

## S2.3

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### STRATEGIC RESERVES OF VACCINES FOR FOOT AND MOUTH DISEASE - NEEDS AND APPLICATIONS

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Within a Community Animal Health Policy striving for «Prevention is better than cure», control measures for exotic diseases are complementary to policies adopted to prevent the introduction and spread of harmful pathogens by, for example, properly enforced import rules, close collaboration with neighbouring countries not free of a particular disease, on-farm biosecurity measures, secure movement conditions for animals and animal products and, as experience has shown, modern biosecurity standards for laboratories handling live FMD-virus.

By adopting Directive 2003/85/EC on Community measures for the control of FMD, the European Community decided to continue a policy aiming at freedom from FMD without practising vaccination. The Directive details the control measures to be taken in relation to susceptible animals and products thereof from the first suspicion until recovery of the free status. The Directive places high demands on disease preparedness, contingency planning, laboratory capacity and expert advice. It provides for a flexible choice of the most effective control strategy and in particular moves emergency vaccination, including a vaccinate-to-live strategy (protective vaccination) from an instrument of last resort more to the forefront of the control measures.

Council Decision 91/666/EEC sets up the EU antigen bank which stores at designated premises about 40 million doses of inactivated antigens of different strains and all serotypes. These stocks are updated by the Commission on advice of the Community Reference Laboratory for FMD and the Research Group of the FAO based European Commission for the Control of FMD (EuFMD).

Vaccines used for protective vaccination must have a marketing authorisation in accordance with Community legislation on veterinary medicines. So far the EU antigen bank has only been operated to provide support to control measures in third countries in which different FMD-viruses circulate. To permit the authorisation of vaccines against antigenically variable viruses, the concept of a Multi-Strain Dossier was introduced.

To regain free status in line with OIE recommendations and EU legislation, the vaccines must meet certain guarantees for purity in order not to confuse the results of post-vaccination surveillance using validated tests for antibodies to non-structural proteins (NSP).

The emergence of new topotypes of the FMD-virus calls upon closer collaboration between reference laboratories and vaccine manufacturers to ensure rapid characterisation of new isolates and their match with available vaccines. Where necessary, vaccine manufacturers should be encouraged to adapt new seed strains for the production of homologous vaccines. Contingency plans are required for scenarios where key diagnostic and/or vaccine manufacturing laboratories are temporarily incapacitated.

The global FMD situation and the efforts for the progressive control of FMD underlines the need for closer collaboration and networking of FMD laboratories and antigen and vaccine banks.