2-2-1. Safety. Carry out the test for each route of administration to be recommended for vaccination, using in each case chickens not older than the minimum recommended age. Use a batch of vaccine containing not less than the maximum potency that may be expected in a batch of vaccine. Use not fewer than 10 chickens from a flock free from specified pathogens (SPF) (5.2.2). Administer by a recommended route and method to each chicken a double dose of vaccine. If the recommended schedule requires a second dose, administer 1 additional dose to each chicken after at least 14 days. Observe the chickens at least daily until at least 21 days after the last administration of the vaccine. The test is invalid if more than 10 per cent of the chickens show abnormal signs or die from causes not attributable to the vaccine. The vaccine complies with the test if no chicken shows abnormal local or systemic reactions or dies from causes attributable to the vaccine.

2-2-2. Immunogenicity. A test is carried out for each route and method of administration to be recommended. The vaccine administered to each animal is of minimum potency. Use for the test not fewer than 60 SPF chickens (5.2.2) not older than the minimum age recommended for vaccination. Vaccinate not fewer than 30 chickens with no more than the minimum recommended number of doses of vaccine. Maintain not fewer than 30 chickens as controls for each group of vaccinates. Challenge both groups, 4 weeks after the last administration of vaccine, by oral administration to each chicken of a sufficient quantity of a strain of *S. enterica* Enteritidis that is able to colonise chickens. Take blood samples from control chickens on the day before challenge. Observe the chickens at least daily for 4 weeks. Take individual fresh faeces samples on day 1 after challenge and at least twice weekly (including day 7) until 14 days after challenge. Test the fresh faeces samples for the presence of *S. enterica* Enteritidis by direct plating. Euthanise all surviving chickens at the end of the observation period, take samples of liver and spleen and test for the presence of *S. enterica* Enteritidis by an appropriate method.

The test is invalid if antibodies against *S. enterica* Enteritidis are found in any control chicken before challenge. The vaccine complies with the test if:

- the number of *S. enterica* Enteritidis in fresh faeces samples from vaccinated chickens after challenge at the different days of sampling is significantly lower in vaccinated chickens than in controls and remains lower until the end of the test;
- the number of positive samples of liver and spleen is significantly lower in vaccinated chickens than in controls.

2-3. MANUFACTURER’S TEST

2-3-1. Batch potency test. It is not necessary to carry out the Potency test (section 3-4) for each batch of the vaccine if it has been carried out using a batch of vaccine with a minimum potency. Where the test is not carried out, an alternative validated method is used, the criteria for acceptance being set with reference to a batch of vaccine that has given satisfactory results in the test described under Potency. The following test may be used.

Use not fewer than 15 SPF chickens (5.2.2). Maintain not fewer than 5 SPF chickens as controls. Administer to each of 10 chickens 1 dose of vaccine by a recommended route. Where the schedule stated on the label requires a booster injection to be given, a booster vaccination may also be given in this test provided it has been demonstrated that this will still provide a suitably sensitive test system. At a given interval after the last injection, collect blood from each vaccinated and control chicken and prepare serum samples. Measure the titre of antibodies against *S. enterica* Enteritidis in each serum sample using a suitable validated serological method. Calculate the titre for the group of vaccinates. The test is invalid if specific *S. enterica* Enteritidis antibodies are found in 1 or more sera from control chickens at a given interval after the time of administration of the vaccine in the vaccinated group.

The vaccine complies with the test if the antibody titres of the group of vaccinates at a given interval after each vaccination, where applicable, are not significantly lower than the value obtained with a batch that has given satisfactory results in the test described under Potency (section 3-4).

3. BATCH TESTS

3-1. Identification. In animals that do not have antibodies against *S. enterica* Enteritidis, the vaccine stimulates the production of such antibodies.

3-2. Bacteria and fungi. The vaccine and, where applicable, the liquid supplied with it comply with the test for sterility prescribed in the monograph Vaccines for veterinary use (0062).

3-3. Safety. Use not fewer than 10 SPF chickens (5.2.2), not older than the minimum age recommended for vaccination. Administer a double dose of vaccine by a recommended route to each chicken. Observe the chickens at least daily for 21 days. The test is invalid if more than 20 per cent of the chickens show abnormal signs or die from causes not attributable to the vaccine. The vaccine complies with the test if no chicken shows notable signs of disease or dies from causes attributable to the vaccine.

3-4. Potency. The vaccine complies with the requirements of the test mentioned under Immunogenicity (section 2-2-2) when administered by a recommended route and method.
2.2. CHOICE OF VACCINE COMPOSITION

The vaccine is shown to be satisfactory with respect to safety (5.2.6) and efficacy (5.2.7) for the birds for which it is intended. The following tests for safety (section 2-2-1) and immunogenicity (section 2-2-2) may be used during the demonstration of safety and efficacy.

2-2-1. Safety. Carry out the test for each route of administration to be recommended for vaccination, using in each case chickens not older than the minimum recommended age. Use a batch of vaccine containing not less than the maximum potency that may be expected in a batch of vaccine.

Use not fewer than 10 chickens from a flock free from specified pathogens (SPF) (5.2.2). Administer by a recommended route and method to each chicken a double dose of vaccine. If the recommended schedule requires a second dose, administer 1 additional dose to each chicken after at least 14 days. Observe the chickens at least daily until at least 21 days after the last administration of the vaccine.

The test is invalid if more than 10 per cent of the chickens show abnormal signs or die from causes not attributable to the vaccine. The vaccine complies with the test if no chicken shows abnormal local or systemic reactions or dies from causes attributable to the vaccine.

2-2-2. Immunogenicity. A test is carried out for each route and method of administration to be recommended. The vaccine administered to each animal is of minimum potency.

Use for the test not fewer than 60 SPF chickens (5.2.2) not older than the minimum age recommended for vaccination. Vaccinate not fewer than 30 chickens with no more than the minimum recommended number of doses of vaccine. Maintain not fewer than 30 chickens as controls for each group of vaccinates. Challenge both groups, 4 weeks after the last administration of vaccine, by oral administration to each chicken of a sufficient quantity of a strain of S. enterica Typhimurium that is able to colonise chickens. Take blood samples from control chickens on the day before challenge. Observe the chickens at least daily for 4 weeks. Take individual fresh faeces samples on day 1 after challenge and at least twice weekly (including day 7) until 14 days after challenge. Test the fresh faeces samples for the presence of S. enterica Typhimurium by direct plating. Euthanise all surviving chickens at the end of the observation period, take samples of liver and spleen and test for the presence of S. enterica Typhimurium by an appropriate method.

The test is invalid if antibodies against S. enterica Typhimurium are found in any control chicken before challenge.

The vaccine complies with the test if:

- the number of S. enterica Typhimurium in fresh faeces samples from vaccinated chickens after challenge at the different days of sampling is significantly lower in vaccinates than in controls and remains lower until the end of the test;
- the number of positive samples of liver and spleen is significantly lower in vaccinates than in controls.

2-3. MANUFACTURER’S TEST

2-3-1. Batch potency test. It is not necessary to carry out the Potency test (section 3-4) for each batch of the vaccine if it has been carried out using a batch of vaccine with a minimum potency. Where the test is not carried out, an alternative validated method is used, the criteria for acceptance being set with reference to a batch of vaccine that has given satisfactory results in the test described under Potency. The following test may be used.

Use not fewer than 15 SPF chickens (5.2.2). Maintain not fewer than 5 SPF chickens as controls. Administer to each of 10 chickens 1 dose of vaccine by a recommended route. Where the schedule stated on the label requires a booster injection to be given, a booster vaccination may also be given in this test provided it has been demonstrated that this will still provide a suitably sensitive test system. At a given interval after the last injection, collect blood from each vaccinated and control chicken and prepare serum samples. Measure the titre of antibodies against S. enterica Typhimurium in each serum sample using a suitable validated serological method. Calculate the titre for the group of vaccinates.

The test is invalid if specific S. enterica Typhimurium antibodies are found in 1 or more sera from control chickens at a given interval after the time of administration of the vaccine in the vaccinated group.

The vaccine complies with the test if the antibody titres of the group of vaccinates at a given interval after each vaccination, where applicable, are not significantly lower than the value obtained with a batch that has given satisfactory results in the test described under Potency (section 2-2-2).

3. BATCH TESTS

3-1. Identification. In animals that do not have antibodies against S. enterica Typhimurium, the vaccine stimulates the production of such antibodies.

3-2. Bacteria and fungi. The vaccine and, where applicable, the liquid supplied with it comply with the test for sterility prescribed in the monograph Vaccines for veterinary use (0062).

3-3. Safety. Use not fewer than 10 SPF chickens (5.2.2), not older than the minimum age recommended for vaccination. Administer a double dose of vaccine by a recommended route to each chicken. Observe the chickens at least daily for 21 days. The test is invalid if more than 20 per cent of the chickens show abnormal signs or die from causes not attributable to the vaccine. The vaccine complies with the test if no chicken shows notable signs of disease or dies from causes attributable to the vaccine.

3-4. Potency. The vaccine complies with the requirements of the test mentioned under Immunogenicity (section 2-2-2) when administered by a recommended route and method.

01/2008:0064

SWINE ERYSIPELAS VACCINE
(INACTIVATED)

Vaccinum erysipelatis suillae inactivatum

1. DEFINITION

Swine erysipelas vaccine (inactivated) is a preparation of one or more suitable strains of Erysipelothrix rhusiopathiae, inactivated while maintaining adequate immunogenic properties. This monograph applies to vaccines intended for the active immunisation of pigs against swine erysipelas.

2. PRODUCTION

The vaccine may be adjuvanted.