World Organisation for Animal Health

Australian Government
Department of Agriculture, Fisheries and Forestry

Data requirements and documentation for audits and regulatory approval

Bill Wang Shuaibiao

General Manager & Veterinarian
DanAg International

Sub -regional training workshop on zoning and compartmentalisation in the facilitation of safe trade, 28-30 April 2026

Presentation covers

- Define essential documentation requirements for audit readiness
- Outline data systems that support regulatory approval processes
- Explain compliance verification frameworks and audit protocols
- Share China's practical implementation as one successful reference model
- Discuss adaptation strategies for diverse national contexts

The Audit and Approval Landscape

Types of Audits:

- Internal audits (self-assessment)
- Third-party certification audits
- Government regulatory inspections
- International/WOAH recognition assessments

Approval Pathways:

- National regulatory approval
- WOAH official disease status recognition
- Self-declaration of disease-free status
- Trading partner acceptance

Common Requirements: All require robust, verifiable documentation

Regulatory Framework Overview

- Chapter 4.4: Zoning and Compartmentalisation
- Chapter 4.5: Application of Compartmentalisation
- ASF Compartmentalisation Guidelines (2021)

WOAH Standards

(Terrestrial Code)

- Veterinary authority oversight
- Legal basis for zone/compartment establishment
- Enforcement mechanisms

National Legislation Requirements

- Bilateral/multilateral recognition
- SPS Agreement compliance (WTO)
- Regional harmonization (ASEAN context)

International Trade Agreements

Documentation Systems Architecture

Three-Tier Documentation Framework:

Strategic Level:

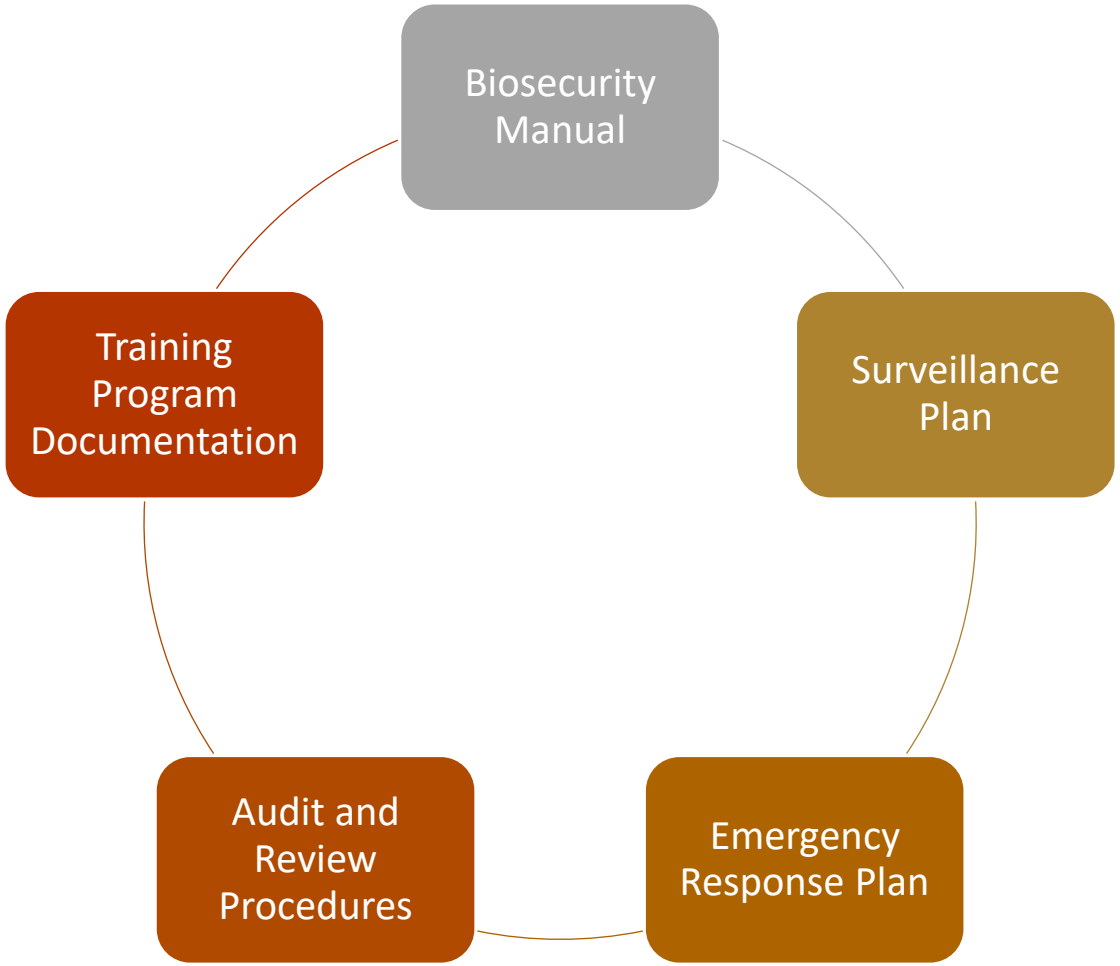
Policies, standards, certification requirements

Operational Level:

SOPs, protocols, monitoring plans

Transactional Level:

Daily records, logs, test results

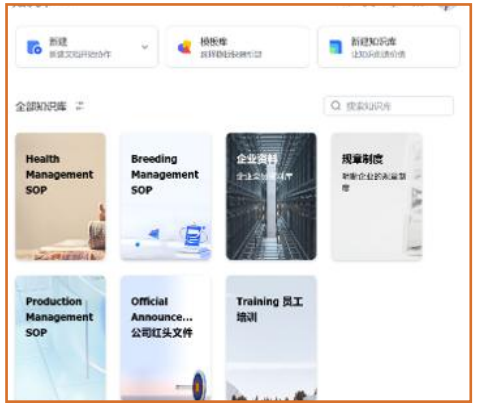


Core Documentation Requirements

Governance and Legal Documentation

- Legal basis for compartment/zone establishment
- Veterinary authority oversight agreements
- Organizational structure and responsibilities

Technical Documentation



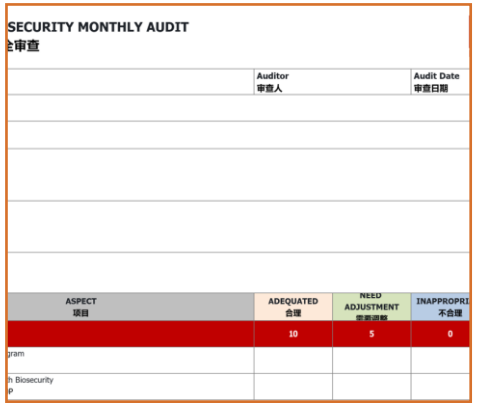
- Detailed description of zone/compartment boundaries
- Biosecurity protocols and SOPs
- Surveillance plan and testing protocols

Operational Records

猪群阶段	检测项目	试剂类型	数量	
	ASFV	试剂	21	
		核酸	20	
	PRRSV	试剂	1	
		核酸	0	
环境	PRRSV	试剂	9	
		核酸	0	
环境	PEDV	试剂	9	
		核酸	0	
仔猪	RV	试剂	1	
		核酸	1	
仔猪	PEDV	试剂	1	
		核酸	0	
仔猪	梭菌	试剂	1	
		核酸	0	

- Daily monitoring logs
- Movement control records
- Training and competency records

Compliance Verification

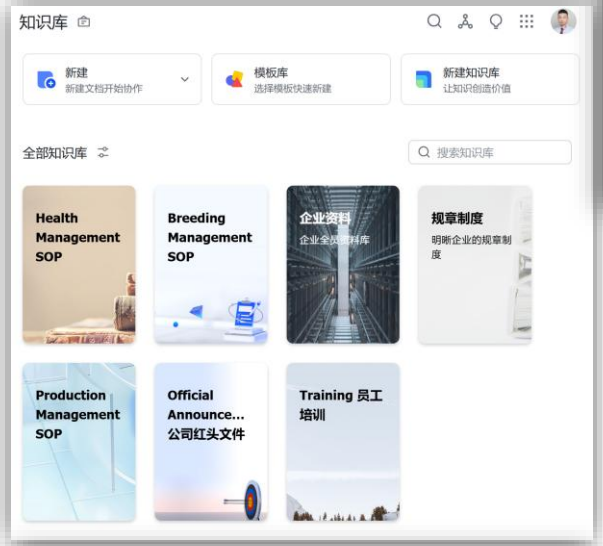

SECURITY MONTHLY AUDIT
全审查

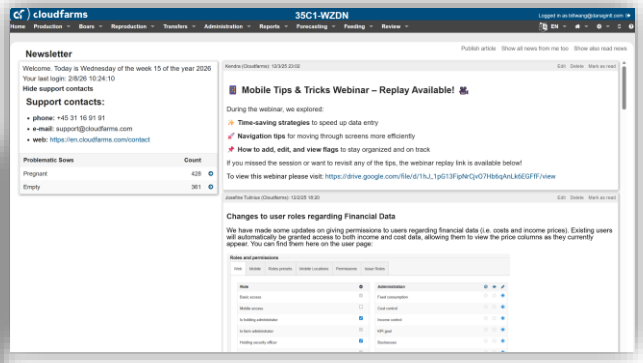
	Auditor 审查人	Audit Date 审查日期

ASPECT 项目	ADEQUATED 合理	NEED ADJUSTMENT 需要调整	INAPPROPRI 不合理
	10	5	0
gram			
h Biosecurity P			

- Audit reports and corrective actions
- Third-party certifications
- Laboratory accreditation documents

Data Systems Architecture





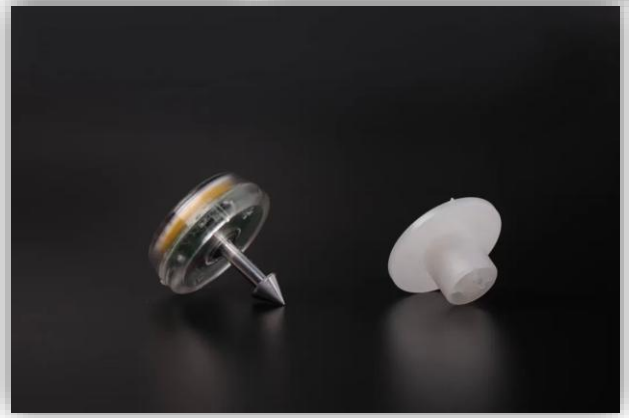
Centralized database with cloud backup

Mobile applications for field data collection

System Architecture:

GPS tracking for vehicle movements

RFID/electronic ear tags for animal identification



Data Requirements for Audit Readiness

Traceability Data

- Complete animal identification and movement history
- Supply chain documentation (feed, genetics, equipment)
- Personnel and visitor access logs

Health and Surveillance Data

	P	Q	R
群段	检测项目	试剂类型	数量
	ASFV	试剂	6
		核酸	6
	PRRSV	试剂	7
		核酸	0
育猪	RV	试剂	3
		核酸	2
	PEDV	试剂	2
		核酸	0
	梭菌	试剂	2
		核酸	0

- Testing results with the laboratory chain of custody
- Vaccination records with batch numbers
- Mortality and morbidity records with diagnosis

Biosecurity Compliance Data

- Access control verification logs
- Cleaning and disinfection records
- Equipment movement and sanitization logs

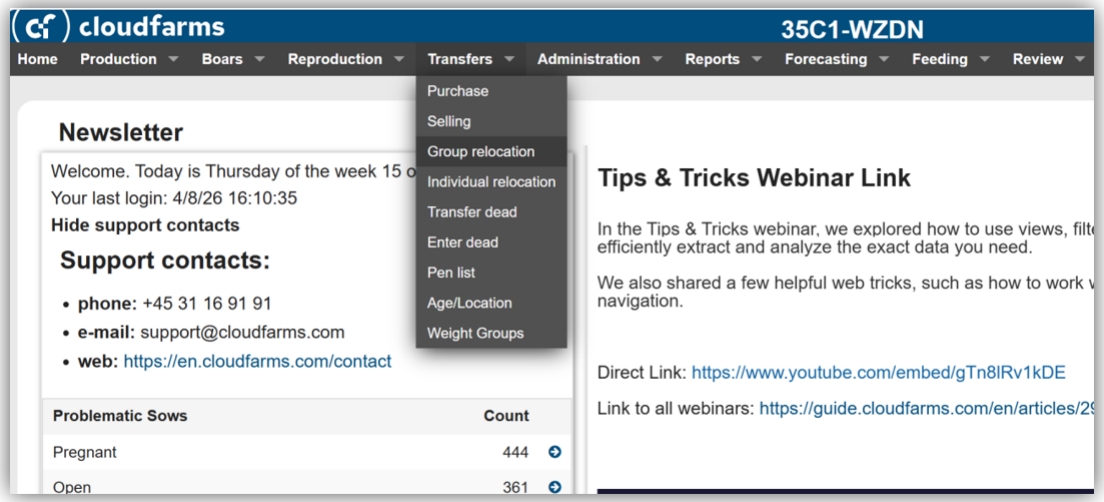
Management System Data

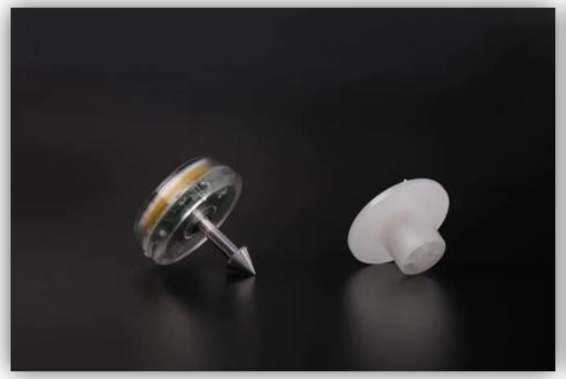
调整进程和现状 ementation/adjustment process and status	A. 已经执行 B. 正在执行 C. 尚未执行	
舍 owing room		
问题 Issues	建议 Recommendation	现状 Status
分娩舍单元烘干 Farrowing Unit drying	1. 单元自然温度大于 20°C以上时，取消烘干炮烘干操作（产房 3 单元实验），打开正压通风、地沟风机和地暖促进干燥。When the natural temperature of the unit exceeds 20°C, cancel the drying operation (unit 3 experiment), and turn on positive pressure ventilation, trench fans, and underfloor heating to promote drying. 2. 如果取消烘干炮烘干不能达到干燥效果，将现有的 3 次烘干减少为 1 次烘干。If canceling the drying gun cannot achieve the drying effect, reduce the existing 3 drying times to 1 drying time.	A B C ☑ ☐ ☐
神经症状倒地 neurological symptoms	保持单元压力 8-12Pa。在现有治疗药物上加 1 针地塞米松（1ml/1kg 体重）。Maintain a unit pressure of 8-12 Pa and add a dose of dexamethasone to the existing therapeutic medication.	A B C ☑ ☐ ☐
三生品牌的氯前列醇的使用效果不好 The SanSheng brand of cloprostenol is not very effective.	三生品牌的氯前列醇使用后，分娩启动时间变晚导致分娩高峰在夜间，对少数母猪无明显作用，建议更换回原来的三马品牌氯前列醇。After using Sanyong's cloprostenol, the onset of labor was delayed, resulting in a peak birthing time during the night, with no significant effect on a small number of sows. It is recommended to switch back to the original Sanyang brand cloprostenol.	A B C ☐ ☑ ☐

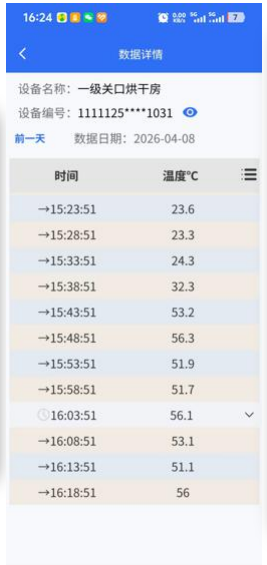
- Training completion records
- Corrective action tracking
- Management review meeting minutes

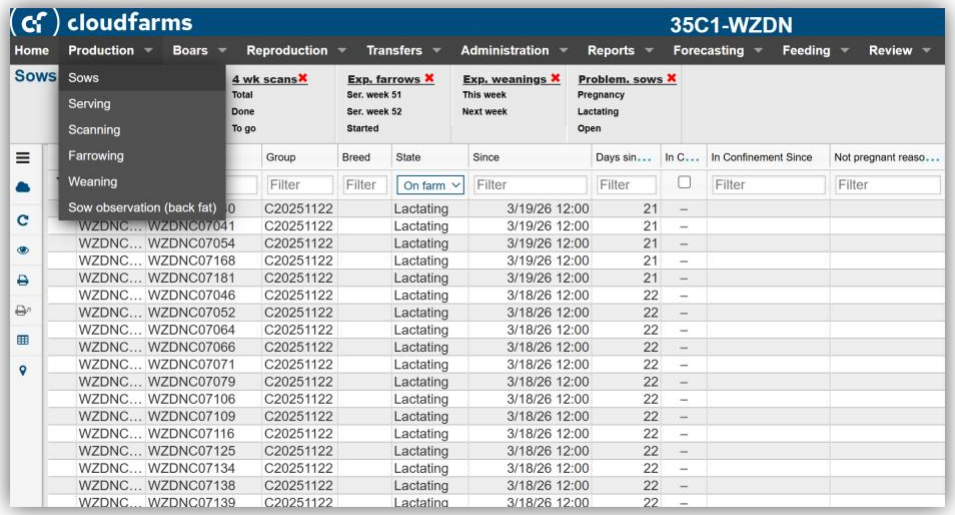
Traceability Data

- Complete animal identification and movement history
- Supply chain documentation (feed, genetics, equipment)
- Personnel and visitor access logs



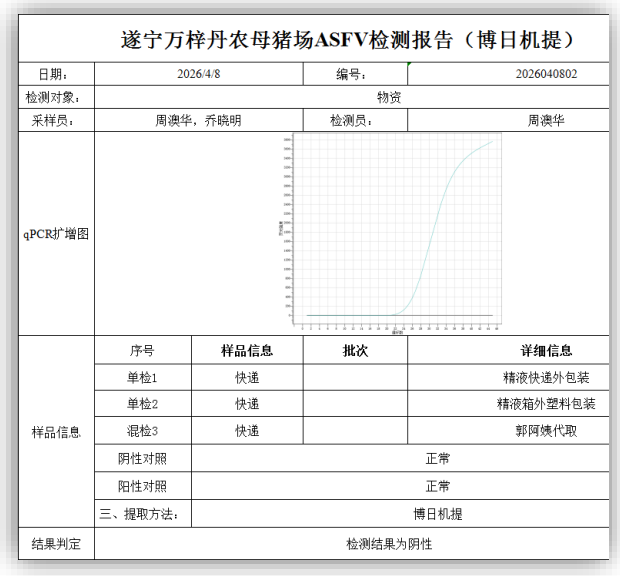






Health and Surveillance Data

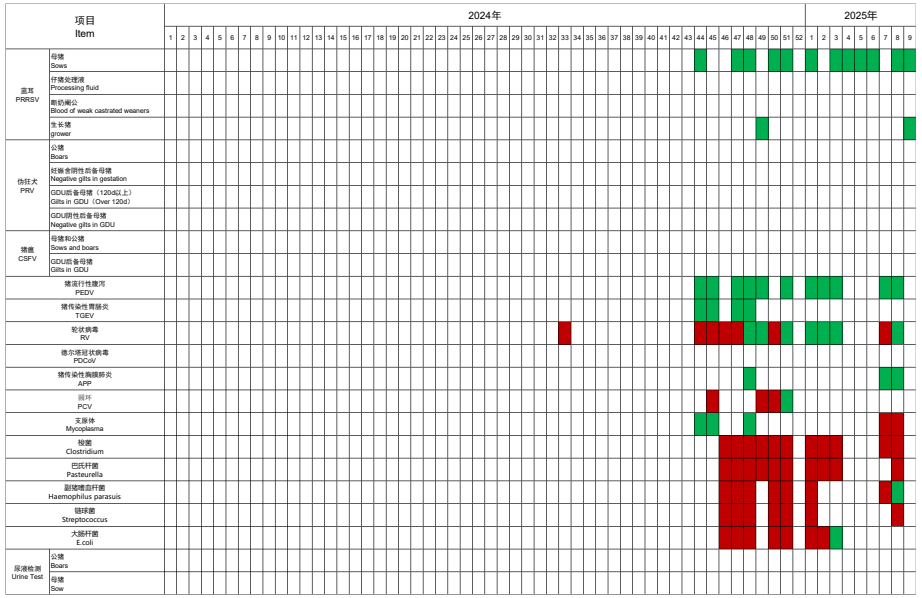
- Testing results with the laboratory chain of custody
- Vaccination records with batch numbers
- Mortality and morbidity records with diagnosis

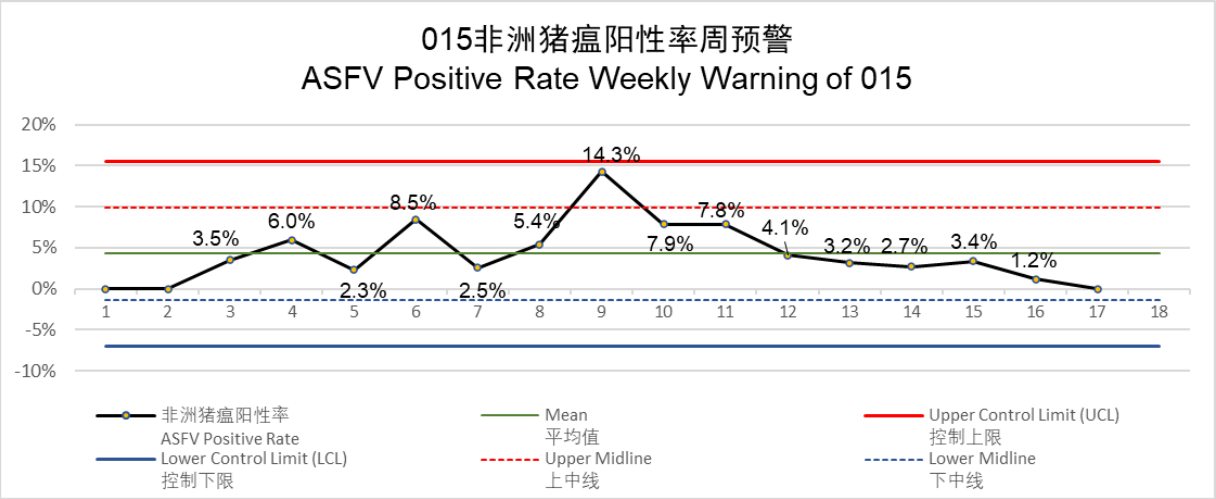


遂宁万梓丹农母猪场ASFV检测报告（博日机提）

日期：	2026/4/8	编号：	2026040802
检测对象：	物资		
采样员：	周澳华，乔晓明	检测员：	周澳华
qPCR扩增图			

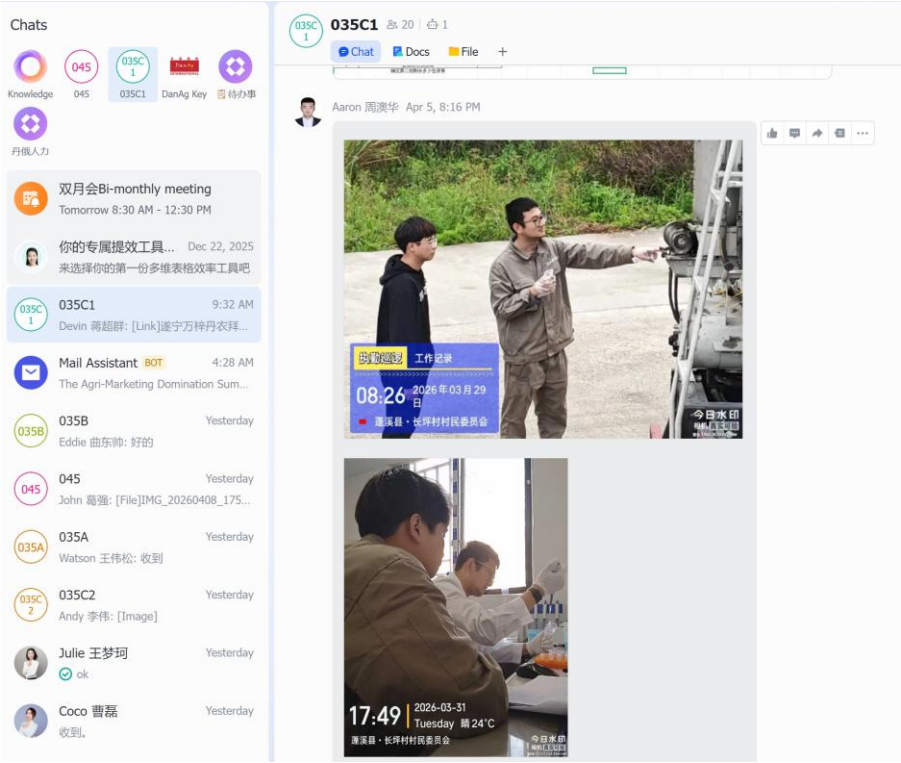
样品信息	序号	样品信息	批次	详细信息
	单检1	快递		精液快递外包装
	单检2	快递		精液箱外塑料包装
	混检3	快递		郭阿姨代取
	阴性对照	正常		
	阳性对照	正常		
	三、提取方法：	博日机提		
结果判定	检测结果为阴性			

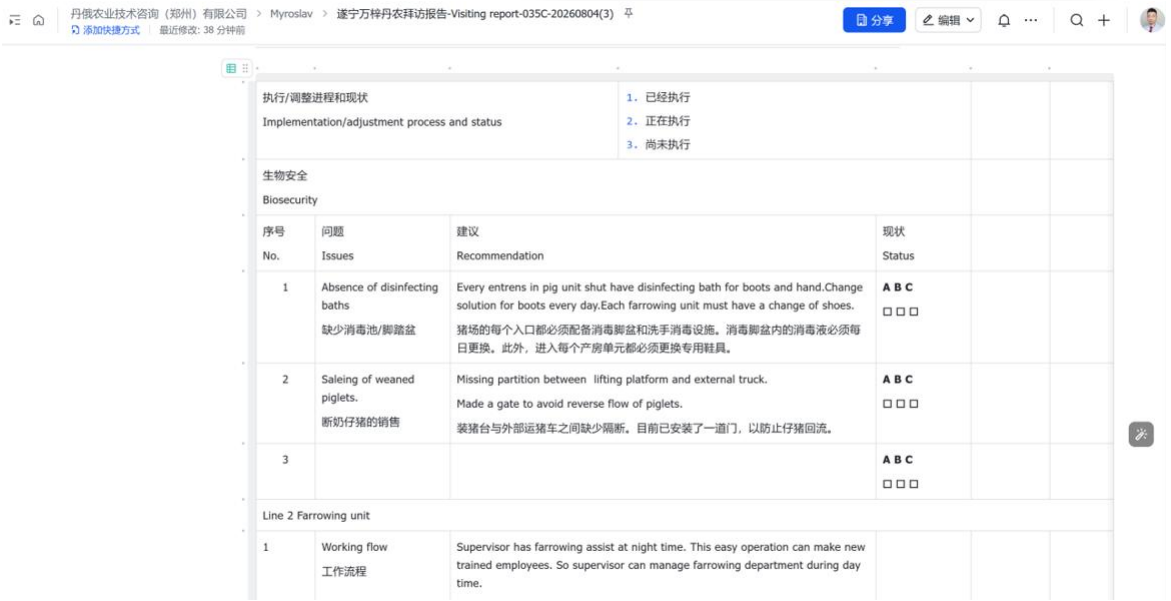




Biosecurity Compliance Data

- Access control verification logs
- Cleaning and disinfection records
- Equipment movement and sanitization logs





丹俄农业技术咨询（郑州）有限公司 > Myroslav > 遂宁万梓丹农拜访报告-Visiting report-035C-20260804(3)

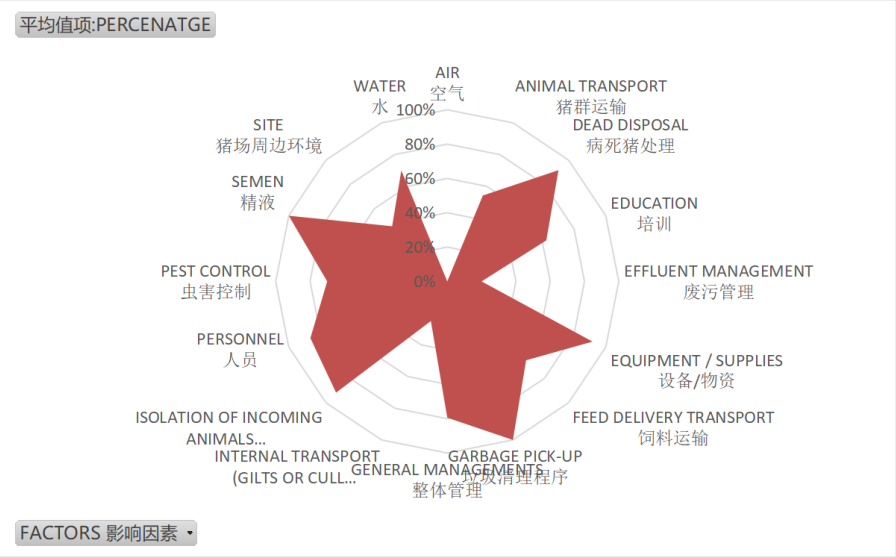
添加快捷方式 最近修改: 38 分钟前

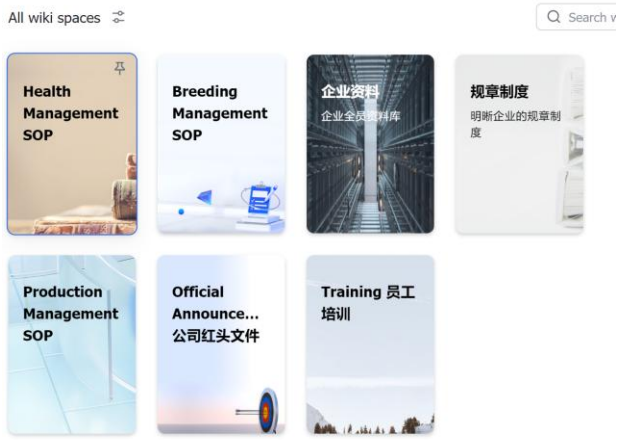
分享 编辑

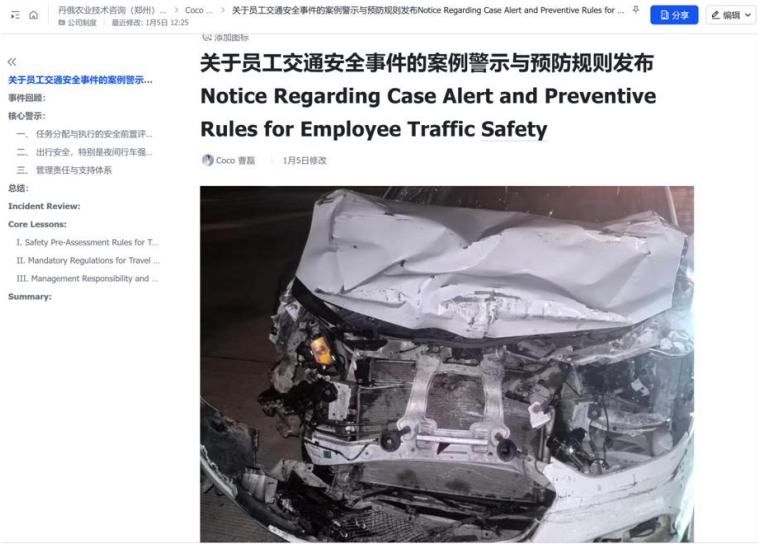
执行/调整进程和现状 Implementation/adjustment process and status		1. 已经执行 2. 正在执行 3. 尚未执行		
生物安全 Biosecurity				
序号 No.	问题 Issues	建议 Recommendation	现状 Status	
1	Absence of disinfecting baths 缺少消毒池/脚踏盆	Every entrens in pig unit shut have disinfecting bath for boots and hand.Change solution for boots every day.Each farrowing unit must have a change of shoes. 猪场的每个入口都必须配备消毒脚盆和洗手消毒设施。消毒脚盆内的消毒液必须每日更换。此外，进入每个产房单元都必须更换专用鞋具。	A B C □ □ □	
2	Saleing of weaned piglets. 断奶仔猪的销售	Missing partition between lifting platform and external truck. Made a gate to avoid reverse flow of piglets. 装猪台与外部运猪车之间缺少隔断。目前已安装了一道门，以防止仔猪回流。	A B C □ □ □	
3			A B C □ □ □	
Line 2 Farrowing unit				
1	Working flow 工作流程	Supervisor has farrowing assist at night time. This easy operation can make new trained employees. So supervisor can manage farrowing department during day time.		

Management System Data

- Training completion records
- Corrective action tracking
- Management review meeting minutes







Audit Process and Documentation Flow

Pre-Audit Phase

- Documentation compilation and review
- Gap analysis against standards
- Internal audit completion

Audit Execution Phase

- Evidence presentation (documents, records, data)
- On-site verification and interviews
- Real-time data system demonstrations

Post-Audit Phase

- Non-conformance documentation
- Corrective action plans and evidence
- Follow-up verification records

Continuous Compliance

- Regular document updates
- Version control systems
- Record retention protocols

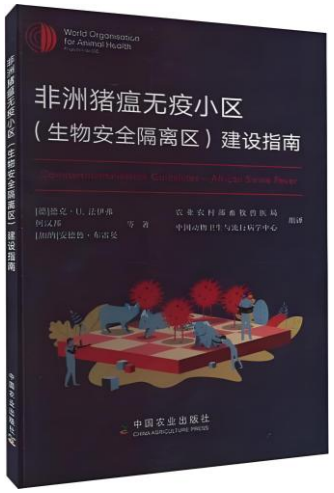
China ASF Free Compartment Program Overview

Context and Scale:

- Initiated 2019 following the ASF introduction to China (2018)
- 281 certified ASF-free compartments (as of 2025)
- National standard: “Management Technical Specifications for Disease-Free Compartments.”

Why China is a Useful Reference:

- Large-scale implementation across diverse production systems
- Rapid development of a standardized evaluation framework
- Integration of digital technologies
- Balance between enterprise responsibility and government oversight



China's 80-Item Evaluation Framework

China's 80-Item Evaluation Framework

Category	Items	Key Focus
Basic Requirements	12	Legal status, geographic boundaries, qualifications
Biosecurity Management	40	Manuals, SOPs, risk assessments, internal audits
Official Oversight	16	Veterinary agency capability, surveillance
Disease Status	12	12-month ASF-free evidence, traceability

42 Regular Items

- General compliance expected

28 Focus Items

- ≤15% "basic compliance" allowed

10 Key Items

- Must all pass
- Provincial approval, legal entity, biosecurity manual, traceability system, veterinary qualifications, 12-month surveillance

China's 80-Item Evaluation Framework

CATEGORY 1: Basic Requirements

Legal status, geographic conditions, and foundational documentation

2 Critical	3 Key Focus	7 Standard

1.1.	Provincial veterinary authority approval document	
1.2.	Enterprise legal entity qualification certificate	
1.3.	Animal epidemic prevention qualification certificate	
1.4.	Geographic concentration within 200km radius	
1.5.	3km buffer zone establishment documentation	
1.6.	12-month ASF-free surveillance evidence	
1.7.	Breeding/seed stock production license (if applicable)	
1.8.	Slaughter/processing license (if applicable)	
1.9.	Feed production license (if applicable)	
1.10.	Waste disposal qualification certificate	
1.11.	Wildlife and vector survey report	
1.12.	Epidemiological isolation assessment	

China's 80-Item Evaluation Framework

CATEGORY 2: Biosecurity Management

Organization, risk assessment, barriers, personnel, vehicles, and materials

2 Critical | 12 Key Focus | 26 Standard | Total: 4

- 2.1.1. Biosecurity management manual
- 2.1.2. Biosecurity organizational structure
- 2.1.3. Designated biosecurity manager
- 2.1.4. Qualified veterinary personnel
- 2.1.5. Biosecurity training program
- 2.1.6. Annual training assessment
- 2.1.7. Biosecurity responsibility system
- 2.1.8. External institution cooperation
- 2.2.1. Risk assessment report
- 2.2.2. Risk factor identification
- 2.2.3. Risk classification criteria
- 2.2.4. Risk control evaluation
- 2.2.5. Risk assessment review
- 2.2.6. Major risk emergency plan
- 2.3.1. Perimeter fencing
- 2.3.2. Entry/exit control points
- 2.3.3. Vehicle wash station
- 2.3.4. Material disinfection channels
- 2.3.5. Pig transfer corridors
- 2.3.6. Dead animal disposal facilities
- 2.3.7. Bird/rodent prevention
- 2.3.8. Water source protection
- 2.4.1. Entry protocol (quarantine)
- 2.4.2. Personnel health monitoring
- 2.4.3. Visitor management system
- 2.4.4. Personnel movement tracking
- 2.4.5. Leave/return management
- 2.4.6. Contractor management
- 2.5.1. Vehicle classification system
- 2.5.2. Wash protocol validation
- 2.5.3. Vehicle GPS tracking
- 2.5.4. Driver & route management
- 2.5.5. Vehicle sampling & testing
- 2.5.6. Maintenance & calibration
- 2.6.1. Feed source verification
- 2.6.2. Feed transport biosecurity
- 2.6.3. Drug/vaccine management
- 2.6.4. Genetic material traceability
- 2.6.5. Equipment disinfection
- 2.6.6. Package management

ASF Free Compartment Assessment | Based on China Standards & WOAH Guidelines

China's 80-Item Evaluation Framework

CATEGORY 3: Disease Surveillance

Monitoring protocols, laboratory testing, and response systems

3 Critical	3 Key Focus	6 Standard

Critical	3.1.	Surveillance protocol & annual monitoring plan
Key Focus	3.2.	Clinical inspection system & records
Key Focus	3.3.	Active surveillance sampling plan
Standard	3.4.	Sampling methods & submission protocols
Critical	3.5.	Laboratory testing capability & accreditation
Key Focus	3.6.	Test method validation & quality control
Standard	3.7.	Test results documentation
Critical	3.8.	Positive result reporting & response protocol
Standard	3.9.	Surveillance data analysis
Standard	3.10.	Surrounding area disease monitoring
Standard	3.11.	Post-mortem examination protocols
Standard	3.12.	Vector & wildlife monitoring

China's 80-Item Evaluation Framework

CATEGORY 4: Traceability & Official Oversight

Animal identification, production records, and regulatory supervision

3 Critical	3 Key Focus	10 Standard

- 4.1.1. Animal ID & pedigree recording system
- 4.1.2. Complete production records
- 4.1.3. Feed & input use records
- 4.1.4. Vaccination & medication records
- 4.1.5. Pig movement & transportation records
- 4.1.6. Traceability data to national platform
- 4.1.7. Data retention (minimum 2 years)
- 4.1.8. Traceability system validation
- 4.2.1. County veterinary supervision plan
- 4.2.2. Regulatory agency staffing
- 4.2.3. Routine inspection records
- 4.2.4. Sample collection records
- 4.2.5. Disease reporting & emergency response
- 4.2.6. Enforcement records
- 4.2.7. Regular communication mechanism
- 4.2.8. Information disclosure protocols

China's 80-Item Evaluation Framework

10 Critical Items for ASF Free Compartment Assessment

非洲猪瘟无疫小区评审关键项（必须100%符合）

1. Provincial Approval Document
   省级主管部门批复文件
2. Enterprise Legal Entity Status
   企业法人实体资格
3. Animal Health Qualification Certificate
   动物防疫条件合格证
4. 12-Month ASF-Free Status
   12个月无非洲猪瘟病例
5. Biosecurity Management Manual
   生物安全管理手册（完整）
6. Qualified Veterinary Personnel
   专职兽医人员资格证书
7. Surveillance Plan & Annual Program
   监测方案及年度监测计划
8. Laboratory Testing Capability
   实验室检测能力及资质
9. Positive Result Response Protocol
   阳性结果报告及处置程序
10. Animal ID & Traceability System
    生猪标识及追溯体系完整

 All 10 items must pass (100% compliance required) | 关键项必须全部符合，一项不符合即评审不通过

China's 80-Item Evaluation Framework

Written review (5 days): Completeness and scientific validity

On-site review (5 days): Physical verification and system operation

Results: Pass (≥80%), Conditional pass (60-80%), Fail (<60%)

Key Innovations from China's Experience

National Digital Platform (fda.cahec.cn)

- Standardized electronic application system
- Real-time status tracking
- Centralized document repository
- Automated compliance alerts

Three-Level Assessment System

- County-level: Initial screening
- Provincial-level: Comprehensive assessment
- National-level: Expert panel final review

Results Achieved

- 95% first-time certification pass rate
- 70% reduction in audit preparation time (compared to paper systems)
- Successful inter-provincial and international movement permits

Continuous Compliance Mechanisms

- Annual status reports (by February 28)
- Triennial comprehensive re-assessment
- Provincial spot-checks and maintenance audits

Lessons from China - What to Adopt vs. Adapt

Elements Highly Transferable to SE Asia

- Structured evaluation checklists
- Digital documentation systems (can use simpler platforms)
- Internal audit requirements
- Clear data retention standards
- Multi-stakeholder coordination frameworks

Elements Requiring Adaptation

- Three-tier assessment may need simplification in smaller countries
- 80-item detail level may be excessive for initial programs
- Digital platform investment may need phased approach
- Large-scale enterprise focus may need adjustment for smallholders

Context-Specific Considerations

- Resource constraints: Start with essential documentation, expand over time
- Institutional capacity: Match assessment complexity to available expertise
- Production systems: Adapt requirements to local farming practices
- Disease status: Adjust surveillance intensity based on regional risk

Adaptation Framework for Southeast Asia

Foundation (Months 1-6)

- Adopt WOAH standard documentation categories
- Develop simplified evaluation checklist (start with 20-30 critical items)
- Establish data retention policies aligned with national regulations
- Pilot with 2-3 volunteer enterprises

System Development (Months 6-12)

- Expand to full WOAH documentation requirements
- Implement basic digital systems (spreadsheets or simple databases)
- Train veterinary and enterprise personnel
- Conduct initial assessments and refine processes

Regional Harmonization (Year 2+)

- Standardize requirements across participating countries
- Develop mutual recognition agreements
- Share laboratory and audit resources
- Progress toward WOAH official recognition

Success Factors:

Start simple, build complexity gradually
Ensure veterinary services capacity before enterprise requirements
Prioritize transparency over perfection
Plan for continuous improvement, not one-time compliance

Summary and Key Takeaways

Universal Principles (All Countries):

- WOAH standards provide the foundational framework
- A two-phase audit (documentary + on-site) is internationally recognized
- Four documentation categories essential: enterprise, biosecurity, surveillance, and traceability
- Data retention: minimum 2 years production, 3 years surveillance
- Digital systems improve efficiency, but are not mandatory

Summary and Key Takeaways

Implementation Insights (China Example):

- Detailed evaluation checklists improve consistency
- National digital platforms enable efficient management at scale
- Three-level assessment provides quality control
- High pass rate demonstrates feasibility with proper preparation

Summary and Key Takeaways

Adaptation Strategy:

- Use WOAH standards as the foundation
- Learn from China's large-scale experience
- Adapt complexity to local resources and context
- Build regional cooperation for mutual benefit

Thank you

Acknowledgements

World Organisation for Animal Health (WOAH)

Prof. Dirk Pfeiffer, Royal Veterinary College

DanAg International Team

Sub -regional training workshop on zoning and compartmentalisation in the facilitation of safe trade