Availability and use of vaccines for FMD in different parts of the world

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Regions FMD vaccine industrial production
Global market FMD vaccines (estimate 2005)

- South America: ± 500 million doses
- European region: ± 15 million doses
- Middle East: ± 20 million doses
- Asia: ± 140 million doses
- Africa: ± 15 million doses

Excluded:
- CIS countries: mostly national producers allowed (50 million doses?)
- China: only national producers allowed (1-2 billion doses?)
- Local producers

25 producers (IICAB)
Continuous investment in capacity and quality by the vaccine industry

Volume relative to 2003

- 2003: 100%
- 2004: 120%
- 2005: 110%
- 2006: 150%
- 2007: 160%
- 2008: 200%

Company example
Continuous investment in capacity and quality by the vaccine industry

Company example
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/86)
- 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
EU recognized FMD vaccine producers

In Annex XI to Directive 2003/85/EC, Part B is replaced by the following:

‘Laboratories authorised to handle live foot-and-mouth disease virus for vaccine production

<table>
<thead>
<tr>
<th>Member State where laboratory is situated</th>
<th>ISO-code</th>
<th>Name</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DE</td>
<td>Germany</td>
<td>Intervet International GmbH, Köln</td>
</tr>
<tr>
<td></td>
<td>FR</td>
<td>France</td>
<td>Merial, S.A.S., Laboratoire IFFA, Lyon</td>
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<tr>
<td></td>
<td>GB</td>
<td>United Kingdom</td>
<td>Merial, S.A.S., Pirbright Laboratory, Pirbright</td>
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<tr>
<td></td>
<td>NL</td>
<td>Netherlands</td>
<td>CIDC-Lelystad, Central Institute for Animal Disease Control, Lelystad</td>
</tr>
</tbody>
</table>
Regulatory aspects of FMD vaccines

- OIE Manual of Standards 2008:
  - Ch. 1.1.8: Principles Veterinary Vaccines
  - Ch. 1.1.10: Guidelines vaccine banks
  - Ch. 2.1.5: FMD vaccines

- EU:
  - European Pharmacopoeia:
    - Vaccines for Vet. Use 01/2002:0062
    - FMD monograph 04/2005:0063
  - EMEA Position Paper 775/02: Requirements FMD vaccines
  - 2009 update biosecurity requirements (EUFMD 1993)
  - Multistrain dossier: principle is now accepted, how will it work in practice?
Challenges ahead

- **Level playing field for all FMD vaccine producers:**
  - Compliance OIE and national standards for vaccines
  - Biosecurity standards (OIE and e.g. EUFMD 2009)

- **Technical feasibility:** Manage the discrepancy between technical and regulatory requirements with regards to speed of development, strain differences, production yields, stability, antigenic coverage etc.

- **Financial feasibility:** Manage the discrepancy between call for cheaper vaccines and increasing regulatory requirements

- Secure that FMD R&D efforts are funded, coordinated and targeted towards key issues, including industrial vaccine production

- Maintain a high profile for FMD at international and company level in order to continue investments in research, product development and production capacity
Thank you very much for your attention!