FMD vaccines and vaccination in China
production use and quality

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Outline of Presentation

- FMD vaccine manufacturer and products
- Vaccination data from 2005 to 2009
- National compulsory vaccination programme
- FMD vaccination programme
- Quality control
- FMD vaccination surveillance
- Constraints and discussion
FMD vaccine manufacturer in China

- Xinjiang Tecon Animal Husbandry Biotechnology Co., Ltd
- Lanzhou Biological Pharmaceutical of China Animal Husbandry Industry Co., Ltd
- QYH Biotech Company Limited
- The Spirit Jinyu Biological Pharmaceutical Co., Ltd
- BWAT Bio. Science and Technology Co., Ltd
- Shenlian Biotech Co., Ltd

The map shows the distribution of these manufacturers across China.
FMD Vaccines products show

- O, A, Asia1 monovalent vaccine, inactivated
- O-A, O-Asia1 bivalent vaccine, inactivated
- O-A-Asia1 multivalent vaccine, inactivated
- Synthetic Peptide Vaccine (Type O)
- Empty Capsid Vaccine (Asia1, temporary certificate)
# Vaccine Producers

<table>
<thead>
<tr>
<th>Producers</th>
<th>Vaccine</th>
<th>Producer located</th>
</tr>
</thead>
<tbody>
<tr>
<td>China Agricultural Vet. Bio. Science and Technology Co., Ltd</td>
<td>All types</td>
<td>Gansu</td>
</tr>
<tr>
<td>Lanzhou Biological Pharmaceutical Industry Co., Ltd</td>
<td>O, Asia1 inactivated</td>
<td>Gansu</td>
</tr>
<tr>
<td>The Spirit Jinyu Biological Pharmaceutical Co., Ltd</td>
<td>O, Asia1 inactivated</td>
<td>Inner-Magnolia</td>
</tr>
<tr>
<td>BWAT Bio. Science and Technology Co., Ltd</td>
<td>O, Asia1 inactivated</td>
<td>Inner-Magnolia</td>
</tr>
<tr>
<td>Xinjiang Tecon Animal Husbandry Bio-technology Co., Ltd. (Tecon)</td>
<td>O, Asia1 inactivated</td>
<td>Xinjiang</td>
</tr>
<tr>
<td>QYH Biotech Company Limited</td>
<td>O, Asia1 inactivated</td>
<td>Yunnan</td>
</tr>
<tr>
<td>Shenlian Biotech Co., Ltd</td>
<td>Synthetic peptide</td>
<td>Shanghai</td>
</tr>
</tbody>
</table>
Vaccination data from 2005 to 2011

Susceptible Animals Vaccination Covered

<table>
<thead>
<tr>
<th>FMD Types</th>
<th>Susceptible Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>Swine, cattle, sheep/goat, camel and and deer</td>
</tr>
<tr>
<td>A</td>
<td>Cow, breeding bull, sheep/goat (at the border areas)</td>
</tr>
<tr>
<td>Asia1</td>
<td>Cattle, sheep/goat, camels and and deer</td>
</tr>
</tbody>
</table>
### Number of Animals Vaccinated (2005 to 2011)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cattle</th>
<th>Buffalo</th>
<th>Pig</th>
<th>Sheep/goat</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>109,900</td>
<td>22,167</td>
<td>433,190</td>
<td>297,920</td>
</tr>
<tr>
<td>2006</td>
<td>104,650</td>
<td>15,047</td>
<td>418,500</td>
<td>283,690</td>
</tr>
<tr>
<td>2007</td>
<td>105,940</td>
<td>14,888</td>
<td>439,890</td>
<td>285,640</td>
</tr>
<tr>
<td>2008</td>
<td>105,760</td>
<td>15,073</td>
<td>462,910</td>
<td>280,840</td>
</tr>
<tr>
<td>2009</td>
<td>107,260</td>
<td>15,200</td>
<td>469,850</td>
<td>284,690</td>
</tr>
</tbody>
</table>

In 2010 used 2.81 billion Milliliters  
In 2011 used 2.82 billion Milliliters
National Compulsory Vaccination Programme

• Terms of Reference
  – Local governments: overall responsibilities for disease control under their purview; organize related agencies to implement the programme and ensure coverage.
  – Veterinary authorities at different levels: programme implementation. Specifically: oversee and control of vaccine purchase, storage, and use; work and carry out compliance plan for compulsory vaccination.
  – Financial departments at different levels: funding programme implementation. Specifically: provide fund for costs related to vaccines, consumable items, labor, evaluation on vaccination results, negative effect treatment, etc., and oversee use of fund related to vaccines and others.
  – Other departments: rule-based supportive functions in programme implementation.
National Compulsory Vaccination Programme

• Terms of Reference
  – National reference labs and specialized labs: animal disease research; following strain variation; carrying out epidemiological investigation as required; evaluation on vaccination results; ensuring supply of diagnosis reagents.
  – Entities and individuals engaging in animal production: compliance and doing vaccination in accordance with laws and requirements of veterinary authorities.
  – Designated vaccine producers: ensuring and accountable for vaccine quality, and providing good services.
FMD Vaccination Programme

• Requirement

− For all pigs: vaccination against type O;
− For all cattle, sheep/goats, camels and deer: vaccination against type O and Asia 1;
− For all cows and breeding bulls: vaccination against type A;
− For cattle and sheep/goats at the border areas of Guangxi, Yunnan, Tibet, Xinjiang, and Xinjiang Production and Construction Corps: vaccination against type A.
FMD Vaccination Programme

• **Vaccination Procedure**
  
  – Vaccination in commercial farms under recommended procedures; mass vaccination in spring and autumn for free-ranged animals; timely vaccination for restocked ones.

  • 1. Animals in commercial farms and breeding stock: piglets and lambs receive initial vaccination at 28-35 days old, and calves at about 90 days, 1 month after which is the intensified vaccination for them, which is followed by further vaccination every 4--6 months.

  • 2. Free-ranged animals: mass vaccination for all susceptible livestock in spring and autumn, and regular vaccination every month for those left. It can be also be done under recommended procedure for commercial farms if possible.
FMD Vaccination Programme

• **Emergency vaccination**

  – Upon a FMD outbreak, an intensified vaccination is done on all susceptible livestock within affected areas and threatened areas. In case of border areas under threat, an intensified vaccination is done on all susceptible livestock within 30 km from the border. Those vaccinated within one month from the time of intensified vaccination are exempted.
FMD Vaccination Programme

• Vaccine Type

  – Cattle, sheep/goats, camels and deer
    • bivalent inactivated vaccine targeting at types O and Asia I;
    • bivalent inactivated vaccine targeting at types O and A;
    • inactivated vaccine against type A.

  – Pigs
    • inactivated vaccine against type O;
    • synthesis peptide vaccine against type O (double-antigen).

  – Application of empty capsid compound vaccines is subject to authorization.
## Administration and Personnel Support for Vaccination

<table>
<thead>
<tr>
<th>National level</th>
<th>Province/Municipality/ Autonomous Region</th>
<th>City/ Prefecture</th>
<th>Country</th>
<th>Township</th>
<th>Administration village</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration Units</td>
<td>1</td>
<td>31</td>
<td>333</td>
<td>2300</td>
<td>40,000</td>
</tr>
<tr>
<td>Animal Disease Control Centers</td>
<td>1</td>
<td>31</td>
<td>333</td>
<td>2300</td>
<td>/</td>
</tr>
<tr>
<td>Veterinary Station</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>34,000</td>
</tr>
<tr>
<td>Personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>120,000</td>
</tr>
</tbody>
</table>

Note: It is Estimated, there are near **one million people** working on animal health in China, including administration officer, veterinary, paraveterinary and support personnel.
# Budgets for FMD and List A Disease in 2011

<table>
<thead>
<tr>
<th>Budget Item</th>
<th>Budget Ratio (%) (central government/province)</th>
<th>Central Budget</th>
<th>Province/Municipality/Autonomous Region</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine (FMD)</td>
<td>East China: 20/80 Central China: 50/50 West China: 80/20</td>
<td>830 million</td>
<td>420 million</td>
<td>1,250 million (about 200 million USD)</td>
</tr>
<tr>
<td>Surveillance (FMD)</td>
<td></td>
<td>10 million</td>
<td>No data yet</td>
<td>&gt;10 million</td>
</tr>
<tr>
<td>Slaughter compensation (list A disease, per animal)</td>
<td>East China: 20/80 Central China: 50/50 West China: 80/20</td>
<td>170 million</td>
<td>Various in province</td>
<td>&gt;170 million</td>
</tr>
<tr>
<td>Dairy cow (2400 yuan)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beef cattle (1200 yuan)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pig (480 yuan)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheep/goat (240 yuan)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subsidy to paraveterinary (list A disease, 645,000 persons)</td>
<td>3,000-4,000 yuan (450-900 US$) per person per year</td>
<td>640 million</td>
<td>1,617.5 million</td>
<td>2,257.5 million</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>1,650 million</td>
<td>&gt;2,037.5 million</td>
<td>&gt;3,687.5 million (567 million US$)</td>
</tr>
</tbody>
</table>

Note: 1 US$ = 6.5 RMB yuan
Quality control standard

- OIE
- GMP(2006.01.01)
- GLP-GCP-GMP-GSP-GUP
supervision department

- **China Institute of Veterinary Drug Control/Center for Veterinary Drug Evaluation (CVDE)**

- CIVDC/CVDE is a national institute responsible for the evaluation of veterinary drugs, inspection, supervision and test of veterinary drugs and appliances, monitoring of veterinary drugs residues, collection of veterinary culture, drafting and revising national standards of veterinary drugs as well as preparation and calibration of the national standards and reference materials of veterinary drugs.
QC Department Lab
FMD Vaccination Surveillance

• The Reporting System
  Weekly report during time of mass vaccination in spring and autumn every year (for about two months).

• Check of vaccination report
  At least two inspections over the vaccination every year, and cross-check be organized among 31 provinces (autonomous regions and municipalities).
Animal ID & Animal Health Traceability System
FMD Vaccination Surveillance

• **Evaluation of vaccination results**
  
  Result evaluation is conducted upon 28 days after vaccination for pigs and 21 days for other animals.

  – **Testing methods:**

  • Asia I
    – LPB-ELISA;
  
  • O
    – IHA and LPB-ELISA for inactivated vaccines;
  
  • Synthesis peptide vaccines
    – VP1 structural protein-based ELISA
  
  • A
    – LPB-ELISA.
FMD Vaccination Surveillance

• Effectiveness threshold
  – Asia1
    • Antibody titers at or above $2^6$ with LPB-ELISA ($\geq 2^6$), indicating that vaccination has generated antibody against FMDV.
  – O
    • Antibody titers at or above $2^5$ with IHA for inactivated vaccines; antibody titers at or above $2^6$ with LPB-ELISA, and at or above $2^5$ with VP1 structural protein-based ELISA for synthesis peptide vaccines, indicating that vaccination have generated antibody against corresponding FMDV respectively.
  – Type A
    • Antibody titers at or above $2^6$ with LPB-ELISA, indicating that vaccination has generated antibody against FMDV.
  – Success rate is set at 70% for antibody generation against FMDV for the whole inventory.
Constraints and Discussion

- Big difficulties in vaccination of free-ranged animals (a better shape in commercial farms).
- Frequent move of raised animals, resulting in difficulty in complete vaccination.
- Immune repress diseases
- Inadequate financial and human resources.
- Proposal for establishment a new standard of FMD vaccine potency examination in pigs
Thank you!