ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:

Live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene (CP7_E2alf) $10^{4.8}$* to $10^{6.5}$ TCID**$_{50}$

* min 100 PD_{50} (protective dose 50%)
** Tissue culture infectious dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
L2 Freeze-drying stabilizer composed as follows:
Dextran 40
Casein hydrolysate
Lactose monohydrate
Sorbitol 70% (solution)
Sodium hydroxide
Water for injections
Dulbecco's Modified Eagle culture medium (DMEM)
Solvent:
Sodium chloride 9 mg/ml (0.9%) solution for injection
Water for injections

Lyophilisate: Off-white.
Solvent: Clear colourless liquid.
After reconstitution, the suspension should be slightly pink clear liquid.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV).

Onset of immunity: 14 days.

Duration of immunity: 6 months.
For active immunisation of breeding females to reduce transplacental infection caused by CSFV.

Onset of immunity: 21 days.
Duration of immunity has not been established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Documentation provided for this vaccine supports that it is only to be used in an outbreak situation in herds within restricted control zones.

Protection against transplacental transmission of CSFV was shown 21 days after vaccination when challenge was applied in 6 pregnant sows with a moderately virulent CSFV strain. Partial protection against transplacental transmission of CSFV was observed when challenge was applied in 6 pregnant sows with a highly virulent CSFV strain.
Birth of persistently infected immunotolerant piglets represent a very high risk since they are shedding field virus and they cannot be identified serologically due to their seronegative status. Vaccination of breeding animals may be included in risk-based control strategies in case of outbreak and considering the above information.

The vaccine has shown reduced protection in studies of piglets with maternally derived antibodies compared to studies of piglets without maternally derived antibodies.

Studies in vaccinated breeding boars addressing potential shedding of virulent challenge virus in semen have not been conducted. Use of the vaccine in experimental studies in breeding boars has not revealed safety concerns.
Therefore, the decision to vaccinate breeding boars and piglets with maternally derived antibodies should be taken based on the actual outbreak case and associated control zones.

RT-PCR tools could be used in outbreak situations to differentiate between the vaccine virus genome and those of field strains based on sequences unique to the CP7_E2alf.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccine virus genome is rarely detectable by RT-PCR in tonsils and lymph nodes for up to 63 days after vaccination and vaccine virus is very rarely detectable by virus isolation in tonsil for the first week after vaccination. Transplacental transmission of the vaccine virus has not been detected in the limited studies performed but cannot be excluded.

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs:

Very Common (>1 animal / 10 animals treated):	Injection site swelling[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2]

[1] Transient, up to 5 mm in diameter and lasting for 1 day.
[2] Transient, up to 2.9 °C within 4 hours after vaccination and spontaneously resolving within 1 day.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
See section 3.4.

3.8 Interaction with other medicinal products 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.

3.9 Administration routes and dosage

Intramuscular use.

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection.
After reconstitution, the suspension should be slightly pink clear liquid.

Basic vaccination:
A single 1 ml dose should be administered intramuscularly to pigs from 7 weeks of age and breeding females.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Council Directive 2001/89/EC and Commission Decision 2002/106 prohibit prophylactic vaccination within the European Union. Specific derogation is required to use this vaccine in an outbreak situation.

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD04

To stimulate active immunity to classical swine fever virus.

The vaccine is a live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene. The virus is grown in porcine cells.

Challenge studies were conducted with the highly virulent reference strain CSFV Koslov (genotype 1) and the moderately virulent, Roesrath strain (genotype 2, Germany 2009). Limited studies in young pigs support protection against CSF1045 (genotype 2, Germany 2009) and CSF1047 (genotype 2, Israel 2009) field strains.

The recombinant vaccine virus has potential marker properties for use in DIVA (differentiation between field virus infected and solely vaccinated animals). Diagnostic tools targeted to detection of antibody responses could enable DIVA strategies. Serological DIVA tools based on detection of CSFV antibodies other than those raised against E2, such as Erns antibody detection should be able to differentiate between antibody responses against Erns-BVDV after solely herd vaccination with CP7_E2alf from responses against Erns-CSFV after natural field CSFV infection.

DIVA efficiency depends on the performance of tests related to fitness for purpose in outbreak situations. Serological DIVA concept has been shown in principle, while actual DIVA tools remain to be tested on large panels of samples from emergency vaccination in outbreak situations.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I hydrolytic glass vials containing 10 or 50 doses of lyophilisate and 10 or 50 ml of solvent.

Lyophilisate: bromobutyl rubber stoppers and aluminium caps.
Solvent: chlorobutyl rubber stoppers and aluminium caps.

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 10 ml solvent.

Cardboard box containing 1 vial with 50 doses of lyophilisate and 1 vial with 50 ml solvent.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/179/001–002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 10/02/2015.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

According to Community Legislation on classical swine fever (Council Directive 2001/89/EC, 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 manipulation, manufacture, storage, supply, distribution and sale of classical swine fever vaccines must be carried out under supervision 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 processing or marking of pig meat from vaccinated pigs.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 1 vial of 10 or 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
Live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene (CP7_E2alf) $10^{4.8}$ to $10^{6.5}$ $TCID_{50}$

3. PACKAGE SIZE

10 doses
50 doses

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/14/179/001 (10 doses)
EU/2/14/179/002 (50 doses)

15. BATCH NUMBER

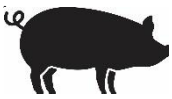
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial (10 and 50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live recombinant CP7_E2alf: $10^{4.8}$ - $10^{6.5}$ $TCID_{50}$

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

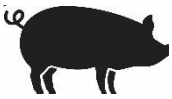
Exp. {mm/yyyy}
Once reconstituted use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial (10 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Suvaxyn CSF Marker



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sodium chloride 9 mg/ml solution for injection.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection for pigs

2. Composition

Active substance:

Live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene (CP7_E2alf) $10^{4.8}$* to $10^{6.5}$ TCID**$_{50}$

* min 100 PD_{50} (protective dose 50%)
** Tissue culture infectious dose

Lyophilisate: Off-white.
Solvent: Clear colourless liquid.

3. Target species

Pigs.

4. Indications for use

For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV).

Onset of immunity: 14 days.
Duration of immunity: 6 months.

For active immunisation of breeding females to reduce transplacental infection caused by CSFV.

Onset of immunity: 21 days.
Duration of immunity has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Documentation provided for this vaccine supports that it is only to be used in an outbreak situation in herds within restricted control zones.

Protection against transplacental transmission of CSFV was shown 21 days after vaccination when challenge was applied in 6 pregnant sows with a moderately virulent CSFV strain. Partial protection

against transplacental transmission of CSFV was observed when challenge was applied in 6 pregnant sows with a highly virulent CSFV strain.

Birth of persistently infected immunotolerant piglets represent a very high risk since they are shedding field virus and they cannot be identified serologically due to their seronegative status. Vaccination of breeding animals may be included in risk-based control strategies in case of outbreak and considering the above information.

The vaccine has shown reduced protection in studies of piglets with maternally derived antibodies compared to studies of piglets without maternally derived antibodies.

Studies in vaccinated breeding boars addressing potential shedding of virulent challenge virus in semen have not been conducted. Use of the vaccine in experimental studies in breeding boars has not revealed safety concerns. Therefore, the decision to vaccinate breeding boars and piglets with maternally derived antibodies should be taken based on the actual outbreak case and associated control zones.

RT-PCR tools could be used in outbreak situations to differentiate between the vaccine virus genome and those of field strains based on sequences unique to the CP7_E2alf.

Special precautions for safe use in the target species:
Vaccine virus genome is rarely detectable by RT-PCR in tonsils and lymph nodes for up to 63 days after vaccination and vaccine virus is very rarely detectable by virus isolation in tonsil for the first week after vaccination. Transplacental transmission of the vaccine virus has not been detected in the limited studies performed but cannot be excluded.

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

Special restrictions for use and special conditions for use:
Council Directive 2001/89/EC and Commission Decision 2002/106 prohibit prophylactic vaccination within the European Union. Specific derogation is required to use this vaccine in an outbreak situation.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

DIVA tests:
The recombinant vaccine virus has potential marker properties for use in DIVA (differentiation between field virus infected and solely vaccinated animals). Diagnostic tools targeted to detection of antibody responses could enable DIVA strategies. Serological DIVA tools based on detection of CSFV antibodies other than those raised against E2, such as Erns antibody detection should be able to differentiate between antibody responses after solely herd vaccination with CP7_E2alf from responses after natural field CSFV infection.

DIVA efficiency depends on the performance of tests related to fitness for purpose in outbreak situations. Serological DIVA concept has been shown in principle, while actual DIVA tools remain to be tested on large panels of samples from emergency vaccination in outbreak situations.

7. Adverse events

Pigs:

Very Common (>1 animal / 10 animals treated):	Injection site swelling[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2]

[1] Transient, up to 5 mm in diameter and lasting for 1 day.
[2] Transient, up to 2.9 °C within 4 hours after vaccination and spontaneously resolving within 1 day.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.

Basic vaccination:
A single 1 ml dose should be administered to pigs from 7 weeks of age and breeding females.

9. Advice on correct administration

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection.
After reconstitution, the suspension should be slightly pink clear liquid.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/14/179/001–002

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 10 ml solvent.
Cardboard box containing 1 vial with 50 doses of lyophilisate and 1 vial with 50 ml solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Zoetis Deutschland GmbH
Schellingstr. 1
DE-10785 Berlin
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgia
Tel: +370 610 05088

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

Lietuva
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Luxembourg/Luxemburg
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belsch
Tél/Tel: +32 (2) 746 80 11

Magyarország
Zoetis Hungary Kft.
Csörsz u. 41.
HU-1124 Budapest
Tel.: +36 1 224 5200

Malta
Agrimed Limited
Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Norge
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmark
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Zoetis Österreich GmbH
Floridsdorfer Hauptstr. 1
AT-1210 Wien
Tel: +43 (0)1 2701100 100
tierarzneimittelsicherheit@zoetis.com

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0)800 73 00 65

Hrvatska
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

Ireland
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Ísland
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmörku
Sími: +45 70 20 73 05
adr.scandinavia@zoetis.com

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Κύπρος
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
15125, Αττική
Ελλάδα
Τηλ: +30 210 6791900

Polska
Zoetis Polska Sp. z o.o.
ul. Postępu 17B
PL - 02-676 Warszawa
Tel.: +48 22 2234800

Portugal
Zoetis Portugal Lda.
Lagoas Park, Edifício 10
PT-2740-271 Porto Salvo
Tel: +351 21 042 72 00

România
Zoetis România S.R.L.
Expo Business Park, 54A Aviator Popișteanu,
Clădirea 2, Etaj 1-3, Sector 1,
București, 012095 - RO
Tel: +40785019479

Slovenija
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2,
10000 Zagreb,
Hrvaška
Tel: +385 1 6441 462

Slovenská republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
150 00 Praha
Česká republika
Tel: +420 257 101 111

Suomi/Finland
Zoetis Finland Oy
Bulevardi 21 / SPACES
FI-00180 Helsinki/Helsingfors
Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 Köpenhamn
Danmark
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

Latvija
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Beļģija
Tel: +370 610 05088

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800