EUROPEAN COMMISSION

Directorate-General for Health & Consumers

STRATEGIC RESERVES OF VACCINES FOR FOOT-AND-MOUTH DISEASE

NEEDS AND APPLICATIONS

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EUROPEAN COMMISSION

Directorate-General for Health & Consumers

EU FMD Policy

Free of FMD and FMDV-infection without practising vaccination

Support mechanisms for EU FMD policy

- Prevention of virus introduction
  - import policy, TCs-inspections, border controls
  - assistance to neighbouring countries
  - collaboration with international organisations
- Detection of infection
  - notifiability, monitoring, diagnostic capacities,
- Prevention of virus spread
  - trade rules, traceability, on-farm biosecurity
- Disease Preparedness
  - contingency planning, antigen reserves

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FMD Directive 2003/85/EC

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Contents

I *Acts whose publication is obligatory*

* **Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (1)** 1

(1) Text with EEA relevance

EN Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other Acts are printed in bold type and preceded by an asterisk.

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http://eur-lex.europa.eu/en/index.htm

http://ec.europa.eu/food/index_en.htm

Emergency Vaccination

- **Suppressive**
  - stamping out
  - preventive killing of dangerous contacts
  - killing of vaccinates
- **Protective**
  - stamping out
  - preventive killing of dangerous contacts
  - marking of vaccinates and restrictions of their movement
  - treatment of products

No trade in vaccinated animals

Exit strategy

Post-vaccination surveillance

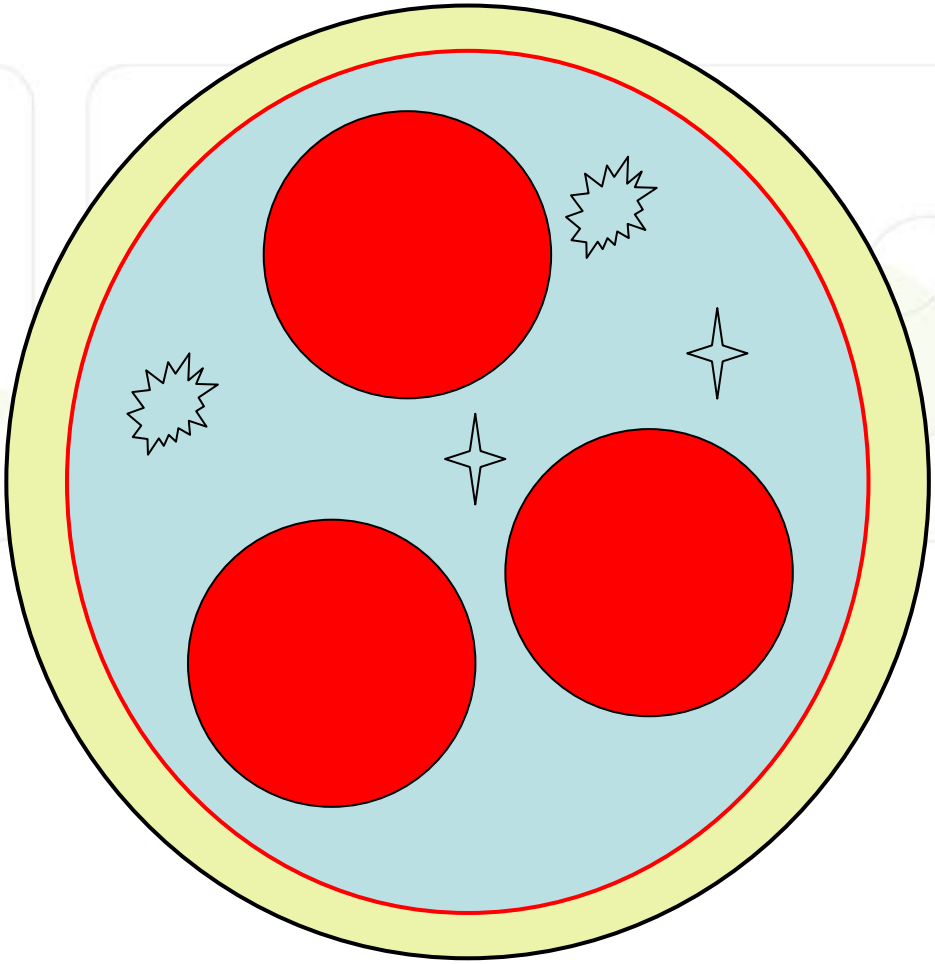
Sheep and cattle not vaccinated

Sheep not vaccinated

Herd vaccinated

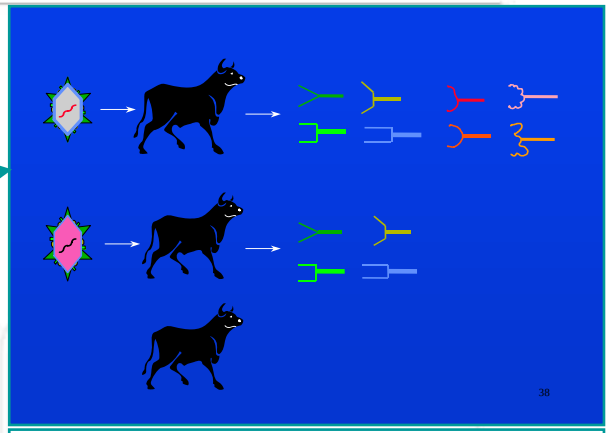
Vaccination zone

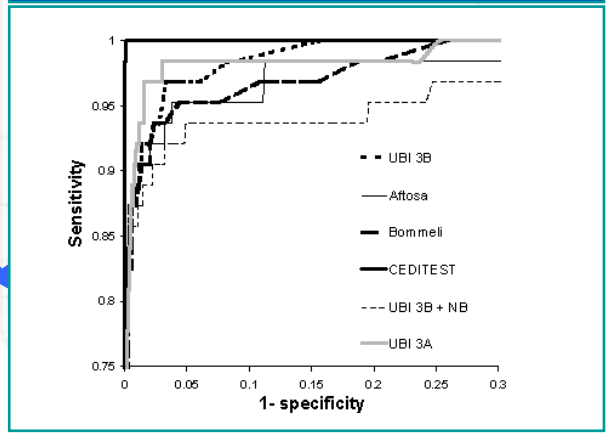
Surveillance zone



Post-vaccination testing

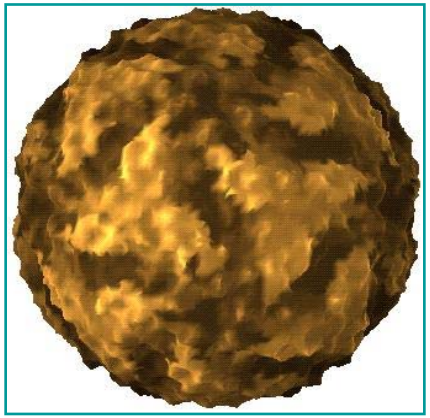
- Vaccines – purified
- Tests for the detection of antibodies against NSP
- Guidelines

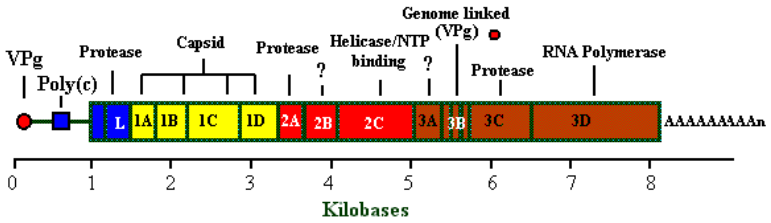




vaccinated no virus

vaccinated and virus





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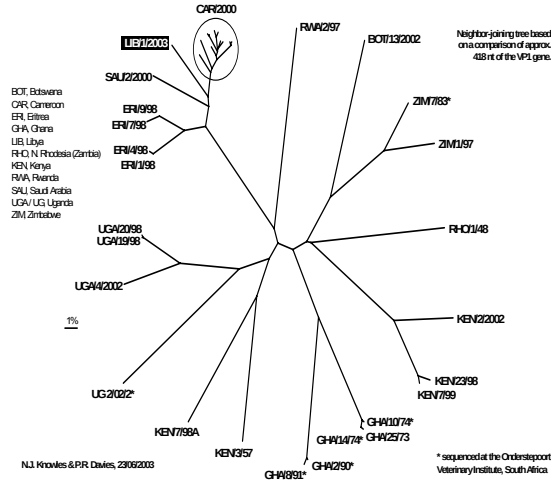
EC FMD Antigen Bank

- about 35 mio doses
- all 7 serotypes
- update of strains
  - epidemiological situation
  - trade patterns

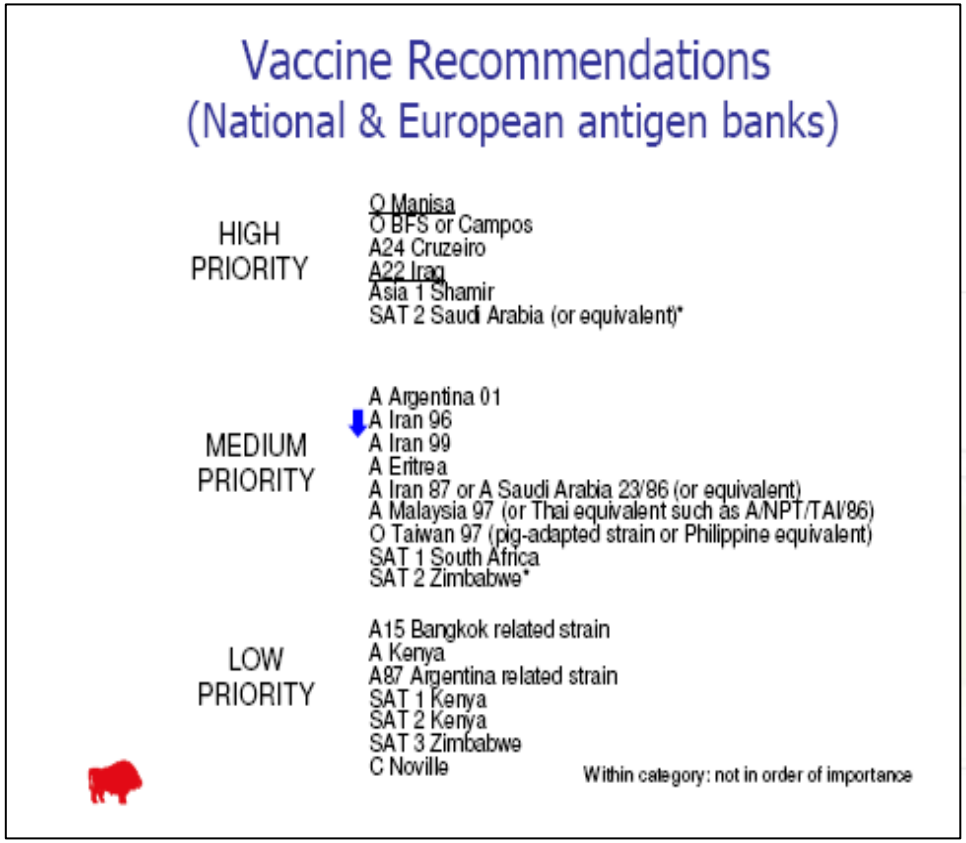


- marketing authorisation
- save storage for >10 years
- repeat testing for potency
- rapid formulation and delivery

Quantities of antigens in bank

- Council Decision 91/666/EEC:
  - at least **2 million** doses of each antigen (about 1% of cattle population)
- Recommendation* of EuFMD:
  - at least **2.5 million** doses of each antigen
  - at least **5 million** doses for vaccine strains covering strains circulating in neighbouring countries
- Coordination of national banks through EuFMD

* Minimum size of antigen stocks in the EU vaccine bank, Position Paper by A. Dekker and P. Barnett, Report of 37 Session of EuFMD , 2007



Antigen priority list

- Community Reference Laboratory
- Research Group of EuFMD

Manufacturers could facilitate choice of antigens by providing

- minimum information on available seed viruses
- hyperimmunsera for vaccine matching with field isolates

Marketing authorisation

FMD vaccines – a special case*

- emergency vaccination = „minor uses”
- certain susceptible species = „minor species”
- limited animal experiments - high containment required
- long time storage of antigens - not covered by derogation for emergency (Article 8 of Directive 2001/82/EC)
- potency test – more a quality check as vaccines are not used against the homologous virus
- customised vaccines
  - compositions of polyvalent vaccines (multi-strain dossier)
  - varying potency of final vaccine
  - different formulation (aqueous, oily)

* POSITION PAPER ON REQUIREMENTS FOR VACCINES AGAINST FMD (EMEA/CVMP/775/02-FINAL)

Antigen production

- Good Manufacturing Practice throughout production and storage
  - Commission Directive 91/412/EEC
- Biosecurity of establishment
  - Annex XII to 2003/85/EC referring to: “Security standards for FMD laboratories” – Report of the 30th Session of EUFMD, 1993, reviewed and adopted at 38th Session of EuFMD 2009
- Cell cultures for virus propagation and other ingredients be tested to verify freedom from bacteria, fungi, mycoplasma and extraneous pathogens
  - List of extraneous agents required to be tested with relation to the European Union General and Species-specific Guidelines (Vol. VII of the Rules Governing Medicinal Products in the European Union)
- Seed cells or ingredients of animal origin shall not be derived from animals infected or suspected to be infected with BSE
  - Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (Doc. Ref. EMEA/410/01 – Rev. 4)

Storage of antigens - delivery of vaccines

- at least two distinct and approved storage and formulation premises per supplier (Council Decision 91/666/EEC)
- formulation of vaccines
  - for pigs - oil emulsion
  - for ruminants - aluminum-hydroxide, saponin- or oil-adjuvanted vaccines
- supply of vaccines formulated from antigens in the bank within the following time limits following notice by the Commission
  - immediate supply, i.e. delivery of a minimum of 300.000 doses and a maximum of **2.000.000 doses** of finished vaccine per formulation site during **4 days**
  - urgent supply, i.e. delivery of 1.500.000 doses in oil emulsion and up to 5.500.000 doses in aqueous formulation within more than 5 but less than 14 days.

Quality requirements for antigens

- Sterility, innocuity, safety
  - OIE requirements
  - European Pharmacopoeia Monograph No 0063 on inactivated FMD vaccine for ruminants (for Europe)
- Potency
  - at least 6 PD_{50} in cattle (European Pharmacopoeia)
- Concentration
  - at least 1/100th, preferably 1/>200th – small dose volume
- Purification and removal of NSP following OIE requirements and EMEA recommendations*
  - the antibody levels against specified NS proteins should be lower than those considered as positive in a validated test after the simulation of 24 vaccinations

* POSITION PAPER ON REQUIREMENTS FOR VACCINES AGAINST FMD (EMEA/CVMP/775/02-FINAL)

Administrative Requirements

- financial provisions (Decision 90/424/EEC)
  - antigen bank is a substantial investment
  - replacement of expired antigens
- detailed contracts
  - supply and storage of antigens
  - formulation, finishing, bottling, labelling and delivery of vaccines reconstituted form the stored antigens
- procedures to operate the bank
- mechanisms to cooperate with other banks
- rules on access to the bank