I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

On 6 August 1998 the company BAYER AG, Germany, submitted to the EMEA a letter of intent for an application for a Community marketing authorisation for BAYOVAC CSF E2.

During its meeting of September 1998, the Committee for Veterinary Medicinal Products appointed Prof. P.P. Pastoret from Belgium as Rapporteur and Prof. M. Moos from Germany as Co-rapporteur for the assessment of the application.

2. Steps taken for the assessment of the product

The company BAYER AG submitted an application to the EMEA on 1 December 1998 for the granting of a Community marketing authorisation for BAYOVAC CSF E2 in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 15 December 1998.

The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on respectively 17 February 1999 and 10 March 1999.

The consolidated list of questions as agreed by the CVMP during its meeting held on 14 April 1999 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 7 October 1999 to assist in its definition of Community vaccination policy for swine fever.

The Applicant circulated the responses to the CVMP list of questions for BAYOVAC CSF E2 by 17 February 2000 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 18 April 2000. The CVMP decided that there was no need for an oral explanation.

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 17 May 2000 a positive opinion for the granting of a Community marketing authorisation for BAYOVAC CSF E2.

An intention to appeal against the Opinion and the grounds for appeal with regard to a quality issue were submitted to the EMEA by the applicant, Bayer AG, Germany, on 5 June 2000. However, on 14 July 2000, the applicant informed the EMEA of the withdrawal of the appeal.

The CVMP reconfirmed on 19 July 2000 its positive opinion of 17 May 2000 in response to the initiation of the appeal procedure.

The EMEA received a letter from the European Commission dated 31 October 2000, informing the EMEA of comments received from the French Standing Committee Member on the Opinion adopted in July 2000, and requesting the CVMP to take into account the comments in formulating the Final Opinion of 19 July 2000 of the CVMP.

Taking into account the comments forwarded by the European Commission, the CVMP issued on 8 November 2000 a revised positive Opinion for the granting of a Community marketing authorisation for BAYOVAC CSF E2.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations

Manufacturer of the medicinal product responsible for batch release:

BAYER AG
Business Group Animal Health
Osterather Strasse 1a
50739 Köln
Germany

Manufacturing Authorisation issued on 17 August 1998 by "Bezirksregierung Köln", Germany

2. Conditions or restrictions of 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 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.

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 Bayovac CSF E2 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)

3. Statement of the MRLs

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

Pharmacologically active substance	Animal Species	Other provisions
Marcol 52= paraffin oil [2]	All food-producing species	
Montanide 80[3]		
Phosphate Buffer Saline = Sodium phosphate[4] (E339)		
Montanox 80=Polysorbate 80 [5]		
Thiomersal [6]		For use only as preservatives in multidose vaccines at a concentration not exceeding 0.02 %

[2] O.J. L 291, of 06.12.95
[3] O.J. L 290, of 05.12.95
[4] O.J. L 272, of 25.10.96
[5] O.J. L 290, of 05.12.95
[6] O.J. L 749/97, of 26.04.97