



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

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This presentation does not necessarily represent the views of the Commission



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



FMD Directive 2003/85/EC

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

es da de el en fr it nl pt fi sv

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English edition **Legislation**

Contents *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) 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://ec.europa.eu/food/index_en.htm

Food Safety - From the Farm to the Fork

EUROPA > European Commission > DG Health and Consumers > Overview

Special Topics
 Avian Influenza
 Bioterrorism
 Veterinary Border Control
 Labelling - Better Regulation
 Animal Health Strategy
 TSE in Goats
 Approved Establishments
 Third Country Establishments List
 BSE
 LHM Fund & Fund
 Animal Transport
 TRADES
 RASFF
 Movements of Pets
 Training Strategy
 EFSA

General mission
 The EU **increased approach to food safety** aims to assure a high level of food safety, animal health, animal welfare and plant health within the European Union through closer farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. [About...](#)

News
 Dedic Training for Safer Food in Africa
 High-level health and plant health conference opens training programme for Africa
 Read more
 The EFACES website has taken off - it's now airborne!
 After five years' cruising on the farmac, TRADES is now flying a mile high, the SANCO website has been refreshed and energized with a new instructive, carnival and colourful update.
 Ben's voyage and a happy landing!
 Read more
 EU ACTION ON PESTICIDES
 The Commission has completed the review of pesticides that were on the market before 1993. This programme concerned about 1 000 substances and led to the removal from the market of more than two thirds of these substances. All reviewed pesticides have undergone a detailed risk assessment with regard to their effects on humans and on the environment. A new database can be consulted on this website to search for the active substances which are approved in Europe.
 Press Release
 Fact sheet
 New database on active substances
 Read more

Commissioner Androulla Vassiliou

Important legal notice
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European Elections
 It's Your Choice

Emergency Vaccination

■ Suppressive

- stamping out
- preventive killing of dangerous contacts
- killing of vaccinates

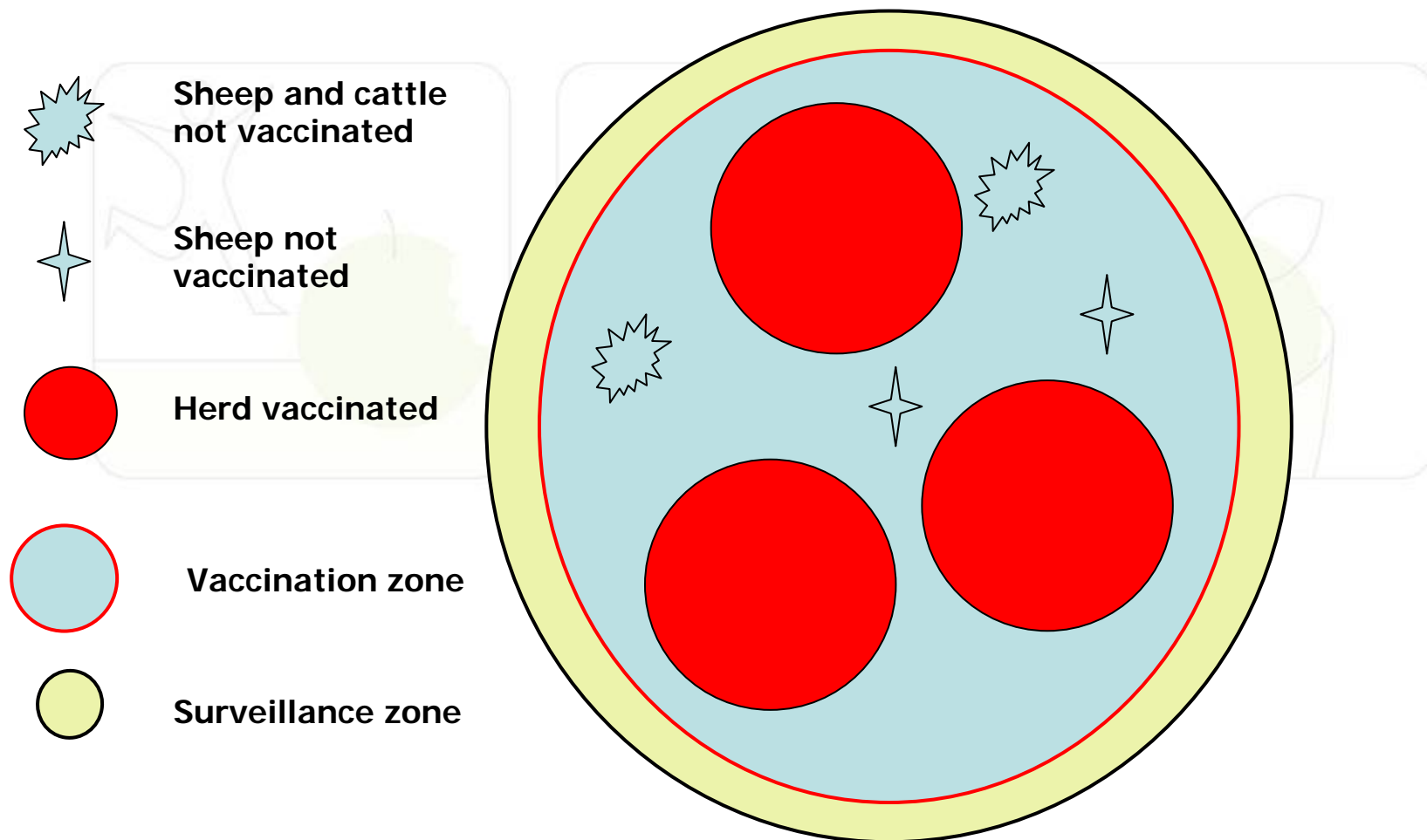
■ Protective

- 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



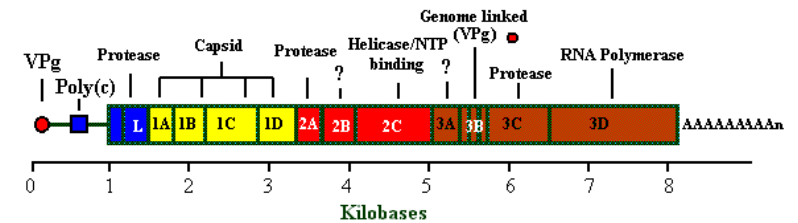
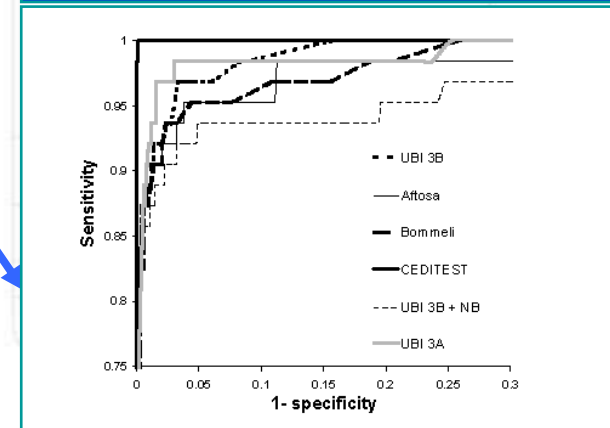
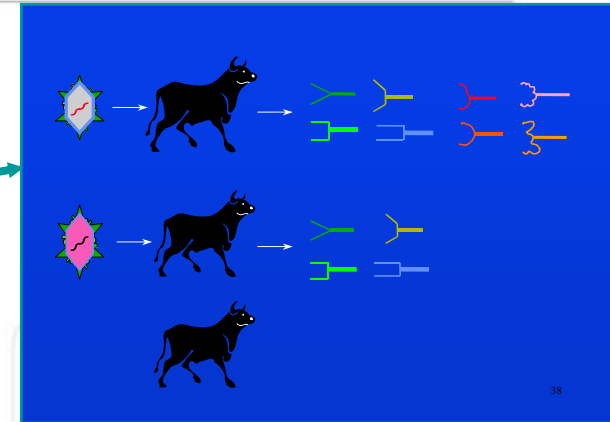
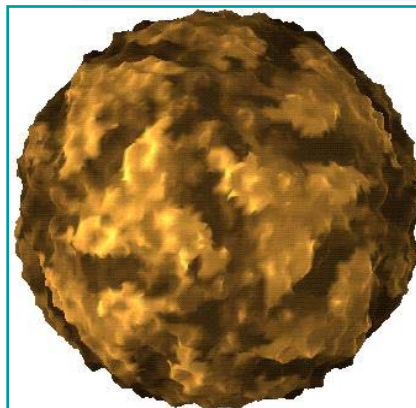
Post-vaccination testing

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

vaccinated
no virus



vaccinated
and virus

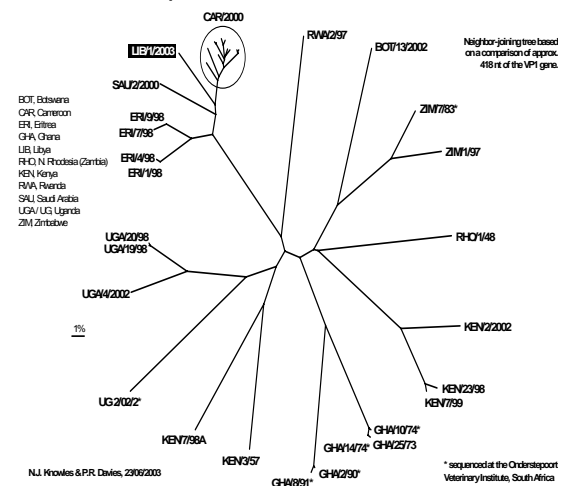


EC FMD Antigen Bank

- ▶ 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

Genetic relationship between FMDV SAT 2 LIB1/2003 and other SAT 2 viruses



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

Vaccine Recommendations (National & European antigen banks)

HIGH PRIORITY

~~O Manisa~~
O BFS or Campos
A24 Cruzeiro
~~A22 Iraq~~
Asia 1 Shamir
SAT 2 Saudi Arabia (or equivalent)*

MEDIUM PRIORITY

A Argentina 01
↓ A Iran 96
A Iran 99
A Eritrea
A Iran 87 or A Saudi Arabia 23/86 (or equivalent)
A Malaysia 97 (or Thai equivalent such as A/NPT/TAI/96)
O Taiwan 97 (pig-adapted strain or Philippine equivalent)
SAT 1 South Africa
SAT 2 Zimbabwe*

LOW PRIORITY

A15 Bangkok related strain
A Kenya
A87 Argentina related strain
SAT 1 Kenya
SAT 2 Kenya
SAT 3 Zimbabwe
C Noville

Within category: not in order of importance



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)

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 PD₅₀ 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 (EMA/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 from the stored antigens
- **procedures to operate the bank**
- **mechanisms to cooperate with other banks**
- **rules on access to the bank**