfied that the team fulfils the requirements in Schedule 3.
- (4) An approval shall be in writing.
- (5) An approval shall be subject to –
 - (a) the condition that the following occurrences are notified to the Minister as soon as is practicable –
 - (i) the replacement of the team veterinarian,
 - (ii) any major change in the organization of the team,
 - (iii) any major change in the laboratories at the disposal of the team, or
 - (iv) any major change in the equipment at the disposal of the team; and
 - (b) such other conditions as the Minister considers are necessary to ensure that these Regulations are complied with.
- (6) On approving an embryo collection team, the Minister shall assign to the team a unique veterinary registration number.
- (7) The Minister shall inform an applicant, in writing, of the refusal of an application under this Regulation, and give reasons for the refusal.

6 Register of embryo collection teams

- (1) The Minister shall maintain a register of approved embryo collection teams and the veterinary registration number assigned to each of them.
- (2) The Minister shall make the register available to Member States and to the public.

7 Variation or withdrawal of approval of embryo collection team

- (1) The Minister may vary the conditions imposed under Regulation 5(5)(b) on the approval of an embryo collection team.
- (2) A variation under paragraph (1) may in particular be made having regard to an occurrence described in Regulation 5(5)(a), but is not limited to being made in those circumstances.
- (3) The Minister shall withdraw the approval of an embryo collection team if the team ceases to fulfil the requirements in Schedule 3 or fails to comply with any condition attached to its approval.
- (4) The Minister shall, in writing, notify the holder of the approval of an embryo collection team of the variation or withdrawal of an approval under this Regulation.
- (5) A notice under paragraph (4) shall –
 - (a) give reasons for the decision; and

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- (b) specify the date when the variation or withdrawal takes effect.
 - (6) Subject to paragraph (7), a variation or withdrawal shall not take effect less than 21 days after notice of it is given to the holder of the approval.
 - (7) Paragraph (6) shall not apply if the Minister considers that a delay of 21 days in the variation or withdrawal taking effect would constitute an unacceptable risk to animal health.

8 Embryo production teams

- (1) An application for approval as an embryo production team shall be made to the Minister.
- (2) An application shall be in writing and contain or be accompanied by such information as the Minister reasonably requires in order to be satisfied that the team fulfils the requirements in Schedules 3 and 4.
- (3) The Minister shall only give an approval if the Minister is satisfied that the team fulfils the requirements in Schedules 3 and 4.
- (4) An approval shall be in writing.
- (5) An approval shall be subject to –
 - (a) the condition that the following occurrences are notified to the Minister as soon as is practicable –
 - (i) the replacement of the team veterinarian,
 - (ii) any major change in the organization of the team,
 - (iii) any major change in the laboratories at the disposal of the team, or
 - (iv) any major change in the equipment at the disposal of the team; and
 - (b) such other conditions as the Minister considers are necessary to ensure that these Regulations are complied with.
- (6) On approving an embryo production team, the Minister shall assign to the team a unique veterinary registration number.
- (7) The Minister shall inform an applicant, in writing, of the refusal of an application under this Regulation, and give reasons for the refusal.

9 Register of embryo production teams

- (1) The Minister shall maintain a register of approved embryo production teams and the veterinary registration number assigned to each of them.
- (2) The Minister shall make the register available to Member States and to the public.

10 Variation or withdrawal of approval of embryo production team

- (1) The Minister may vary the conditions imposed under Regulation 8(5)(b) of the approval of an embryo production team.

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- (2) A variation under paragraph (1) may in particular be made having regard to an occurrence described in Regulation 8(5)(a), but is not limited to being made in those circumstances.
 - (3) The Minister shall withdraw the approval of an embryo production team if the team ceases to fulfil the requirements in Schedules 3 and 4 or fails to comply with any condition attached to its approval.
 - (4) The Minister shall, in writing, notify the holder of the approval of an embryo production team of the variation or withdrawal of an approval under this Regulation.
 - (5) A notice under paragraph (4) shall –
 - (a) give reasons for the decision; and
 - (b) specify the date when the variation or withdrawal takes effect.
 - (6) Subject to paragraph (7), a variation or withdrawal shall not take effect less than 21 days after notice of it is given to the holder of the approval.
 - (7) Paragraph (6) shall not apply if the Minister considers that a delay of 21 days in the variation or withdrawal taking effect would constitute an unacceptable risk to animal health.

11 Bovine embryo storage facilities

- (1) An application for approval of a bovine embryo storage facility shall be made to the Minister.
- (2) An application shall be in writing and contain or be accompanied by such information as the Minister reasonably requires in order to be satisfied that the facility satisfies the requirements of paragraph 2(2) and (3) of Schedule 2.
- (3) The Minister shall only give an approval if the Minister is satisfied that the facility satisfies the requirements of paragraph 2(2) and (3) of Schedule 2.
- (4) An approval shall be in writing.
- (5) An approval shall be subject to such conditions as the Minister considers are necessary to ensure that these Regulations are complied with.
- (6) The Minister shall inform an applicant, in writing, of the refusal of an application under this Regulation, and give reasons for the refusal.
- (7) The approval by the Minister of premises as a bovine embryo storage facility also approves those premises for the storage of bovine semen.

12 Variation or withdrawal of approval of bovine embryo storage facility

- (1) The Minister may vary the conditions imposed under Regulation 11(5) of the approval of a bovine embryo storage facility.
- (2) The Minister shall withdraw the approval of a bovine embryo storage facility if the facility ceases to fulfil the requirements in paragraph 2(2) and (3) of Schedule 2 or fails to comply with any condition attached to its approval.

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- (3) The Minister shall, in writing, notify the holder of the approval of a bovine embryo storage facility of the variation or withdrawal of an approval under this Regulation.
 - (4) A notice under paragraph (3) shall –
 - (a) give reasons for the decision; and
 - (b) specify the date when the variation or withdrawal takes effect.
 - (5) Subject to paragraph (6), a variation or withdrawal shall not take effect less than 21 days after notice of it is given to the holder of the approval.
 - (6) Paragraph (5) shall not apply if the Minister considers that a delay of 21 days in the variation or withdrawal taking effect would constitute an unacceptable risk to animal health.

13 Review of decision of Minister

- (1) An applicant for an approval under Regulation 5, 8 or 11 may apply to the Royal Court for a review of the decision of the Minister –
 - (a) to refuse an approval; or
 - (b) to impose conditions on the approval, in accordance with –
 - (i) in the case of an application for approval of an embryo collection team, Regulation 5(5)(b),
 - (ii) in the case of an application for approval of an embryo production team, Regulation 8(5)(b),
 - (iii) in the case of an approval of a bovine embryo storage facility, Regulation 11(5).
- (2) The holder of an approval given under Regulation 5, 8 or 11 may apply to the Royal Court for a review of the decision of the Minister –
 - (a) to vary the conditions imposed on the approval; or
 - (b) to withdraw the approval.
- (3) An application under this Regulation must be made within 21 days of the of the applicant being notified of the decision to be reviewed.
- (4) The Royal Court may extend the period mentioned in paragraph (3).
- (5) The Royal Court may, on an application under this Regulation, make such orders as it thinks fit.

14 Animal health certificates

- (1) An official veterinarian may issue an animal health certificate for a consignment of embryos intended for a single place of destination.
- (2) An animal health certificate –
 - (a) shall be in the form set out in Annex C to the Community Provision;
 - (b) shall be drawn up in at least the official language of the other Member State that is the place of destination; and

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- (c) shall be made out to a single consignee.

PART 4

THIRD COUNTRY IMPORTS

15 Health rules for importation of embryos from a third country

- (1) A person shall not import embryos from an unlisted third country.
- (2) An unlisted third country is one that does not appear in Annex I to the Commission Decision of 4 January 2006 establishing the animal health and veterinary certification requirements for imports into the Community of bovine embryos and repealing Decision 2005/217/EC (2006/168/EC, OJ L 57, 28.2.2006, p.19⁷), as amended up to 1st January 2010.
- (3) A person shall not import embryos from a third country unless the embryos –
 - (a) are dispatched by an embryo collection team or embryo production team that is on the list of approved teams communicated by the competent authority of the third country and made available to the public in accordance with Article 8 of the Community Provision;
 - (b) come from donor animals which, immediately prior to the collection of the embryos, have remained for at least 6 months in the territory of the third country concerned, and in a maximum of 2 herds complying with Article 9.2 of the Community Provision; and
 - (c) comply with the animal health requirements adopted in accordance with the procedure laid down in Article 18 of the Community Provision for imports of embryos from that country.

16 Checks required for importation of embryos from a third country

- (1) Importation of embryos from a third country shall be authorized only on submission of an animal health certificate –
 - (a) drawn up and signed by an official veterinarian of the third country of collection; and
 - (b) satisfying the requirements of Article 10 of the Community Provision.
- (2) Importation of embryos from a third country shall be authorized only where –
 - (a) the embryos are transported to their place of destination in Jersey after passing through a border inspection post and without subsequently entering the territory of a third country; and
 - (b) the veterinary checks required by the Council Directive of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (97/78/EC, OJ L 24, 30.1.1998,

p.9⁸), as amended up to 1st January 2007, are conducted at the border inspection post.

PART 5

CONTROL MEASURES AND ENFORCEMENT

17 Checks and powers of entry

- (1) An official veterinarian and any other person authorized by the Minister for the purposes of this Regulation may, on producing the person's authority, enter at all reasonable times any premises occupied by the holder of an approval given under these Regulations and used for or in connection with any of the purposes authorized by the approval, for the purpose of checking for compliance with the conditions attached to the approval and with any conditions in the Schedules that are relevant to the approval.
- (2) An official veterinarian and any other person authorized by the Minister for the purposes of this Regulation may, on producing the person's authority, enter at all reasonable times any premises on which, or in connection with which, the person has reasonable grounds for suspecting that an offence under these Regulations is being or has been committed.
- (3) A person who enters premises in exercise of the powers conferred by paragraph (1) or (2) may –
 - (a) inspect the premises and any equipment and animals on them;
 - (b) carry out such tests or other investigations, whether on the premises, equipment on the premises, or animals or embryos on the premises, or on samples taken from the premises, equipment, animals or embryos, as the person thinks fit in order to ascertain whether the provisions of these Regulations, or the conditions subject to which any approval or licence is given under these Regulations, are being complied with; and
 - (c) for the purposes of any such test or investigation, require the occupier of the premises, and any person in the employment of such occupier, to furnish such information as is in that person's power to give.

18 Power to obtain information from approved teams

The Minister and any person authorized by or on behalf of the Minister for the purposes of this Regulation may require any holder of an approval given under these Regulations to furnish him or her, within such time and in such manner as he or she specifies, with such returns and other information as he or she requires for the purpose of monitoring the operation of these Regulations and checking for compliance with any condition attached to the approval and with any conditions in the Schedules that are relevant to the approval.

19 Offences

- (1) A person who contravenes Regulation 3, 4 or 15 is guilty of an offence and liable to a fine of level 4 on the standard scale.
- (2) A person who –
 - (a) hinders or obstructs a person in the exercise of the person’s powers under Regulation 17; or
 - (b) refuses or neglects to furnish, in the time and manner specified, any return or information when required to do so under Regulation 18,

is guilty of an offence and liable to imprisonment for a term of 6 months and a fine of level 4 on the standard scale.

- (3) A person who knowingly or recklessly contravenes any condition subject to which an approval is given under these Regulations or any condition in the Schedules that is relevant to the approval is guilty of an offence and liable to a fine of level 4 on the standard scale.
- (4) The holder of an approval given under these Regulations is guilty of an offence and liable to a fine of level 4 on the standard scale if any condition subject to which the approval was given or any condition in the Schedules that is relevant to the approval is contravened and the holder of the approval did not take all reasonable precautions and exercise due diligence to avoid the contravention.
- (5) A person who –
 - (a) in an application for approval under these Regulations or for the purpose of obtaining an animal health certificate makes any statement knowing that, or reckless as to whether, it is false in a material particular;
 - (b) furnishes any return or information when required to do so under these Regulations, knowing that, or reckless as to whether, the return or information is false in a material particular; or
 - (c) fraudulently alters or uses or permits to be fraudulently used any certificate or approval given under these Regulations or otherwise issued and required as evidence that a requirement of these Regulations is satisfied,

is guilty of an offence and liable to imprisonment for a term of 6 months and a fine of level 4 on the standard scale.

20 Offences: general

- (1) Where an offence against these Regulations committed by a limited liability partnership or body corporate is proved to have been committed with the consent or connivance of –
 - (a) a person who is a partner of the partnership, or director, manager, secretary or other similar officer of the body corporate; or
 - (b) any person purporting to act in any such capacity,

the person shall also be guilty of the offence and liable in the same manner as the partnership or body corporate to the penalty provided for that offence.

- (2) Where the affairs of a body corporate are managed by its members, paragraph (1) shall apply in relation to acts and defaults of a member in connection with the member's functions of management as if the member were a director of the body corporate.

PART 6

CLOSING PROVISIONS

21 Orders amending these Regulations

- (1) The Minister may by Order amend any reference in these Regulations to a Community instrument.
- (2) The Minister may by Order amend the Schedules.

22 Fees for certificates, approvals and inspections

- (1) The Minister may, by Order, prescribe fees for the issue of certificates under these Regulations.
- (2) Where a fee is prescribed under paragraph (1), the certificate shall not be issued until the fee has been paid.
- (3) The Minister may, by Order, prescribe fees for any application for, or the grant of, any approval to be given, or given, under these Regulations.
- (4) Where a fee is prescribed under paragraph (3) the Minister shall not consider the application for the approval until the fee has been paid.
- (5) The Minister may, by Order, prescribe fees for any inspection, test or official examination carried out by or on behalf of an official veterinarian in the discharge of functions under these Regulations.
- (6) Fees prescribed by the Minister under this Regulation may be determined by reference to rates which represent the reasonable costs and expenses incurred in employing or contracting for an official veterinarian to undertake an inspection, test or official examination, during any given unit of time, whether for the purpose of the issue of a certificate or the grant of an approval or otherwise in the discharge of functions under these Regulations.
- (7) Fees prescribed by reference to a rate for an official veterinarian shall be charged in units of no more than half an hour.

23 Citation and commencement

These Regulations may be cited as the Community Provisions (Bovine Embryos) (Jersey) Regulations 201- and shall come into force 7 days after they are made.

SCHEDULE 1

(Regulation 3(2)(b))

**CONDITIONS APPLYING TO DONOR ANIMALS FOR EMBRYO
COLLECTION**

1 Health history of donor animal

For the purposes of embryo collection, donor animals must meet the following requirements –

- (a) they must have spent at least the previous 6 months within Jersey;
- (b) they must have been present in the herd of origin for at least 30 days prior to collection;
- (c) they must come from herds which are –
 - (i) officially tuberculosis free,
 - (ii) officially brucellosis free or brucellosis free,
 - (iii) enzootic bovine leucosis free, or, they may come from a herd which is not, or herds which are not, leucosis-free but for which certification has been obtained that there has not been any clinical case of enzootic bovine leucosis during the past 3 years;
- (d) during the previous year, they must not have been present in a herd (or herds) which have shown any clinical sign of infectious bovine rhinotracheitis or infectious pustular vulvovaginitis.

2 Health of donor animal on day of collection

On the day of embryo collection the donor cow –

- (a) shall be kept in a holding which is not subject to veterinary prohibition or quarantine measures;
- (b) shall show no clinical signs of disease.

3 Oocyte donation

Paragraphs 1 and 2 shall also apply to live animals intended as donors of oocytes by ovum pickup or ovariectomy.

4 Collection after slaughter

- (1) In the case of donors of ovaries and other tissues to be collected after slaughter in the public slaughterhouse, they 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.

- (2) At the time of collection the public slaughterhouse must not be situated in a zone subject to prohibition or quarantine measures.

SCHEDULE 2

(Regulations 3(2)(c) and 11(3))

**CONDITIONS RELATING TO THE COLLECTION, PROCESSING,
STORAGE AND TRANSPORT OF EMBRYOS**

1 Collection and processing

- (1) Embryos shall be collected and processed by an approved collection team, without coming into contact with any other consignment of embryos not meeting the requirements of these Regulations relating to trade in bovine embryos with another Member State.
- (2) Embryos shall be collected in a place which is isolated from other parts of the premises or holding and which must be in good repair and easy to cleanse and disinfect.
- (3) Embryos shall be processed (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.
- (4) All implements which come into contact with the embryos or the donor animal during collection and processing shall be disposable or shall be properly disinfected or sterilized prior to use.
- (5) Products of animal origin used during collection of the embryos and in the transport medium shall be obtained from sources which present no animal health risk or are to be so treated prior to use so that such risk is prevented. All media and solutions shall be sterilized by approved methods according to the recommendations of the manual of the International Embryo Transfer Society (being the Society 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). Antibiotics may be added to the media in accordance with that Society's manual.
- (6) Storage flasks and transport flasks shall be properly disinfected or sterilized before the commencement of each filling operation.
- (7) The cryogenic agent used shall not have been previously used for other products of animal origin.
- (8) Each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor dam, as well as the registration number of the team can be readily established.
- (9) Each embryo shall be washed at least 10 times in a special fluid for embryos which shall be changed each time and which shall contain

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- trypsin, in accordance with internationally recognized procedures. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.
- (10) After the last wash each embryo shall be subjected to microscopic examination at a magnification of at least $\times 50$ 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 embryo having an intact zona pellucida.
- (11) Each consignment of embryos that has successfully undergone the examination provided for in sub-paragraph (10) shall be placed in a sterile container marked in accordance with sub-paragraph (8) and which shall be sealed immediately.
- (12) Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian and which is subject to regular inspection by an official veterinarian.
- (13) Each collection team must, when required to do so by the Minister, submit routine samples of flushing fluids, washing fluids, disintegrated embryos, non-fertilized ova etc., resulting from its activities to the Minister for official examination for bacterial and viral contamination.
- (14) Each collection team must keep a record of its activities in respect of embryo collection during the 12 months before and 12 months after storage 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* fertilization and/or *in vitro* culture which have been performed on the embryos. In the case of embryos derived by *in vitro* fertilization, the identification may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries and/or oocytes. It must also be possible to identify the herd of origin of the donor animals.
- (15) The conditions laid down in sub-paragraphs (1) to (14) shall apply as appropriate to the collection, processing, storage and transport of ovaries, oocytes and other tissues for use in *in vitro* fertilization and/or *in vitro* culture.
- (16) The conditions in sub-paragraphs (17) to (22) shall apply in addition to the conditions in sub-paragraphs (1) to (14).
- (17) When ovaries and other tissues are to be collected post-mortem, this may only be done at the public slaughterhouse.
- (18) Materials and equipment coming into direct contact with ovaries and other tissues shall be sterilized before use and after sterilization, used

exclusively for those purposes. Separate equipment shall be used to handle oocytes and embryos from different batches of donor animals.

- (19) Ovaries and other tissues shall not be allowed to enter the processing laboratory until completion of the post-mortem inspection of the batch. If relevant disease is found in the batch of donors, or in any animals slaughtered in the public slaughterhouse on that day, all tissues from that batch must be traced and discarded.
- (20) The washing and examination procedure laid down in sub-paragraphs (9) and (10) shall be carried out after the culture procedure has been completed.
- (21) Any micromanipulation which involves penetration of the zona pellucida shall be carried out in accordance with the provisions of sub-paragraph (10), after the procedures laid down in sub-paragraph (20) have been completed.
- (22) Only embryos from the same batch of donors should be stored in the same ampoule/straw.

2 Storage

- (1) Each embryo collection or production team shall ensure that the embryos are stored at suitable temperatures in a bovine embryo storage facility.
- (2) In order to be approved the facility must –
 - (a) comprise at least one lockable room intended exclusively for embryo storage;
 - (b) be easy to cleanse and disinfect;
 - (c) have permanent records of all incoming and outgoing movements of embryos which shall, in particular, specify the final destination of the embryos; and
 - (d) be subject to inspection by an official veterinarian.
- (3) If bovine semen is to be stored in a bovine embryo storage facility, the facility must satisfy the conditions for the grant of a licence as an EC storage centre under the Bovine Semen Order.

3 Transport

- (1) Embryos for trade must be transported in satisfactory hygienic conditions in sealed containers from the approved bovine embryo storage facility until their arrival at their destination.
- (2) The containers must be marked in such a way that the number coincides with the number on the animal health certificate.

SCHEDULE 3

(Regulations 5 and 8)

**CONDITIONS FOR THE APPROVAL OF EMBRYO COLLECTION AND
EMBRYO PRODUCTION TEAMS**

In order to be given approval each embryo collection team must fulfil the following requirements –

- (a) the collection, processing and storage of embryos must be carried out either by a team veterinarian or under his or her responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene;
- (b) the team must have at its disposal permanent or mobile laboratory facilities where embryos can be examined, processed and packed, consisting of at least a work surface, a microscope and cryogenic equipment;
- (c) in the case of a permanently sited laboratory, the team must have at its disposal –
 - (i) a room where embryos can be manipulated which is adjacent to but physically separate from the area used to handle the donor animals during collection, and
 - (ii) a room or area equipped for cleansing and sterilizing instruments and equipment used in embryo collection and manipulation;
- (d) where micromanipulation of the embryo which involves penetration of the zona pellucida is to be carried out, this shall be done in suitable laminar-flow facilities which shall be properly cleaned and disinfected between batches;
- (e) the team must have at its disposal in the case of a mobile laboratory a specially equipped part of the vehicle consisting of 2 separate sections –
 - (i) one for the examination and manipulation of embryos which shall be a clean section, and
 - (ii) the other for accommodating equipment and materials used in contact with the donor animals.

A mobile laboratory shall always have contact with a permanently sited laboratory to ensure the sterilization of its equipment and the provision of fluids and other products necessary for the collection and manipulation of embryos.

SCHEDULE 4

(Regulation 8)

**ADDITIONAL CONDITIONS FOR THE APPROVAL OF EMBRYO
PRODUCTION TEAMS**

In order to be given approval each embryo production team must fulfil the following requirements, in addition to the requirements in Schedule 3 –

- (a) the personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions;
- (b) the team must have at its disposal a permanently-sited processing laboratory which must –
 - (i) have adequate equipment and facilities, including a separate room for recovering oocytes from ovaries, and separate rooms or areas for processing oocytes and embryos, and storing embryos, and
 - (ii) have laminar-flow facilities under which all oocytes, semen and embryos must be processed; however, the centrifugation of semen may be carried out outside the laminar-flow facility, as long as full hygienic precautions are taken;
- (c) where oocytes and other tissues are to be collected in the public slaughterhouse, the 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.

¹ *chapter 17.245*

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0496:EN:NOT>

³ *chapter 01.480.10*

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0556:EN:NOT>

⁵ *chapter 02.400*

⁶ *chapter 02.900*

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0168:EN:NOT>

⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997L0078:EN:NOT>