ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Pesti emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:
Classical Swine Fever Virus (CSFV) -E2 subunit antigen: 120 Elisa Units (EU)

Adjuvant:
941.4 mg liquid paraffin

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Active immunisation of pigs from the age of 5 weeks onwards to prevent mortality and to reduce clinical signs of Classical Swine Fever, as well as to reduce infection with and excretion of CSF field virus.
The onset of protection is 2 weeks.
The duration of protection is 6 months.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

A local and in most cases transient swelling at the injection site may occur up to 4 weeks after administration of each dose of the vaccine. Transient hyperthermia may occur post the second dose. Abscesses may be observed at the injection site. Since safety after giving both inoculations at the same site has not been examined, it is advised to carry out the second vaccination at a different site than the first vaccination.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy but may not prevent transplacental transmission of Classical swine fever field virus from the sow to foetuses.

4.8 Interaction with other medicinal product and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Shake well before use.
Administer one dose (2 ml) by deep intramuscular injection in the neck area behind the ear.

Vaccination scheme:
Basic vaccination: Inject one dose per pig followed by a second injection 4 weeks after the first injection.
Re-vaccination: Every 6 months, using a single dose.

Before use, allow the vaccine to reach room temperature.
Use sterile syringes and needles. Avoid the introduction of contamination.
.
It is recommended to use a closed multiject vaccination system.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of an overdose, local reactions at the injection site may be more pronounced.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Classical Swine Fever vaccine, ATC vet code: QI09AA06
The active substance stimulates active immunity against Classical Swine Fever (CSF). The product contains Classical Swine Fever virus E2 immunogen incorporated in an emulsion in order to prolong stimulation of the immune system of the target species. As a consequence of the subunit nature of the vaccine, vaccination does not induce production of antibodies against CSF virus antigens, other than E2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sorbitan oleate

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months
Shelf life after first broaching the bottle: 3 hours.

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8°C). Do not freeze.

6.5 Nature and composition of immediate packaging

Bottles of type I hydrolytic glass or polyethylene terephthalate (PET) containing 50 ml for 25 doses, 100 ml for 50 doses and 250 ml for 125 doses presentation.
The bottles are closed with a nitryle rubber stopper and sealed with a coded aluminium cap.
The bottles are packed individually in a carton box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/99/016/001-006

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/2000 - 06/2005

10. DATE OF REVISION OF THE TEXT

{DD/MM/YYYY}

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Porcilis Pesti is only allowed under the particular conditions established by European Community legislation on the control of CSF (Council Directive 80/217/EEC, as amended). Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the Member State.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Manufacturer of the biological active substance:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

According to Community Legislation on Classical swine fever (Council Directive 80/217/EEC, as amended), in the European Union:

a) The use of classical swine fever vaccines is prohibited. However, the use of vaccines may be authorised in the framework of an emergency vaccination plan, implemented by the competent authority of a Member State following confirmation of disease, in accordance with Community Legislation on control and eradication of classical swine fever;

b) The storage, supply, distribution and sale of classical swine fever vaccines must be carried out under the control of and in accordance with the eventual instructions established by the competent authority of the Member State;

c) Special provisions regulate the movement of pigs from areas where classical swine fever vaccine is being or has been used and the marking of pig meat from vaccinated pigs.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council, Member States prohibit or/ may prohibit the import, sale, supply and/or use of Porcilis Pesti on the whole or part of their territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programmes for the diagnosis, control and elimination of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals

b) the disease to which the product is intended to confer immunity is largely absent from the territory.

D. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{50ml Bottle/ 100ml Bottle/250ml Bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Pesti emulsion for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:
120 Elisa Units CSF-E2 antigen.
Liquid paraffin : 941.4 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml (25 doses) – 100 ml (50 doses) – 250 ml (125 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Vaccine against Classical Swine Fever

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM injection of 2 ml

8. WITHDRAWAL PERIOD

Withdrawal period -Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous

10. EXPIRY DATE

<EXP {month/year}>
Once broached, use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.,
NL – 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/99/016/001 - EU/2/99/016/006

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON Bottle Label

{50ml/100ml/250ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Pesti emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

120 Elisa Units CSF E2 antigen/2ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml (25 doses) – 100 ml (50 doses) – 250 ml (125 doses)

4. ROUTE(S) OF ADMINISTRATION

IM injection

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

<EXP {month/year}>
Once broached, use within 3 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Pesti emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 2 ml contains:
120 Elisa Units Classical Swine Fever Virus-E2 subunit antigen
Liquid paraffin as adjuvant: 941.4 mg

4. INDICATION(S)

Active immunisation of pigs from the age of 5 weeks onwards to prevent mortality and to reduce clinical signs of Classical Swine Fever, as well as to reduce infection with and excretion of CSF field virus.
The onset of protection is 2 weeks.
The duration of protection is 6 months.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A local and in most cases transient swelling at the injection site may occur up to 4 weeks after administration of each dose of the vaccine. Transient hyperthermia may occur post the second dose.
Abscesses may be observed at the injection site. Since safety after giving both inoculations at the same site has not been examined, it is advised to carry out the second vaccination at a different site than the first vaccination.

If you notice any serious side effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Administer one dose (2 ml) by deep intramuscular injection in the neck area behind the ear.
Vaccination scheme:
Basic vaccination: Inject one dose per pig followed by a second injection 4 weeks after the first injection.
Re-vaccination: Every 6 months, using a single dose.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.
Before use, allow the vaccine to reach room temperature.
Use sterile syringes and needles.
It is recommended to use a closed multiject vaccination system.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a refrigerator (2°C to 8°C).
Do not freeze.
Shelf-life after first broaching the bottle: 3 hours.
Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

Vaccinate only healthy animals.

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

The product can be used during pregnancy but may not prevent transplacental transmission of Classical swine fever field virus from the sow to foetuses.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

After administration of an overdose, local reactions at the injection site may be more pronounced.

Do not mix with any other veterinary medicinal product.

The import, sale, supply and/or use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of CSF (Council Directive 80/217/EEC, as amended). Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the Member State.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

15. OTHER INFORMATION

As a consequence of the subunit nature of the vaccine, vaccination does not induce production of antibodies against CSF virus antigen, other than E2.

50 ml/100 ml/250 ml multidose glass bottle
50 ml/100 ml/250 ml multidose PET bottle

Not all pack sizes may be marketed.