Steps taken for the assessment of the product

- The CVMP at its meeting in February 1998 agreed on that Porcilis Pesti was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system since this vaccine has been constructed via biotechnological (recombinant Baculovirus/insect cell system) techniques and therefore is in accordance with Part A of the Annex of Council Regulation (EEC) No 2309/93.

- The company Intervet International B.V. submitted an application to the EMEA on 30 June 1998 for the granting of a Community marketing authorisation for Porcilis Pesti in accordance with Council Regulation (EEC) No 2309/93.

- The application was validated on 14 July 1998.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on respectively 22 September 1998 and 7 October 1998.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11 November 1998 was sent to the Applicant and the clock stopped.

- At the request of the European Commission (DGVI) and with the approval of the applicant, the assessment reports and list of questions referred to above have been provided to the Commission on 12 November 1998 to assist in its definition of Community vaccination policy for swine fever.

- The Applicant circulated the responses to the CVMP list of questions for Porcilis Pesti by 15 April 1999 at which point the clock was restarted.

- The joint Rapporteur and Co-rapporteur assessment report on the responses to the consolidated list of questions were circulated to all CVMP Members on 17 May 1999.

- The joint Rapporteur and Co-rapporteur assessment report were discussed during the meeting of the Committee held on 16 June 1999. The CVMP decided that there was a need for an oral explanation. A list of outstanding issues as agreed by the CVMP was sent to the Applicant and the clock stopped.

- The Outstanding Issues were addressed during an oral explanation held on 15 September 1999.

- The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 13 October a positive opinion for the granting of a Community marketing authorisation for Porcilis Pesti.

- The EMEA received on 11 January 2000 a letter from the European Commission dated 30 December 1999, informing the EMEA of comments received from DG SANCO on the Opinion adopted in October 1999, and requesting the CVMP to take into account the comments in formulating the Opinion of the CVMP.

- The CVMP, having evaluated the comments from DG SANCO, issued on 9 February 2000 a positive revised opinion for the granting of a Community marketing authorisation for Porcilis Pesti.

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GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE IN THE EUROPEAN ECONOMIC AREA

Intervet International bv
Wim de Körverstraat 35
P.O. Box 31
5830 AA Boxmeer
The NETHERLANDS

Manufacturing Authorisation issued on 5 August 1997 by the "Ministerie van landbouw, natuurbeheer en visserij", The Hague, The Netherlands.

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND 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 accordane 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. PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC[1] 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.

[1] Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC an the approximation of laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary products (OJ N°L 373 of 31.12.1990)

D. STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Animal Species	Other provisions
Liquid paraffin (Mineral hydrocarbons)[2]	All food-producing species	
Polysorbate 80 [3]		
Sorbitan mono-oleate [4] (E494)		

[2] OJ No. L 291 of 06.12.95
[3] OJ No. L 290 of 05.12.95
[4] OJ No. L 272 of 25.10.96