ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advasure emulsion for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml:

Active substance:

E2 glycoprotein of Classical Swine Fever (CSF) virus minimum 32 µg

Adjuvant:

Adjuvant composition - Double oil emulsion:	
Mineral oil	0.64 ml
Emulsifiers	0.064 ml
Phosphate buffered saline	0.63 ml

Preservative:

Thiomersal	maximum 1:10,000

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, over the age of 2 weeks, against Classical Swine Fever (CSF), to prevent mortality, reduce clinical signs of the disease and the excretion of 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

The pigs should be vaccinated in time before the expected exposure to the field virus, preferably prior to housing (crowding) or transfer to new groups. It is strongly recommended to vaccinate all pigs in the herd.

4.5 Special precautions for use

None known.

Special precautions for use in animals

See section 4.4.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show the package insert to a physician.

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 insert 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)

Swelling at the injection site may occur, which usually disappears spontaneously within approximately one week after vaccination. These effects are particularly evident in very young animals. Other side effects such as a slight increase in body temperature can occur. In very rare cases diarrhoea, anorexia, depression and vomiting may be observed. Symptomatic treatment should be considered when serious side effects are observed.
As part of the immune reaction following vaccination, mild to moderate granulomas may occur in the muscle tissue at the injection site. In some cases also formation of abscesses was observed. Although not reported so far, very rarely cases of allergic reactions may occur, therefore vaccinated animals should be observed for approximately 30 minutes following vaccination. In those cases, appropriate treatment should be administered.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy. The vaccine has been shown to prevent transplacental transmission of low virulence strains after two vaccinations of the sow. However it may not prevent transplacental transmission of highly virulent strains from the sow to the foetuses.

4.8 Interaction with other medicinal products and other forms of interaction

The use of immunosuppressive veterinary medicinal products (e.g. corticosteroids) or modified live Porcine Reproductive and Respiratory Syndrome (PRRS) vaccines within 7 days before and 7 days after application of Advasure may interfere with the induction of immunity and should therefore be avoided.

4.9 Amounts to be administered and administration route

Posology:
The dosage for pigs, over the age of 2 weeks, is 2 ml of the vaccine.

Mode of administration:
In emergency situations the basic immunisation consists of one intramuscular injection with one dose (2 ml) for all pigs over the age of 2 weeks, irrespective of the level of maternal antibodies.
Depending on the infection pressure and the disease situation sows and piglets over the age of 2 weeks (irrespective of the level of maternal antibodies) may be vaccinated twice with one dose (2 ml), 4–6 weeks apart. For fattening pigs over the age of 10 weeks, however, one intramuscular injection with one dose is administered.

Re-vaccination:
One dose (2 ml) at 6 months intervals.

The vaccine is to be administered aseptically by intramuscular injection closely behind the ear.

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

An overdose of the product can result in a moderate swelling at the injection site that can persist for 2-3 weeks.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI09AA06

Summary presentation of the active ingredients:
The Classical Swine Fever (CSF, Hog Cholera) virus, a member of the Pestivirus genus, codes for a number of structural and non-structural glycoproteins, e.g. E2, E1, Erns, gp54 and gp80. The E2 glycoprotein is considered to be the main immunogen of the CSF virus against which the neutralising antibodies are directed. The gene coding for the E2 glycoprotein (E2 gene) is a rather conserved region. The E2 glycoprotein is considered to be immunologically cross-reactive with all field strains.

The E2 glycoprotein gene was inserted into the genome of a baculovirus, an insect virus. The vaccine contains only the E2 but no other proteins of the CSF virus.

Immunological properties:
The vaccine, as formulated with the mineral oil and the emulsifiers, induces protection in pigs against clinical signs caused by the Classical Swine Fever (CSF) virus. 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

Phosphate buffered saline.

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

14 months

After first broaching the container, the contents may be used for up to 8 hours if stored at 2°C-8°C.

6.4. Special precautions for storage

Store at 2°C-8°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Multidose containers with appropriate overfill:
- 1 glass vial, type 2, containing 20 ml (10 doses) vaccine, closed with rubber stopper and sealed with an aluminium seal, packed as 54 vials in 1 styrofoam box
- 1 glass vial, type 1, containing 50 ml (25 doses) vaccine, closed with rubber stopper and sealed with an aluminium seal, packed as 35 vials in 1 styrofoam box
- 1 glass vial, type 1, containing 100 ml (50 doses) vaccine, closed with rubber stopper and sealed with an aluminium seal, packed as 12 vials in 1 styrofoam box
- 1 glass vial, type 1, containing 250 ml (125 doses) vaccine, closed with rubber stopper and sealed with an aluminium seal, packed as 10 vials in 1 styrofoam box

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

Pfizer Ltd.
Sandwich
Kent, CT13 9NJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/025/001 - 004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02-02-2001 / 13-02-2006

10. DATE OF REVISION OF THE TEXT

13-02-2006

PROHIBITION OF SALE, SUPPLY AND/OR USE

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 authorized 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

Name and address of the manufacturer(s) of the biological active substance(s)

ID-DLO
Edelhertweg 15, P.O. Box 65
8200 AB Lelystad
The Netherlands

Name and address of the manufacturer(s) responsible for batch release

Bayer AG
Business Group Animal Health
Osterather Strasse 1a
D-50739 Köln
Germany

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

Veterinary medicinal product subject to 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 authorized 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 pigmeat 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 4 of Council Directive 90/677/EEC Member States prohibit or/ may prohibit the import, sale, supply and/or use of Advasure 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

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX CONTAINING 54 Vials / 35 Vials / 12 Vials / 10 Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advasure

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:

Active substance:
E2 glycoprotein of Classical Swine Fever (CSF) virus minimum 32 µg

Other substances:
Mineral oil, Emulsifiers, Phosphate buffered saline, Thiomersal

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

54 vials with 20 ml
35 vials with 50 ml
12 vials with 100 ml
10 vials with 250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Active immunisation of pigs, over the age of 2 weeks, against Classical Swine Fever (CSF), to prevent mortality, reduce clinical signs of the disease and the excretion of field virus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package insert before use.
The vaccine Advasure can only be used 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.

10. EXPIRY DATE

EXP:…….
Once broached, use within 8 hours if stored at 2°C-8°C

11. SPECIAL STORAGE CONDITIONS

Store at 2°C-8°C. Do not freeze. Protect from light.

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

Precautions for disposal of unused product or waste material see package insert.

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

For animal treatment only.

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

Pfizer Ltd.
Sandwich
Kent, CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/025/001
EU/2/00/025/002
EU/2/00/025/003
EU/2/00/025/004

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml Vial/ 50 ml Vial / 100 ml Vial / 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advasure

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose: E2 glycoprotein of CSF virus minimum 32 µg

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

10 doses
25 doses
50 doses
125 doses

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Not currently manufactured.

7. EXPIRY DATE

EXP (MONTH/YEAR)
Once broached, use within 8 hours if stored at 2°C-8°C

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

Marketing authorisation holder:
Pfizer Ltd.
Sandwich
Kent, CT13 9NJ
United Kingdom

Manufacturer responsible for batch release:
Bayer AG
Business Group Animal Health
Osterather Strasse 1a
D-50739 Köln
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advasure

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

Per dose of 2 ml:

Active substance

E2 glycoprotein of Classical Swine Fever (CSF) virus minimum 32 µg

Adjuvant

Adjuvant composition - Double oil emulsion:

Mineral oil	0.64 ml
Emulsifiers	0.064 ml
Phosphate buffered saline	0.63 ml

Preservative:

Thiomersal	maximum 1:10,000

4. INDICATION(S)

Active immunisation of pigs, over the age of 2 weeks, against Classical Swine Fever (CSF), to prevent mortality, reduce clinical signs of the disease and the excretion of field virus.
The onset of protection is 2 weeks.
The duration of protection is 6 months.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The dosage for pigs, over 2 weeks, is 2 ml of the vaccine

Intramuscular injection

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine is to be administered aseptically by intramuscular injection closely behind the ear of the pig.
The pigs should be vaccinated in time before the expected exposure to the field virus, preferably prior to housing (crowding) or transfer to new groups. It is strongly recommended to vaccinate all pigs in the herd.

The dosage for pigs, over the age of 2 weeks, is 2 ml of the vaccine.

In emergency situations the basic immunisation consists of one intramuscular injection with one dose (2 ml) for all pigs over the age of 2 weeks, irrespective of the level of maternal antibodies.
Depending on the infection pressure and the disease situation sows and piglets over the age of 2 weeks (irrespective of the level of maternal antibodies) may be vaccinated twice with one dose (2 ml), 4–6 weeks apart. For fattening pigs over the age of 10 weeks, however, one intramuscular injection with one dose is administered.

Re-vaccination:
one dose (2 ml) at 6 months intervals.

Can be used during pregnancy. The vaccine has been shown to prevent transplacental transmission of low virulence strains after two vaccinations of the sow. However it may not prevent transplacental transmission of highly virulent strains from the sow to the foetuses.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store out of reach and sight of children.
Store at 2°C – 8°C Do not freeze. Protect from light.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

The use of immunosuppressive veterinary medicinal products (e.g. corticosteroids) or modified live Porcine Reproductive and Respiratory Syndrome (PRRS) vaccines within 7 days before and 7 days after application of Advasure may interfere with the induction of immunity and should therefore be avoided.

Do not mix with any other vaccine/immunological product.

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 insert 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 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

13-02-2006

15. OTHER INFORMATION

The Classical Swine Fever (CSF, Hog Cholera) virus, a member of the *Pestivirus genus*, carries a number of structural and non-structural glycoproteins, e.g. E2, E1, E^{rns}, gp54, gp80. The E2 glycoprotein is considered to be the main immunogen of the CSF virus against which the neutralising antibodies are directed. The gene coding for the E2 glycoprotein (E2 gene) is a rather conserved region. The E2 glycoprotein is considered to be immunologically cross-reactive with all field strains.

Immunological properties:
The vaccine, as formulated with the mineral oil and the emulsifiers, induces protection in pigs against clinical signs caused by the Classical Swine Fever (CSF) virus. As a consequence of the subunit nature of the vaccine, vaccination does not induce production of antibodies against CSF virus antigens, other than E2.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Italia

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Hungary

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Eesti

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