

PRC Recognition of FMD Free Zone of Foreign Countries

——The Application and Effect of Regionalized Management of Animal Diseases in China

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(1) Background



▶ (2) Development

1995

1998

2000

2003

2012年

•The 1995 SPS Agreement puts forward the principle of regionalization. OIE first recognized FMD regionally.

OIE officially introduced the concept of regionalization into the "Code".

•OIE conducts regionalization of rinderpest (the world is free of rinderpest in 2011).

For the first time, the concept of biosafety quarantine was proposed on the SPS committee.

OIE regionally recognizes bovine infectious pleuropneumonia.

•OIE officially introduced the concept of biosafety quarantine into the "Code".

OIE recognized the risk status of bovine spongiform encephalopathy

• In 2012, regionalization was approved for African horse plague.

- ►(3) Interpretation
- ▶1. Zone (zone/region)

For the purpose of international trade, to take necessary monitoring, control and biosecurity measures for specific diseases based on geographic boundaries, and the sanitary status of animal subgroups and clearly demarcated areas.

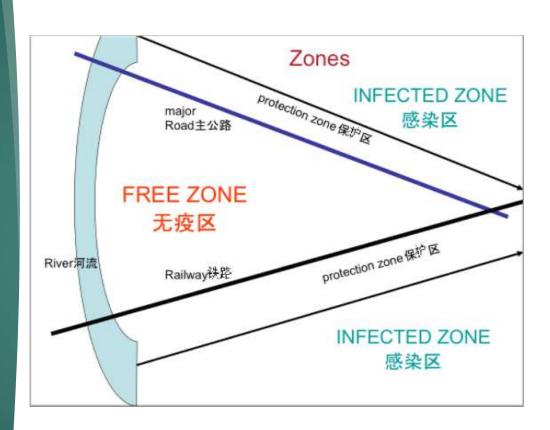


Figure 1. Regionalization pattern diagram

- ►(3) Interpretation
- ▶2. Biosafety compartmentalization (compartmentalization of epidemic-free communities)
- ▶It refers to the effective isolation of animal subgroups containing one or more animal farms from other susceptible animal subgroups through the same biosafety management system for the purpose of international trade or disease prevention and control in a country or region, and Necessary monitoring, biosafety and control measures have been taken for the infection or infestation of one or more specific animal diseases in this subgroup, so that it has the same animal health status.

Compartment

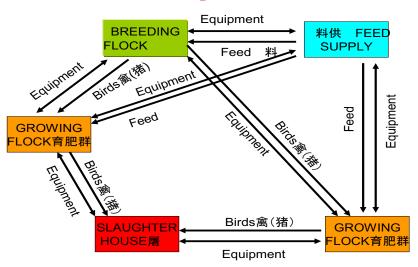




Figure 2. Biosafety quarantine model diagram (poultry/pig)

(4) Application of regionalization

OIE's recognition of animal disease status

 Officially recognized animal diseases: foot-and-mouth disease, rinderpest, mad cow disease, bovine infectious pleuropneumonia, African horse fever, petit ruminant disease, classical swine fever.

Contents

2. China recognizes the overseas animal diseases regionalization

2. China recognizes the overseas animal diseases regionalization

(1) Legal basis

1. Article 6, paragraph 3, of the SPS Agreement

• Exporting Members claiming that areas within their territories are pest — or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest— or disease—free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Risk assessment is a common practice in all countries

2. China recognizes the overseas animal diseases regionalization

- (1) The legal basis
- 2. Chinese law

Chapter 1, Article 6, of the Law of the People's Republic of China on Animal and Plant Quarantine for Entry and Exit

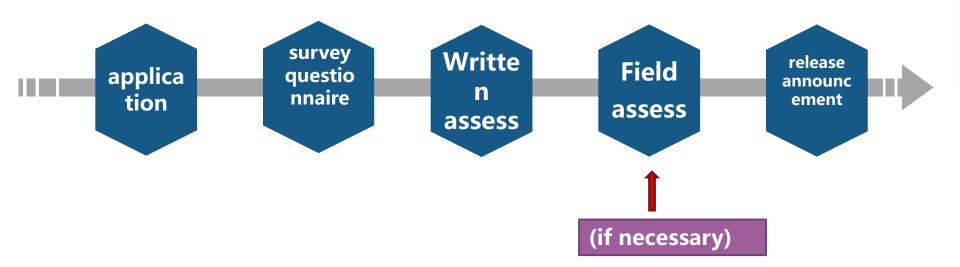
Article 23 of Chapter II of the Biosecurity Law of the People's Republic of China

Article 29 of Chapter III of the Regulations on the Implementation of the Law of the People's Republic of China on Animal and Plant Quarantine

Chapter III, Article 12, Regulations on risk analysis and management of incoming animals and animal products (General Administration of Customs Order No. 238).

2. China's recognition of the regionalization of foot-and-mouth disease outside China

(ii) Assessment procedures



2. China's recognition of the regionalization of foot-and-mouth disease outside China

(ii) Assessment procedures

1. Application

The official competent authority of the country where it is located submitted an application for approval to the General Administration of Customs of China, and the General Administration of Customs initiated the acceptance.

- 2. Questionnaire (take foot-and-mouth disease immunized countries/regions as an example)
 - 2.1 Basic information
 - 2.2 Veterinary system
 - 2.3 Eradication of foot-and-mouth disease
 - 2.4 Diagnosis of Foot-and-Mouth Disease2.5 Surveillance of foot-and-mouth disease

 - 2.6 Prevention of Foot-and-Mouth Disease
 - 2.7 Control measures and emergency plans, simulation exercises

2. China's recognition of the regionalization of foot-and-mouth disease outside China

(ii) Assessment procedures

3. Written evaluation
Written assessment is generally conducted by GACC in conjunction with MARA experts
Evaluation opinions are required for each element of the questionnaire materials

Elements of written assessment

- 1. Prove that there has been no FMD outbreak in the past 2 years; no signs of FMDV infection have been found in the past 12 months.
- 2. Prove that no FMDV infection has occurred in animals that have not been immunized in the past 2 years; immunized animals have not had FMDV circulation; supervision measures for prevention and early detection of FMD have been implemented; mandatory and systematic vaccination of FMD vaccines for target groups to achieve sufficient immunization coverage and population Immunity rate; the vaccines for vaccination are prepared by selecting the appropriate strains.

2. China's recognition of the regionalization of foot-and-mouth disease outside China

(ii) Assessment procedures

3. Written assessment

Elements of a written assessment

- 3. Prove that the following measures have been taken and effective supervision has been carried out:
- ——If you apply for an FMD-free area for immunization, clearly define the boundary setting of the area.
- -If a protected area is established, the boundaries of the protected area and the measures taken in the protected area.
- ——Established a system to prevent the introduction of FMDV into FMD-free countries or regions, including the control of the transfer of susceptible animals, especially if there is a direct transfer of FMD susceptible animals from the infected area or infection control area to immune or non-immune Slaughter in FMD-free areas, or imported domestic ruminants and pigs from FMD-infected countries or regions that implement official control plans.
- ——The control measures for the movement of susceptible animals and their products into the country or region where the FMD is free of epidemics.
 - 4. OIE accreditation status and annual review report.

2. China's recognition of the regionalization of foot-and-mouth disease outside China (ii) Assessment procedures

4. On-site assessment (if necessary)

The field assessment expert group is generally composed of GACC and MARA experts. The purpose of the on-site assessment is to verify and verify the authenticity of the information provided in the written materials and the effectiveness of disease prevention and control measures, and to conduct on-site communication on the problems found in the written assessment.

4.1. Assessment locations that should be included

Veterinary institutions, breeding farms or/and animal isolation plants, slaughterhouses, production and processing plants, laboratories, non-hazardous treatment sites, border checkpoints, epidemic and non-epidemic areas, etc. in the country/region of the application. Determined according to the evaluation schedule agreed by both parties.

2. China's recognition of the regionalization of foot-and-mouth

dicacca outcida China

(ii) Assessment procedures

4.2. On-site assessment elements

- ——Whether the country/region's FMD prevention and control laws and regulations are sound and whether the prevention and control measures are effectively implemented.
- ——Whether the country/region's FMD prevention and control monitoring standards meet the FMD monitoring requirements of the Code.
- ——What are the similarities and differences between the treatment after the FMD outbreak and the treatment principles recommended by OIE.
- —— FMD testing laboratory sample storage, biological safety protection and quality assurance conditions are safe and effective, the similarities and differences between FMD testing methods and international general methods.
- —Whether the biosafety measures of the breeding farm are in place, the use of veterinary drugs, vaccines and other inputs, and whether the traceability of the transportation of live cloven hoofed animals is effective.
 - -Slaughter quarantine and product traceability.
- ——The setting and implementation of key control points in the processing of cloven hoofed animal products.
- ——The country/region imports live cloven ungulates and cloven-toed animal products and their uses and control measures.

2. China's recognition of the regionalization of foot-and-mouth

dicacca outcida China

(ii) Assessment procedures

4.3 Assessment report

The on-site assessment expert group combines written assessments and on-site assessments to comprehensively make assessment opinions, put forward risk management measures, suggestions, or indicate the differences between the two parties that require further technical exchanges and consultations. If rectification is required, the expert team will feedback the rectification opinions to the assessed party for rectification, and make a final assessment conclusion after the rectification is completed

5. Publish the announcement of lifting the ban

If the assessment conclusion recognizes the FMD control level of the applying country/region and meets China's accreditation requirements for FMD-free or immunized regions, the General Administration of Customs and the Ministry of Agriculture and Rural Affairs will jointly issue an announcement to remove or partially remove the applicant country/region Ban. The General Administration of Customs will also update the "List of Animals and Animal Products Prohibited to Import from Animal Endemic Countries/Regions" and publish it on the official Chinese website to restore or allow the export of animals and animal products that meet the quarantine requirements determined by both parties to China.

Content s

3. Standards for the regionalization of foreign FMD zone

(1) Veterinary system

1 Laws and regulations

•The exporting country's animal health laws and regulations concerning the construction, management, and maintenance of epidemic-free areas are complete and effective, with clear management measures and technical specifications, and penalties and regulations for violations of laws and regulations.

2 Veterinary institutions

•Government agencies are in place to manage animal health work, with human, material, and financial resources to maintain the functions of the agency. Animal health technicians shall have relevant qualifications and capabilities. The government can effectively organize and implement animal health management, including animal disease immunization, monitoring, epidemiological investigation, quarantine supervision, animal identification traceability, and emergency response to animal epidemics.

(1) Veterinary system

3. Laboratory system

- (1) Have the ability to undertake animal disease diagnosis, monitoring, epidemiological investigation and personnel training.
- (2) Equipped with corresponding professional and technical personnel, the equipment can meet the needs of normal work.
- (3) The laboratory shall establish a complete quality assurance system and ensure the effective operation of quality assurance documents.

(2) Boundary settings

1 Disease-free Zone

- The epidemic-free area should be delimited based on geographic barriers, laws and artificial barriers. The regions are concentrated and contiguous, with clear geographical boundaries, and a certain scale, as consistent as possible with the administrative region, and released through official channels.
- The barrier system of the epidemic-free area can be a geographic barrier, or artificial barriers such as animal health supervision and inspection stations, isolation facilities, and blockade facilities can be established around the area to effectively prevent animals from entering and leaving the epidemic-free area at will.
- · Animal health supervision and inspection stations, blockade and isolation facilities, etc. should be equipped with necessary quarantine and epidemic prevention facilities and equipment, and warning signs should be set up at traffic crossings entering the epidemic-free area.
- Relevant government departments of the exporting country determine and announce the ports and transportation channels that allow animals to enter and exit the epidemic-free area, including roads, ports and other lines and entrances to and from the epidemic-free area. Checkpoints should be set up at the channels and entrances.

(2) Boundary settings

2 Protected areas

• Set up protection areas 3 km around the epidemic-free area, and implement susceptible animal movement control and compulsory immunization measures.

3 Centralized feeding area

• Set up a centralized feeding area 3-50km around the epidemic-free area, implement bio-safety and epidemic prevention management in accordance with the requirements of the OIE Code, and conduct identification, immunization, centralized fattening and quarantine before entering the epidemic-free area for cloven hoofed animals for export slaughter.

(3) Regionalization management measures

1 Label traceability

• Establish a traceability system for susceptible animals and their products, add animal identification, the identification code should be unique, and establish a file record and query system.

2 Vaccination

- · The vaccine should be an inactivated vaccine against the footand-mouth disease strains circulating in the source and related areas, and meet the requirements of the OIE "Manual".
- The cold chain system for vaccine storage and transportation is complete.
- Before susceptible animals enter the epidemic-free area, compulsory immunization is carried out according to the regulations, and the immunization density reaches 100%. The immune density of susceptible animals in the epidemic-free area is maintained at more than 95% all year round.

(4) Monitoring

- 1. The newly-built epidemic-free area has not had foot-andmouth disease in the past 2 years, and no FMDV transmission has been found in the past 12 months. The susceptible animals in the epidemic-free area shall be monitored and processed by FMD according to the method recommended by the OIE "Manual".
- 2. Sampling according to the method recommended by the OIE "Handbook" for testing the level of immune antibodies, the qualified rate of immune antibodies is above 70%.
- 3. Place no less than 30 sentinel animals that are 8 months to 24 months old, negative for foot-and-mouth disease serology, and clinically healthy in the epidemic-free area. If clinical symptoms of foot-and-mouth disease are found, the serological monitoring is positive, according to OIE and the national governments of both parties The prescribed processing.

(5) Movement control

- 1. Susceptible animals should be kept in the centralized breeding area for more than 45 days before being transferred to the epidemic-free area, and there should be no clinical symptoms of infectious diseases. Animals suspected of being infected should be eliminated in time.
- ·2. Animals must have traceable identification.
- ·3. Transport according to the stipulated transportation route.
- 4. Transport vehicles and tools should be cleaned and disinfected before and after use.

(6) Investigation, reporting and disposal of epidemic

- 1. Formulate emergency response plans for foot-and-mouth disease.
- •2. Conduct epidemiological investigations when a suspected footand-mouth disease epidemic occurs in centralized breeding areas, protected areas, and epidemic-free areas, and report the results of the investigation.
- 3. Once the epidemic situation is confirmed, establish an infection control area as soon as possible in accordance with the requirements of the OIE "Code", take emergency blockade and epidemic elimination measures to the infection control area, carry out thorough disinfection, effectively identify susceptible animals, stop transportation, and carry out emergency immunization and serology Surveillance and detection of non-structural protein antibodies of foot-and-mouth disease virus, culling and harmless treatment of confirmed infected animals on the spot.

(6) Investigation, reporting and disposal of epidemic

- ·4. Within 28 days from the occurrence of the epidemic to the confirmation of culling, the epidemic-free areas affected by the epidemic will suspend the export of animals for slaughter, the affected protected areas and centralized breeding areas will suspend the transportation of susceptible animals to the epidemic-free areas, and infection control is strictly prohibited The susceptible animals and their products in the area are transferred to the epidemic-free area or exported. Carry out continuous monitoring in infection control areas, and implement passive and targeted monitoring in epidemic-free areas, protected areas, concentrated breeding areas and other areas affected by the epidemic. Relevant areas can be reactivated after corresponding measures are taken and confirmed by the official veterinary department.
- ·5. The emergency personnel and materials are adequately guaranteed.
- 6. Veterinary institutions and veterinary laboratories shall promptly conduct diagnostic tests and emergency treatment of suspected cases.

(7) Record management

• A work record system should be established for each work link. The records should be standardized, accurate, and complete, and should be kept in a unified manner for future reference.

Content

4. Application of the principle of equivalence in China

(1) Establish an appropriate level of animal health protection in China

·"List of Entry Animal Quarantine Diseases of the People's Republic of China"

• Refer to the OIE List of Statutory Reported Animal Diseases, in accordance with the provisions of the Animal Epidemic Prevention Law of the People's Republic of China, the Entry and Exit Animal and Plant Quarantine Law of the People's Republic of China, and the National Medium and Long-term Animal Disease Prevention and Control Plan (2012-2020), on the basis of risk assessment, the "List of Entry Animal Quarantine Diseases of the People's Republic of China" and the "List of Type I, II, and III Animal Diseases" were formulated.

The total number of diseases listed is 211

- 16 are Class 1 disease, 154 are Class 2 disease, 41 are others.
- When entering animal quarantine, if Class 1 disease is detected, the entire group of animals shall be returned or the group shall be culled, and the carcasses shall be destroyed. When Class 2 infectious diseases or parasitic are detected, the diseased animals shall be returned or culled.

Class 1 diseases in the List of Entry Animal Quarantine Epidemics of the People's Republic of China

- Class 1 infectious disease and parasitic disease (List A disease, 16 species):
- Foot and mouth disease, Swine vesicular disease, Classical swine fever, African swine fever, Nipah virus encephalitis, African horse sickness, Contagious bovine pleuropneumonia, Bovine spongiform encephalopathy, Lumpy skin disease, scrapie, Bluetongue, Peste des petits ruminants, Sheep pox and Goat pox, highly pathogenic Highly pathogenic avian influenza, Newcastle disease, Ebola haemorrhagic fever

(2) Conducting an overseas accreditation assessment in accordance with international rules

 Developed overseas evaluation procedures, including questionnaires, evaluation points, and evaluation procedures, all of which are equivalent to adopting OIE standards.

·(3) Equivalent adoption of OIE accreditation results

- In 2007, the results of the regionalization of foot-and-mouth disease in Argentina were recognized.
- The regionalization results of Brazil's foot-and-mouth disease were recognized in 2009.
- In 2016 and 2018, the results of the regionalization of Kazakhstan's foot-and-mouth disease were recognized twice
- In 2018, the results of the regionalization of Colombia's foot-and-mouth disease were recognized.
- Recognize the regionalization results of South Africa's foot-andmouth disease in 2019.
- Recognize the regionalization results of Russia's foot-and-mouth disease in 2019.
- The results of the regionalization of Botswana's foot-and-mouth disease will be recognized in 2020.

中华人民共和国国家质量监督检验检疫总局中 华 人 民 共 和 国 农 业 部

公 告

2016年第94号

质检总局 农业部关于解除哈萨克斯坦国 部分地区口蹄疫禁令的公告

根据我国对哈萨克斯坦国口蹄疫疫情状况的风险分析结果。



中华人民共和国海关总署中华人民共和国农业农村部

公 告

2018年 第36号

根据风险分析结果,自本公告发布之日起,认可哈萨克斯坦 共和国阿拉木图州(Almaty)、东哈萨克斯坦州(East Kazakhstan)、 南哈萨克斯坦州(South Kazakhstan)、江布尔州(Zhambyl)和克 致勒奥尔达州(Kyzylorda)5个州为免疫无口蹄疫地区。

原国家出入境检验检疫局 1999 年第 22 号公告对哈萨克斯坦 上述 5 个地区的口蹄疫疫情禁令同时终止。

特此公告。





(4) To assist in the construction of epidemic-free areas

In view of the fact that the regionalization of OIE is only a principled regulation, there is no specific implementation standard. In order to help relevant countries to prevent and control animal diseases and promote international trade of products, China has formulated standards for the construction of overseas FMD-free areas to make the construction of epidemic-free areas more convenient. Implementation and technical assistance. Currently, Mongolia, Laos and other countries have been helped to build foot-andmouth disease immunization areas. and the export of slaughtered sheep and slaughtered cattle to China has been realized. Cooperation agreements have been signed with Pakistan, Kyrayzstan and other countries on the construction of footand-mouth disease-free areas, and relevant construction work is being actively promoted.

Memorandum on the requirements of FMD free zone v varcination is practiced between the State Inspectoral Veterinary and Phytosanitary Security under the Governm Kyrgyr Republic and the General Administration of Cu the People's Republic of China

The State Impoctorate for Veterinary and Phytosanstary Sectific Government of the Kyrgyz Republic and the Main Administration of the People's Republic of China hereinafter togeth to as the "Parties", within the scope of their competence, for the export of articolary) unimals and their products from the Kyrgyx S the People's Republic of China, the General Administration of C The People's Republic of China through friendly discussions, have sign this Memorandam "On the establishment of a free assue from Soct and mouth disease, where vaccination is reactived."

The free some from Soci and would disease on the territory of the Kyrgyst Republic should be provided according to the agreed common requirements, and the Chinese side will render technical assistance and support.

For the purpose of implementation of this Monoraration, the Parties will early out bilateral consultations, if accessing, as well as by murical consent of the Parties amendments and abbitions may be made issued to this Monoraration by separate protocols that will be an integral part of this Memorandum.

The Memorandism occurs into force from the date of its signing by the Parties for a period of 5 years and is automatically extended for the scent 5 years periods unless neither party notifies the other party of its intention to nominane it in written form at least these months prior the expiration of the next rehresat period.

This Memorandum is signed in the city of Beijing, on 6th June 2018, in deplicate, in Chinese, Russian, and English languages, in case of disagreement in the interpretation of the tool, the Parties will refer to the text

Memorandam on the requirements of Foot and Month Disease (FMD) free zone where vaccination is practiced between the General Administration of Customs of the People's Republic of China and the Ministry of National Food Security&Resmarch of the Islamic Republic of Pakistan

The General Administration of Customs of the Pumple's Republic of China and the Ministry of Variance Food Successy Affectives of the Intensic Republic of Palistan Inscisable: reduced to individually as "Parry" or cellectively as the "Parties" William the scope of their computation, for the purpose of expect of articolocyl animals and their products from the Islamic Republic of Palistan to the Propile's Republic of Coins, the General Administration of Customs of the Propile's Republic of Crista, farringh through discussions, here agreed to sign this Memorandians "On the outablications of the Propile" is Republic of Crista, farringh through discussions, here agreed to sign this Memorandians "On the outablications of Foot and Month Discusso(TMD) Fine Zone, where vaccination will be practiced "The PMD free zone will be constructed within the territory of the Intensic Republic of Palistan according to the agreed common requirements of parties, and the Chinana date will market reduction assistance and support.

For the purpose of implementation of this Monormodors, the Parties will some and Material commitations, if necessary, amendments and additions protected may be made based on motaut council of the parties, those protected that will be considered as an integral part of this Microrroticlem and abundable customed into femo on the date of signatures by the parties.

All the differences and disputes from or concerting with the application or insupposition of this Microcandom shall be articably settled through named annualisations and repolations between the Parties.

In order to ensure the effective implementation of coordination under the nanominables, the Parties may designate their respective fixed persons.

This memorandum corner into force from the date of its eigentures by the Parties for a period of 5 years and will be automatically extended for the next 5 years periods unless either Party notifies the other Party of its intention to

(5) Explore new management models

 With regard to highly pathogenic avian influenza, which is spread by migratory birds, and African swine fever is spread by wild animals and tick-borne diseases, OIE has no regulations for regional recognition of these diseases. China is cautious about these diseases and actively explores biosafety isolation. The regionalization management model is cooperating with France to study and formulate African swine fever regionalization/biosafety isolation zoning management standards, and explore the feasibility of regionalization/biosafety isolation zoning management measures, so as to mutually recognize management results and develop service trade. Developed the standards for the construction of biosafety isolation zones for highly pathogenic avian influenza, and carried out technical cooperation with Russia, the United States, and the European Union.

·(6) Equivalent adoption of OIE standard

• For products that are not affected by the epidemic as stipulated by the OIE Code, China has formulated a positive list of products that are not affected by the epidemic on the basis of risk analysis, allowing animal products that are free of the risk of disease transmission or that meet the processing requirements to enter the country. If it is equivalent to adopting OIE regulations, deboned beef will not be restricted by bovine nodular skin diseases. The fur that meets the OIE process is not restricted by the epidemic situation of foot-and-mouth disease. Specific management measures have also been adopted for the import of fur from the five Central Asian countries.

Content

5. PRC achievement on regionalization of animal disease management

5. PRC achievement on regionalization of animal disease management

OIE's recognition of China's regionalization

- In May 2010, the European Union issued Resolution No. 2010/266, recognizing my country's Guangzhou Conghua's noregulated equine animal disease area, and including this area in the list of countries and regions that can permanently export horses to the European Union, which was the 16th meeting of the year. The Asian Games equestrian competition laid a good foundation. This area was approved by the OIE Non-Regulated Equine Disease Area in 2013.
- In 2014, the 82nd OIE International Congress recognized that China has obtained the status of no rinderpest, no bovine pneumonia, no African horse plague, and negligible risk of mad cow disease.
- The 88th International Congress in 2020 approved the maintenance of China's mad cow disease risk status as negligible, and China has no rinderpest, no bovine lung disease, and no African horse plague status.

5. PRC achievement on regionalization of animal disease management

Biosecurity quarantine area construction

- According to the relevant regulations and guidelines of OIE epidemic-free areas, combined with the actual situation of epidemic prevention and control in my country, the "African Swine Fever Free Area Standard" and the "Technical Specifications for the Management of Areas Without Regulations for Animal Diseases" and "Management Techniques for Areas Without Regulations for Animal Diseases" were formulated Specification" and so on. The construction of foot-and-mouth disease, avian flu, African swine fever free zones and biosafety quarantine zones is underway in China.
- · Equine melioidosis and equine-borne anemia have been included in the national elimination plan.

Thank you!