



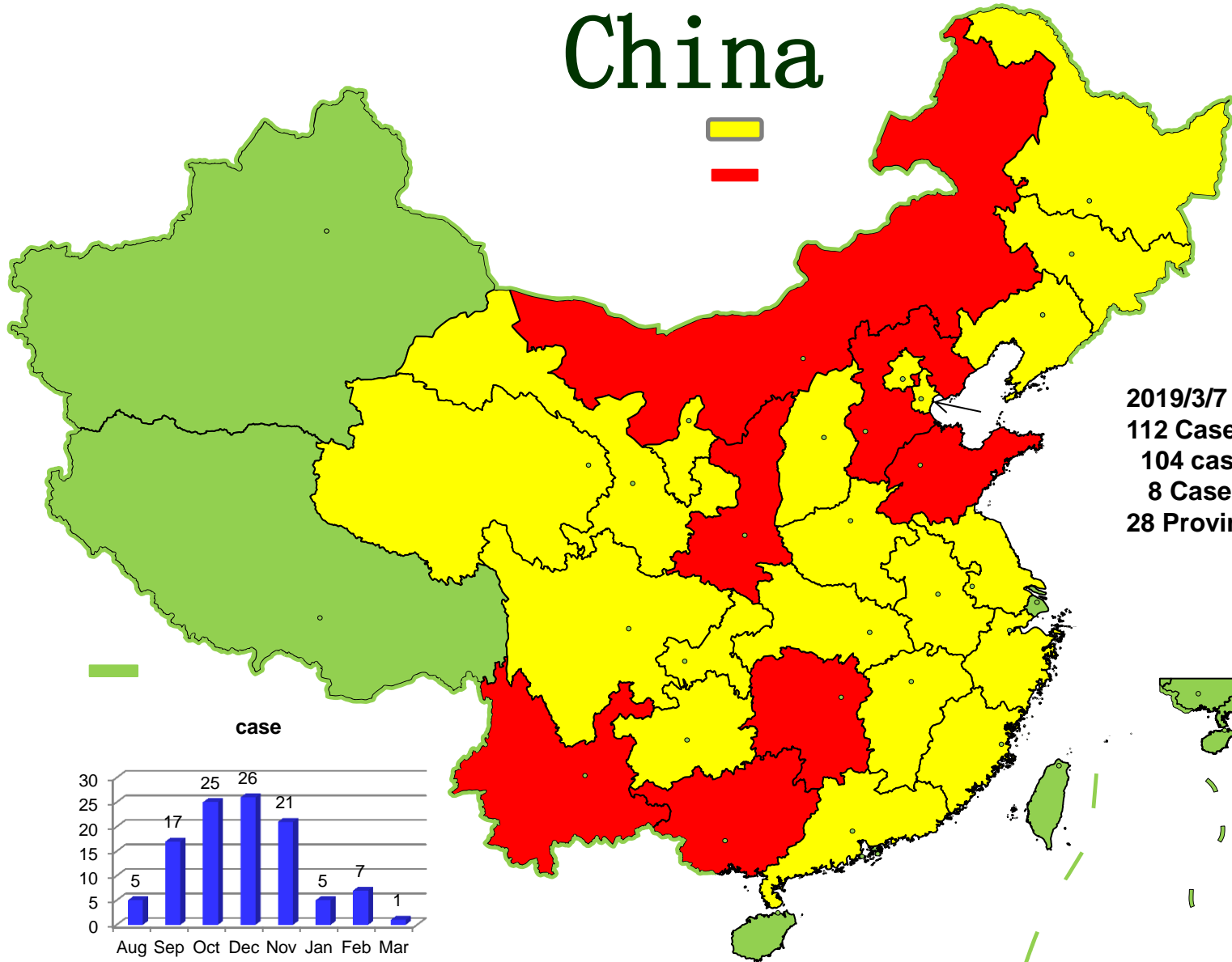
Risk of African Swine Fever Transmission in Veterinary biologics

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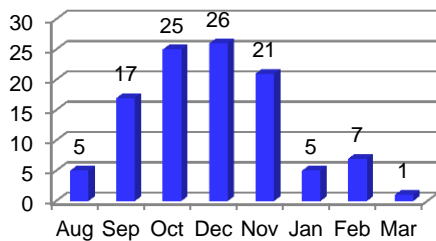
2019.03 Beijing

African Swine Fever in China



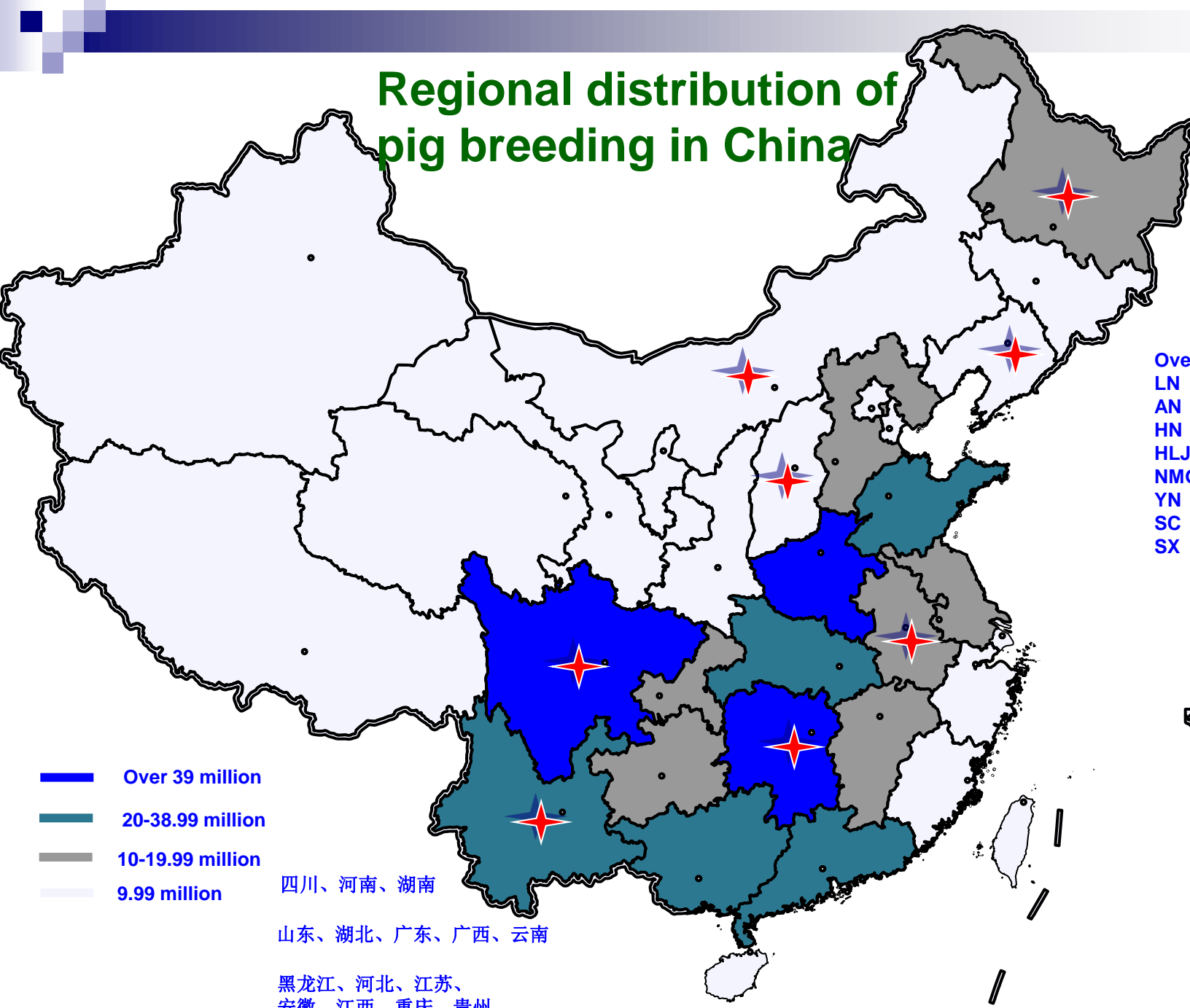
2019/3/7
112 Cases
104 cases
8 Cases
28 Provinces

case





Regional distribution of pig breeding in China



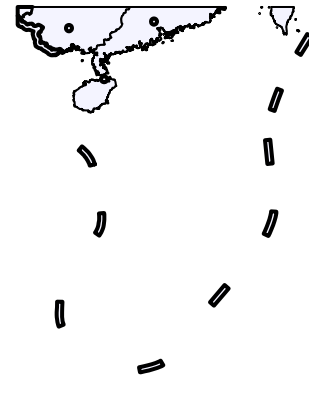
Over 5 cases	
LN	14
AN	9
HN	8
HLJ	6
NMG	6
YN	6
SC	5
SX	5

- Over 39 million
- 20-38.99 million
- 10-19.99 million
- 9.99 million

四川、河南、湖南

山东、湖北、广东、广西、云南

黑龙江、河北、江苏、
安徽、江西、重庆、贵州



Entry and Spread



contaminated left food from aircraft, boat and yacht

Harbor container imported contaminated goods

Infected semen and embryo

illegal trade pig and products

E-commerce, International Mail from Epidemic Areas



Free movement of wild boar in border areas

pork and products illegally carried by passengers





Risk assessment of Veterinary Biologics

- African swine fever is a foreign animal disease in China before 2018, Aug.
- Doubts have been raised about the introduction of veterinary biological products.
- Are veterinary biologics at risk of spreading ASF?





Imported pig biologicals products

- Nine companies have registered and sold VB in China, some of which have been merged.
- Two companies for in vitro products.
- Inactivated vaccines and live vaccines
- PCV2 (killed) , PRRS (live) , PRV (live) ,
- Mycoplasma Hyopneumoniae Bacterin (live or killed) and other 9 Bacterial Vaccine
- Data 2010-2019.3



Biological products for pigs in China

- 97 GMP Companies in producing.
- Viral products, CSF, FMD, PRRS, PRV, PCV2, PPR, PEDV, et al.
- Bacterial products, Mycoplasma pneumonia, streptococcus suis, Haemophilus Parasuis, et al.
- Immunomodulators, interferon, transfer factor and so on
- In vitro Diagnosis kits



Quality control of raw materials in Veterinary Biological product

- Without test.
- Trypsin, for cell culture
- Swine sera for culture medium
- Tissues from products, such as Leukocyte in peripheral blood, spleen and animals placenta.
- In vitro Diagnosis kits quality control agent.



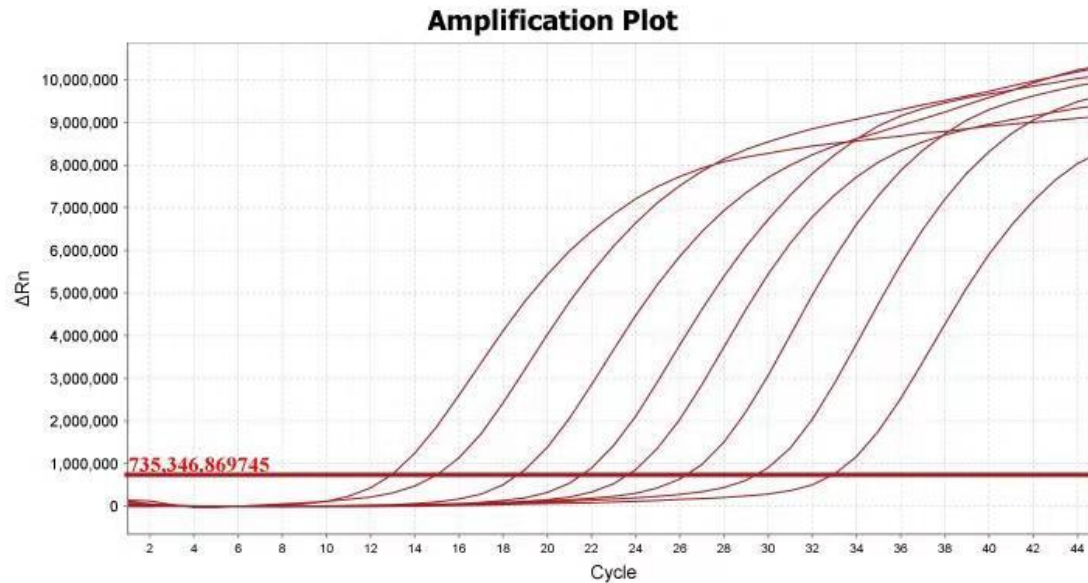
Risk assessment results

- Transfer factor is produced directly from pig, and interferon from pig blood lymphocytes, which is a high-risk biological product of African swine fever.
- Mycoplasma pneumoniae vaccine in the production process to add 10-20% pig sera as medium components, is a risk of African swine fever biological products.
- Cell culture live vaccine, trypsin was to splice cell, that is mostly produced by pig pancreas, and in order to maintain the activity of trypsin, there is the possibility of residual virus and also the risk of African swine fever pollution.



Screening of detection methods

- Real time PCR,
- The sensitivity and specificity of the primer pairs were compared. Meanwhile, the extraction methods of nucleic acid in biological products were explored.





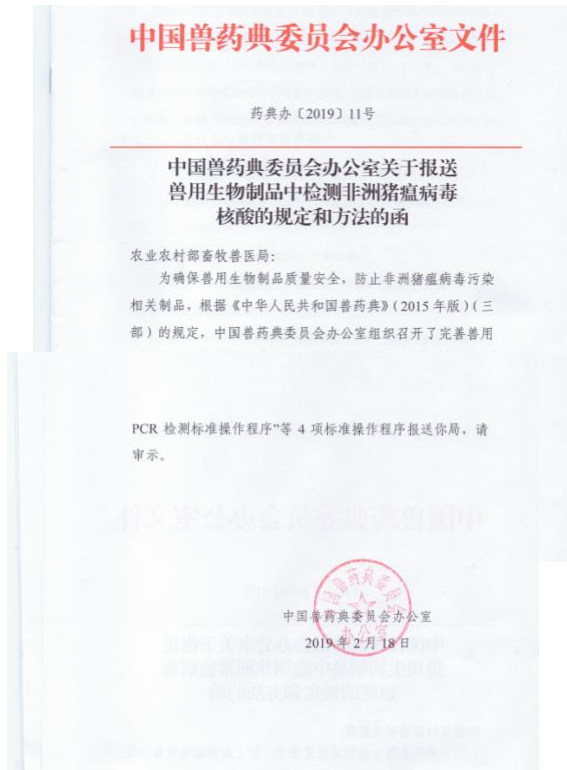
Sampling inspection

- 29 home enterprises and 6 overseas enterprises, 102 batches of products
- Swine interferon, Porcine splenic transfer factor, Live Mycoplasma pneumoniae vaccine, CSF live vaccine
- PRRS live vaccine, PRV vaccine.
- The results showed that all 102 batches of biological products tested were negative for ASF nucleic acid by realtime PCR.



Regulate detect in producing

■ Unified method and training



	2012-2019	2018,8-2019
IF	274	11
TF	762	101
WTF	84	10
MPV live	469	85
MPV killed	448	87



Risks and Challenges

- For Biosafety and Security, weaken other animal infected diseases prevention
- Weakening clinical trials in vaccine development due to biosafety.
- ASF assays,
Speed, sensitivity, specificity, cheap
- Vaccine evaluation
Traditional methods, new unique technologies in vaccine development
To keep up with the progress of research, scientifically evaluate the effectiveness of vaccines,
To communicate with research teams and timely understand the vaccine is reasonable and scientific.



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