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

Paul van Aarle DVM
Intervet/Schering-Plough Animal Health

Intervet
Schering-Plough Animal Health

Regions FMD vaccine industrial production

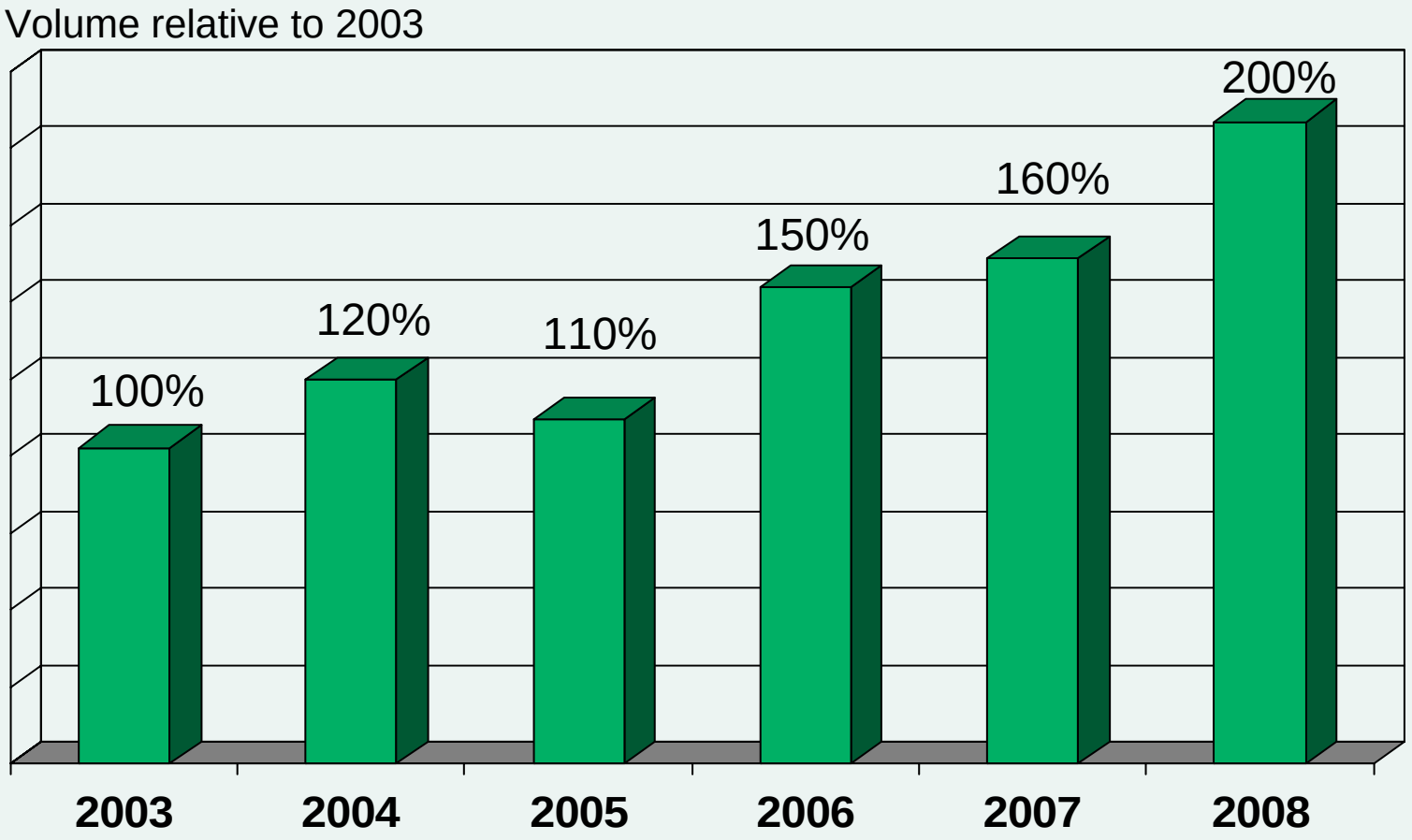
Global market FMD vaccines (estimate 2005)

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

} 25 producers (IICAB)

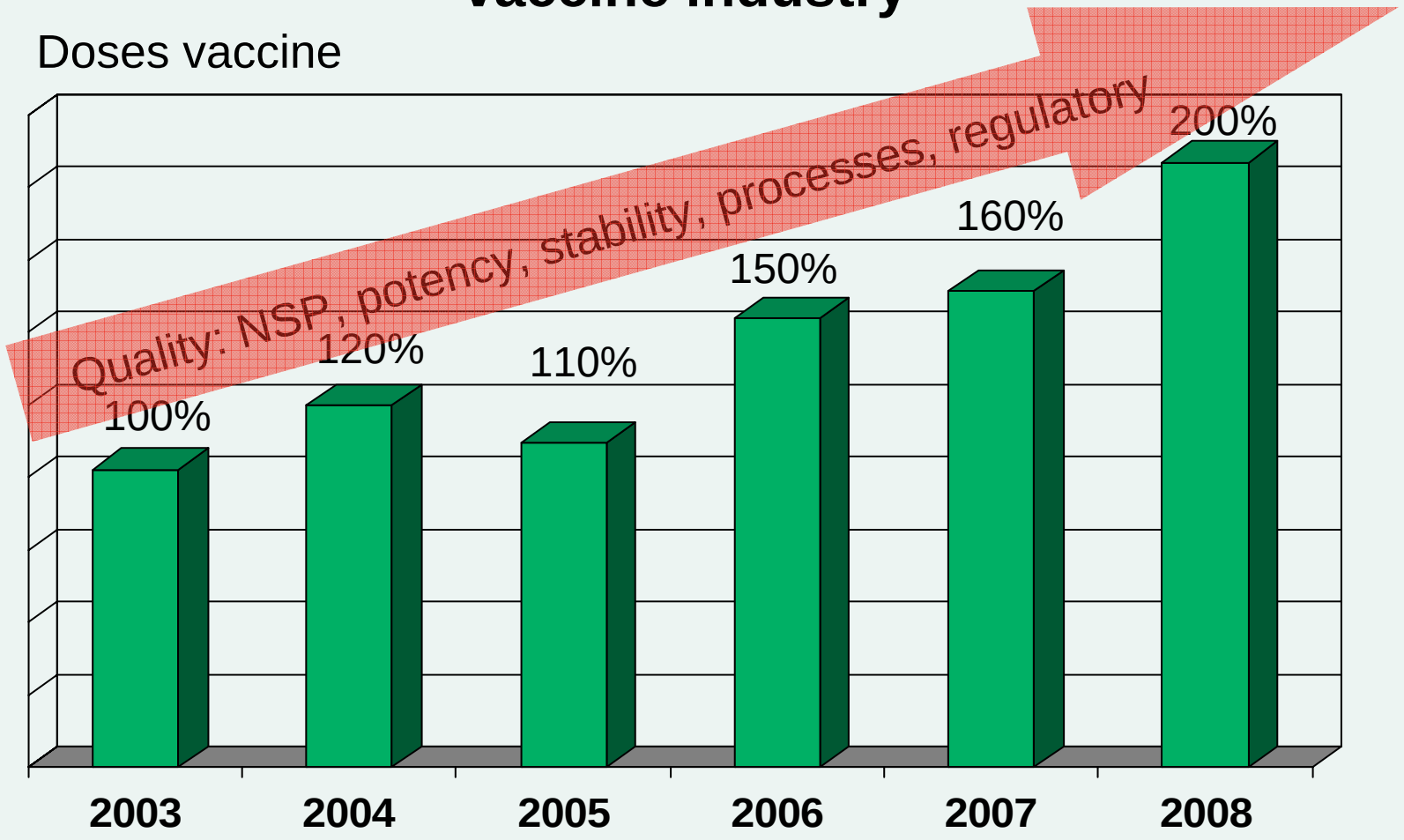
- Excluded:
  - CIS countries: mostly national producers allowed (50 million doses?)
  - China: only national producers allowed (1-2 billion doses?)
  - Local producers

Continuous investment in capacity and quality by the vaccine industry



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

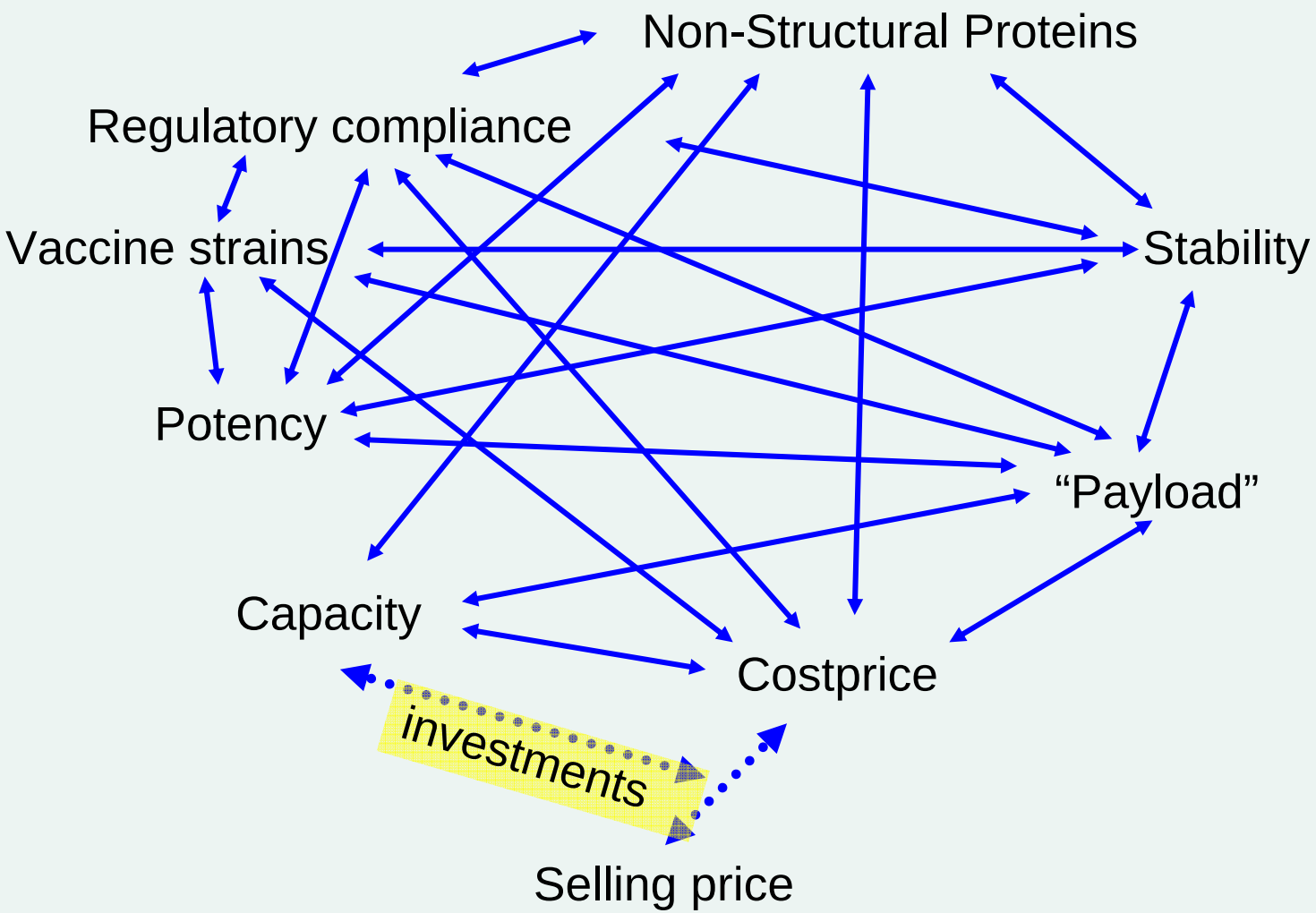
EU recognized FMD vaccine producers

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

Member State where laboratory is situated		Laboratory
ISO-code	Name	
DE	Germany	Intervet International GmbH, Köln
FR	France	Merial, S.A.S., Laboratoire IFFA, Lyon
GB	United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright
NL	Netherlands	CIDC-Lelystad, Central Institute for Animal Disease Control, Lelystad'

Issues


Non-Structural Proteins
Regulatory compliance
Vaccine strains
Stability
Potency
“Payload”
Capacity
Costprice
investments
Selling price

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:**
  - EU Directive EC/726/2004
  - 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!