ANNEX III

***IN VITRO*-PRODUCED EMBRYOS OF DOMESTIC ANIMALS OF THE BOVINE SPECIES FOR IMPORT, CONCEIVED USING SEMEN COMPLYING WITH COUNCIL DIRECTIVE 88/407/EEC**

L-ANNESS III

EMBRIJUNI PRODOTTI IN VITRO TA' ANNIMALI DOMESTIĊI TA' L-ISPEĊI BOVINA GĦALL-IMPORTAZZJONI, KONĊEPITI BL-UŻU TA' SEMEN KONFORMI MAD-DIRETTIVA TAL-KUNSILL 88/407/KEE

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code

I.2.
I.2.a.Local reference number:

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code

I.6.

I.7.Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code

I.11. Place of origin
Embryo team ☐
Name Approval number
Address
Name Approval number
Address
Name Approval number
Address

I.12. Place of destination
Holding ☐ Embryo team ☐ Approved body ☐
Name Approval number
Address
Postal code

I.13.

I.14. Estimated date and time of arrival

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16.

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.

I.25. Commodity certified for
Artificial reproduction ☐

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐
Definitive import ☐

I.28. Identification of the animals/products

Species (Scientific name) Identification mark Category

PAJJIZ **Ic-certifikat veterinarju ghall-UE**

Parti I : Dettalji tal-kunsinja mibghuta

I.1. Kunsinnatur
☐ Isem
Indirizz
Kodici Postali

I.2.

I.2.a. Numru lokali ta' riferenza

I.3. Awtorita Centrali kompetenti

I.4. Awtorita lokali kompetenti

I.5. Destinatarju
Isem
Indirizz
Kodici Postali

I.6.

I.7. Pajjiz ta' origini	Kodici ISO	I.8. Regjun ta' origini	Kodici	I.9. Pajjiz ta' destinazzjoni	Kodici ISO	I.10. Regjun ta' destinazzjoni	Kodici

I.11. Pajjiz ta' origini/Pajjiz ta' hsad
Tim embrijoniku ☐
Isem Numru approvat
Indirizz
Isem Numru approvat
Indirizz
Isem Numru approvat
Indirizz

I.12. Post ta' destinazzjoni
Fond ☐ Tim embrijoniku ☐ Korp approvat ☐
Isem Numru approvat
Indirizz
Kodici Postali

I.13.

I.14. Estimazzjoni tad-data u l-hin tal-wasla

I.15. Mezz ta' trasport
Ajruplan ☐ Vaxxel ☐ Vagun ☐
Vejikolu tat-triq ☐ Ohrajn ☐
Identifikazzjoni
Referenzi Dokumentarji:

I.16.

I.17.

I.18. Deskrizzjoni tal-prodott

I.19. Kodici tal-Komodita (Kodici CN)

I.20. Numru/Kwantita

I.21.

I.22. Numru ta' pakketti

I.23. Identifikazzjoni tal-kontenitur/ Numru ta' sigill

I.24.

I.25. Prodotti ccertifikati
Riproduzzjoni artificjali ☐

I.26. Ghat-tranżitu fl-UE lejn Pajjiż Terz ☐
Pajjiz terz Kodici ISO

I.27. Ghall-importazzjoni jew l-ammissjoni fl-UE ☐
Importazzjoni definitiva ☐

I.28.Identifikazzjoni tal-prodotti
Speci (Isem xjentifiku) Marka ta' identifikazzjoni Kategorija

COUNTRY
PAJJIŻ

In vitro-produced bovine embryos
Embrijuni bovini prodotti in vitro

Part II: Certification/ Parti II: Ċertifikazzjoni

II. Health information ☐ Tagħrif fuq is-saħħa ☐	II.a. Certificate reference number Numru ta' referenza taċ-ċertifikat	II.b. Local reference number Numru ta' referenza lokali

I, the undersigned, official veterinarian of the Government of

……..……, (insert name of exporting country)

Jiena, hawn taħt iffirmat, veterinarju uffiċjali tal-Gvern ta'

……..……, (daħħal isem il-pajjiż esportatur)

certify that:
niċċertifika li:

1.1. the embryo production team identified above:

- has been approved in accordance with Chapter I of Annex A to Directive 89/556/EEC;
- carried out the production, processing, storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC;
- is subject to inspection by an official veterinarian at least twice a year.

l-iskwadra ta' produzzjoni ta' l-embrijuni identifikata hawn fuq:

- kienet approvata skond il-Kapitolu I fl-Anness A għad-Direttiva 89/556/KEE;
- ipproduċiet, ipproċessat, ħażnet u ttrasportat l-embrijuni deskritti hawn fuq skond il-Kapitolu II fl-Anness A għad-Direttiva 89/556/KEE;
- hija suġġetta għall-ispezzjoni minn veterinarju uffiċjali għallinqas darbtejn fis-sena.

1.2. The embryos to be exported were produced in the exporting country, which according to official findings:

L-embrijuni għall-esportazzjoni ġew prodotti fil-pajjiż esportatur, li skond ir-riżultati uffiċjali:

1.2.1. was free from rinderpest during the 12 months immediately prior to their production;
kien ħieles mir-rinderpest matul it-12-il xahar immedjatament qabel il-produzzjoni tagħhom;

1.2.2.

1.2.2.1. either was free from foot-and-mouth disease during the 12 months immediately prior to their production and did not carry out vaccination against foot-and-mouth disease during that period([1]),
jew kien ħieles mill-marda ta' l-ilsien u d-dwiefer matul it-12-il xahar immedjatament qabel il-produzzjoni tagħhom u ma laqqamx kontra l-marda ta' l-ilsien u d-dwiefer matul dak il-perjodu([1]),

1.2.2.2. or was not free from foot-and-mouth disease during the 12 months immediately prior to their production and/or carried out vaccination against foot-and-mouth disease during that period, and

- the embryos were produced without penetration of the *zona pellucida,*
- the embryos were stored under approved conditions for at least 30 days immediately after their production, and
- the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during the 30 days prior to collection and no animal of a susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least the 30 days after, the oocytes were collected([1]).

jew ma kienx ħieles mill-marda ta' l-ilsien u d-dwiefer matul it-12-il xahar immedjatament qabel il-produzzjoni tagħhom u/jew laqqam kontra l-marda ta' l-ilsien u d-dwiefer matul dak il-perjodu u

– l-embrijuni ġew prodotti mingħajr penetrazzjoni taż-żona pellućida,

– l-embrijuni nħażnu skond il-kondizzjonijiet approvati għal mill-inqas 30 jum immedjatament wara l-produzzjoni tagħhom, u

– d-donaturi femminili ġew minn oqsma fejn l-ebda annimal ma tlaqqam kontra l-marda ta' l-ilsien u d-dwiefer matul it-30 jum qabel il-ġbir u l-ebda annimal ta' speċi suxxettibbli ma wera sinjali kliniċi tal-marda ta' l-ilsien u d-dwiefer matul it-30 jum ta' qabel, u mill-inqas it-30 jum ta' wara, il-ġbir ta' l-ooċiti ([1]).

1.3. The oocytes used in the production of the embryos to be exported were collected from donor females complying with the following requirements:

L-ooċiti (ċelluli tal-bajd) użati fil-produzzjoni ta' l-embrijuni għall-esportazzjoni nġabru minn donaturi femminili konformi mal-ħtiġijiet li ġejjin:

1.3.1. The donor females:

– were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the oocytes[(1)];

Id-donaturi femminili:

– inżammu f'pajjiż jew żona ħielsa mill-vajrus tal-bluetongue għal mill-inqas 60 jum qabel, u matul, il-ġbir ta' l-ooċiti[(1)];

or/ jew

1.3.2.

– were kept during a seasonally free period or protected from the competent vector *Culicoides* for at least 60 days prior to, and during, the collection of the oocytes, and the embryos were produced without penetration of the *zona pellucida,* except if the donors underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results and the embryos were stored for at least 30 days[(1)];

– inżammu matul perjodu staġonali ħieles jew protetti mill-organiżmu li jġorr il-Culicoides għal mill-inqas 60 jum qabel, u matul, il-ġbir ta' l-ooċiti, u l-embrijuni ġew prodotti mingħajr penetrazzjoni taż-żona pellućida, ħlief jekk id-donaturi sarilhom test seroloġiku biex jiskopri antikorpi tal-grupp tal-vajrus tal-bluetongue, magħmul skond il-Manwal tat-Testijiet Dijanjostiċi u l-Vaċċini għall-Annimali Terrestri bejn 21 u 60 jum wara l-ġbir u rriżultaw negattivi għalih u l-embrijuni nħażnu għal mill-inqas 30 jum[(1)];

or/ jew

1.3.3.

– underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results, and the embryos were stored for at least 30 days[(1)];

– sarilhom test seroloġiku biex jiskopri antikorpi tal-grupp tal-vajrus tal-bluetongue, magħmul skond il-Manwal tat-Testijiet Dijanjostiċi u l-Vaċċini għall-Annimali Terrestri bejn 21 u 60 jum wara l-ġbir u rriżultaw negattivi għalih, u l-embrijuni nħażnu għal mill-inqas 30 jum[(1)];

or/ jew

1.3.4.

– underwent an agent identification test, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of collection or the day of slaughtering and giving negative results – the embryos having been produced, in the latter case, without penetration of the *zona pellucida*[(1)].

– sarilhom test ta' identifikazzjoni ta' l-aġent, magħmul skond il-Manwal tat-Testijiet Dijanjostiċi u l-Vaċċini għall-Annimali Terrestri fuq kampjun tad-demm meħud fil-jum tal-ġbir jew il-jum tat-tbiċċir u rriżultaw negattivi għalih – u l-embrijuni jkunu ġew prodotti, fil-każ ta' l-aħħar, mingħajr penetrazzjoni taż-żona pellućida[(1)].

1.4.

1.4.1. Within a 10-km radius of the premises on which the oocytes used in the production of the embryos to be exported were collected and processed, according to official findings there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia in the 30 days immediately prior to their collection and, in the case of embryos certified under 11.2.2.2, in the 30 days after their collection as well.

F'raġġ ta' 10 km mill-post fejn l-ooċiti użati fil-produzzjoni ta' l-embrijuni għall-esportazzjoni nġabru u ġew ipproċessati, skond ir-riżultati uffiċjali ma kien hemm l-ebda inċidenza tal-marda ta' l-ilsien u d-dwiefer, tal-bluetongue, tal-marda emorraġika epiżootika, ta' l-istomatite veżikulari, tad-deni Rift Valley jew tal-plewropnewmonite bovina kontaġjuża fit-30 jum immedjatament qabel il-ġbir tagħhom u, fil-każ ta' embrijuni ċċertifikati skond 11.2.2.2, fit-30 jum wara l-ġbir tagħhom ukoll.

1.4.2. From the time of collection until 30 days thereafter, the embryos to be exported were stored at all times on approved premises within a 10-km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever.

Mill-ħin tal-ġbir sa 30 jum wara, l-embrijuni għall-esportazzjoni nħażnu f'kull ħin f'post approvat li skond ir-riżultati uffiċjali, f'raġġ ta' 10 km madwaru, ma kien hemm l-ebda inċidenza tal-marda ta' l-ilsien u d-dwiefer, ta' l-istomatite veżikulari u tad-deni Rift Valley.

1.5. The donors of oocytes used in the production of the embryos to be exported:

Id-donaturi ta' l-ooċiti użati fil-produzzjoni ta' l-embrijuni għall-esportazzjoni:

1.5.1. were located, during the 30 days immediately prior to collection of the oocytes, on premises within a 10-km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

inżammu, matul it-30 jum immedjatament qabel il-ġbir ta' l-ooċiti, f'post li f'raġġ ta' 10 km madwaru, skond ir-riżultati uffiċjali, ma kien hemm l-ebda inċidenza tal-marda ta' l-ilsien u d-dwiefer, tal-bluetongue, tal-marda emorraġika epiżootika, ta' l-istomatite veżikulari kontaġjuża, tad-deni Rift Valley jew tal-plewropnewmonite bovina kontaġjuża;

1.5.2. showed no clinical signs of disease on the day of collection;

ma wrew ebda sinjali kliniċi ta' mard fil-jum tal-ġbir;

1.5.3. spent the six months immediately prior to collection within the territory of the exporting country in no more than two herds:

– which, according to official findings, were free from tuberculosis during that time,

– which, according to official findings, were free from brucellosis during that time,

– which were free from enzootic bovine leukosis or in which no animal showed clinical signs of enzootic bovine leukosis during the previous three years,

– in which no bovine animal showed clinical signs of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months.

qattgħu s-sitt xhur immedjatament qabel il-ġbir fit-territorju tal-pajjiż esportatur f'mhux aktar minn żewġ merħliet:

– li, skond ir-riżultati uffiċjali, kienu ħielsa mit-tuberkuloži matul dak il-perjodu,

– li, skond ir-riżultati uffiċjali, kienu ħielsa mill-bruċelloži matul dak il-perjodu,

– li kienu ħielsa mil-lewkoži bovina enżootika jew li fihom ebda annimal ma wera sinjali kliniċi ta' lewkoži bovina enżootika matul it-tliet snin ta' qabel,

– li fihom l-ebda annimal bovin ma wera sinjali kliniċi ta' rinotrakejite infettiva/pustular vulvo-vaginitis infettiva matul it-12-il xahar ta' qabel.

1.6. The embryos to be exported provide the following additional guarantees([3]):

L-embrijuni għall-esportazzjoni jipprovdu l-garanziji addizzjonali li ġejjin([3]):

1.6.1. either the embryos to be exported were produced in the exporting country, which according to official findings is free from Akabane disease([1]),

jew l-embrijuni għall-esportazzjoni ġew prodotti fil-pajjiż esportatur, li skond ir-riżultati uffiċjali huwa ħieles mill-marda ta' l-Akabane([1]),

1.6.2. or the embryos were produced in the exporting country, which according to official findings is not free from Akabane disease ([1]), and

– the embryos were produced without penetration of the *zona pellucida;*

– the embryos were stored under approved conditions for at least 30 days immediately after production, and

– the donors of the oocytes used in the production of embryos underwent a serum neutralisation test for Akabane disease giving negative results and carried out on a blood sample taken not less than 21 days following their collection, or an agent identification test carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of slaughtering([1]).

jew l-embrijuni ġew prodotti fil-pajjiż esportatur, li skond ir-riżultati uffiċjali mhux ħieles mill-marda ta' l-Akabane([1]), u

– l-embrijuni ġew prodotti mingħajr penetrazzjoni taż-żona pellucida;

– l-embrijuni nħażnu skond il-kondizzjonijiet approvati għal mill-inqas 30 jum immedjatament wara l-produzzjoni, u

– d-donaturi ta' l-ooċiti użati fil-produzzjoni ta' l-embrijuni sarilhom test ta' newtralizzazzjoni tas-serum għall-marda ta' l-Akabane li għalih irriżultaw negattivi, magħmul fuq kampjun tad-demm meħud mhux inqas minn 21 jum wara l-ġbir tagħhom, jew test ta' identifikazzjoni ta' l-aġent li sar skond il-Manwal tat-Testijiet Dijanjostiċi u l-Vaċċini għall-Annimali Terrestri fuq kampjun tad-demm meħud fil-jum tat-tbiċċir([1]).

1.7. The embryos to be exported were conceived by *in vitro* fertilisation using semen coming from semen collection or storage centres located in a Member State of the European Community or in a third country and approved in accordance with Article 5(1) and Article 9(1) respectively of Directive 88/407/EEC([5]).

L-embrijuni għall-esportazzjoni ġew ikkonċepiti permezz tal-fertilizzazzjoni in vitro bl-użu ta' semen ġej minn ċentri ta' ġbir jew ta' ħżin tas-semen li jinsabu fi Stat Membru tal-Komunità Ewropea jew f'pajjiż terz u approvati f'konformità ma' l-Artikolu 5(1) u l-Artikolu 9(1) rispettivament tad-Direttiva 88/407/KEE([5])

Notes

(1) Delete as appropriate.
(2) [Box reference no. I.28 in Part I]:
Identification mark: corresponding to the identification of the donor cows and the date of collection.
Category: specify if a) penetration or b) non penetration of *zona pellucida*.
(3) See remarks for exporting country concerned in Annex I to Decision 2006/168/EC.
(4) The signature and the stamp must be of a different colour from that of the printed form.
(5) Semen collection and storage centres approved in accordance with EC legislation are listed on the Commission's website http://europa.eu.int/comm/food/index_en.htm.

Noti

(1) Ħassar kif meħtieġ.
(2) [Kaxxa bin-nru ta' referenza. I.28 f'Parti I]:
Marka ta' identifikazzjoni: tikkorrispondi għall-identifikazzjoni tal-baqar donaturi u d-data tal-ġbir.
Kategorija: speċifika jekk a) penetrazzjoni jew b) mingħajr-penetrazzjoni taż-żona pellucida.
(3) Ara r-rimarki għall-pajjiż esportatur ikkonċernat fl-Anness I għad-Deċiżjoni Decision 2006/168/EC.
(4) Il-firma u t-timbru jridu jkunu ta' kulur differenti mill-formola stampata.
(5) Iċ-ċentri għall-ġbir u l-ħżin tas-semen approvati skond il-leġiżlazzjoni tal-KE huma elenkati fil-websajt tal-Kummissjoni f'http://europa.eu.int/comm/food/index_en.htm

NB: This certificate must:

(a) be drawn up in at least one official language of the Member State of destination and of the Member State where the embryos will enter Community territory;
(b) be made out to a single consignee;
(c) accompany the embryos in the original.

NB: Dan iċ-ċertifikat għandu:

(a) jitħejja f'mill-inqas lingwa waħda uffiċjali ta' l-Istat Membru destinatarju u ta' l-Istat Membru li minnu l-embrijuni jidħlu fit-territorju tal-Komunità;
(b) jinħareġ għal destinatarju wieħed;
(c) jakkumpanja l-embrijuni bil-kopja oriġinali.

	Official veterinarian Name (in Capital): Qualification and title Date: Signature: Stamp Veterinarju uffiċjali Isem (b'ittri Kapitali): Kwalifika u titlu Data: Firma: Timbru