



Regional Workshop on Animal Disease Preparedness

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Better Training For Safer Food

*Disease preparedness –
risk assessment*

Terminology

RISK – combination of the probability of occurrence of a hazard generating harm and severity of the harm

- HARM – injury or damage to the health of animals, people, environment
- HAZARD – potential cause of harm
- PROBABILITY OF OCCURRENCE OF THE HARM – the likelihood of the harm occurring

Terminology

Risk Assessment: a strategic approach to planning, at all levels and across all functions of an organization, that identifies exposures of activities and assists in making risk adjusted decisions...

Risk Assessment steps

The main steps of a risk assessment are:

- – Framing the risk question;
- – Identifying the hazard(s);
- – Outlining the risk pathways;
- – Identifying data needs;
- – Collecting data;
- – Assessing the risk.

Four components of risk analysis

HAZARD IDENTIFICATION

RISK ASSESSMENT

RISK MANAGEMENT

RISK COMMUNICATION AT ALL STAGES

Hazard identification

- Hazard identification is a **categorization step**, identifying biological agents as hazards or not.
- For exporting country;
 - Availability of disease information via OIE;
 - Evaluation of Veterinary Services;
 - Surveillance and control programmes;
 - Zoning and compartmentalization;
 - Animal identification and movement controls;
 - Early detection and notification.

Principles of risk assessment

Flexibility – no single method is applicable in all cases.

Both **qualitative and quantitative methods** are valid.

Transparency with all involved parties - cooperation.

Assessment must be based **on best scientific knowledge**, well documented and supported by references to scientific works.

Should be **updated with additional information** available

Risk assessment steps - Entry assessment

- Consists of describing the probability of the „entry“ of each of the hazards (pathogenic agents) under each specified set of conditions with respect to amount and timing and how these might change as a result of various actions, events.
- Possible **inputs for entry assessment.**
- **Biological factors:** species, age, breed, vaccination, testing, quarantine .

Entry assessment

Country factors: incidence or prevalence, evaluation of Veterinary Services, surveillance and control programmes and zoning and compartmentalization systems of exporting country;

Commodity factors: quantity of commodity to be imported, ease of contamination, effect of processing, effect of storage and transport.

Exposure assessment

Consists of describing the **pathway necessary for exposure** to the hazards and estimation of **probability of occurring**.

Biological factors: properties of the agent.

Country factors: presence of vectors, human and animal demographics, cultural practices, geographical characteristics.

Commodity factors: quantity of commodity, intended use of animals/products, disposal practices.

Consequence assessment

- Consists of **describing the relationship between specified exposures and the consequences.**
- **Direct consequences:** disease and production losses.
- **Indirect consequences:** surveillance and control costs, compensation costs, potential trade losses, adverse consequences to environment.

Risk estimation

Consists of **integrating the results of entry assessment, exposure assessment and consequence assessment.**

Output may include.

Estimated number of herds, animals, people affected;

Portrayal of the variance of all model inputs;

Sensitivity analysis to rank all inputs;

Analysis of the dependence and correlation between model inputs.

Risk management components

Risk evaluation: comparing the estimated risk in risk assessment with the reduction of risk by expected risk management measures

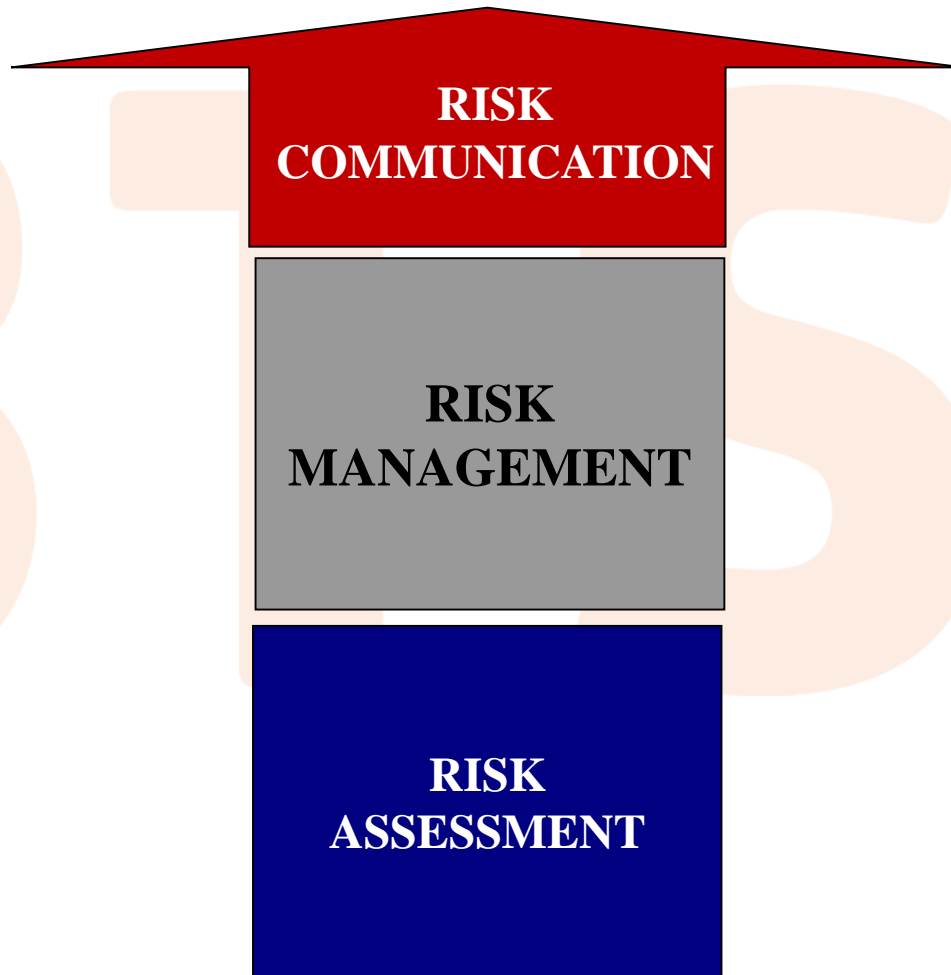
- **Option evaluation:** identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk.
- **Implementation:** process ensuring that selected risk management measures (finances, manpower, restrictions, culling) are in place.

Monitoring and review: risk management measures are constantly audited to ensure they achieve planned result.



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RISK COMMUNICATION



Risk communication


Process by which information about hazards and risks are gathered from potentially affected and interested parties during the risk analysis and by which the results of risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties.

- Strategy should be in place.
- Peer review is a component of risk communication to obtain scientific critique and to ensure the data, information, methods and assumptions are the best available.

RISK COMMUNICATION

- It's a consumer right to know, what's happened!
- The preventive effect;
- Gain trust;
- Prevent outrage;
- Find better solutions;
- Obtain understanding and support.

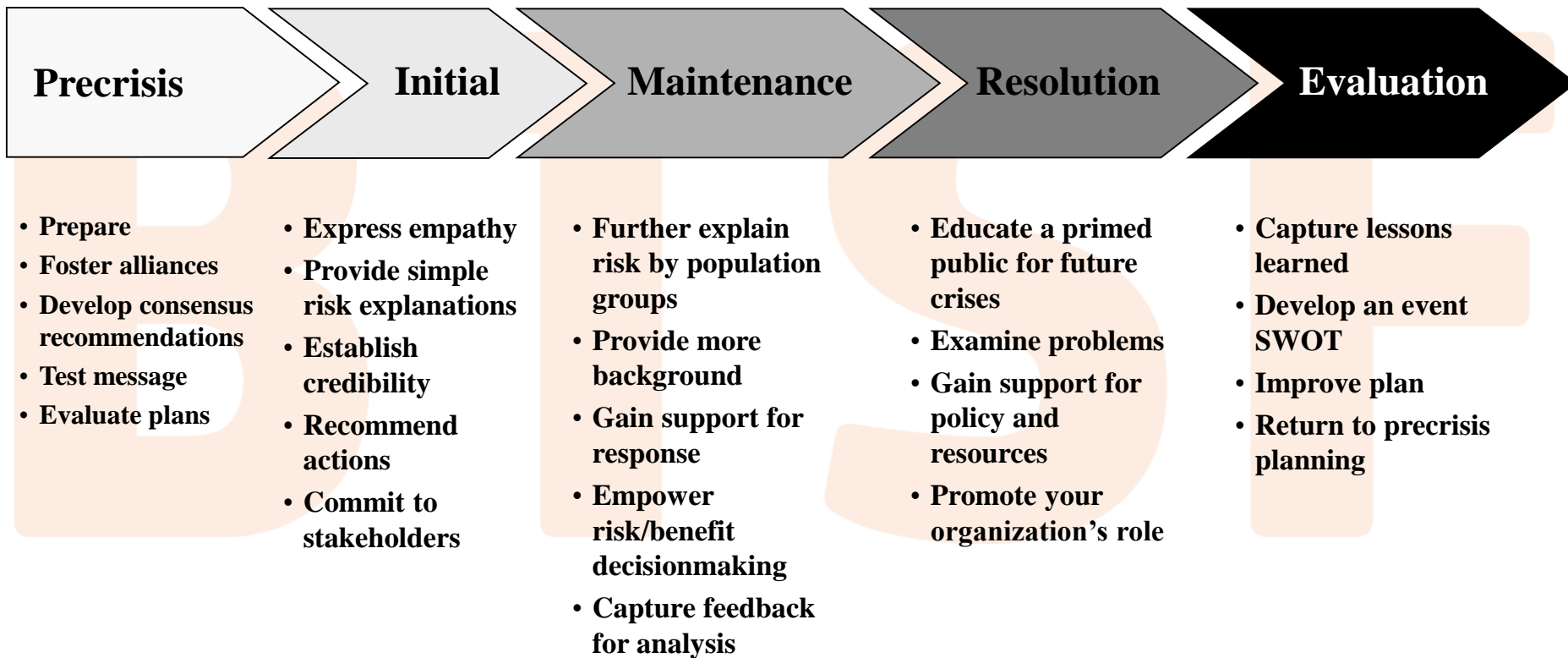
Communication is based on the main principles

- 
- Build trust;
 - Announce early;
 - Be transparent;
 - Respect public concerns;
 - Decrease fear;
 - Plan in advance.

Risk communication planning: summary



Crisis Communication Lifecycle







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B T S F
THANK YOU !!!



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Regional Workshop **on Animal Disease Preparedness**

Stefano Marangon

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Contingency planning

Epidemic disease emergencies

Emergency: a serious, unexpected and harmful event that requires **immediate action** and availability of **extra resources**

Disease emergency: introduction of a highly contagious disease in a free country or zone (exotic disease) such as FMD, AI, CSF, ASF

The aim of contingency planning is to arrange in advance for an epidemic that may or may not happen, if it happens:

- disease control and eradication actions shall be immediately enforced
- necessary resources must be available
- a legal and administrative framework shall be in place

Control of epidemic diseases of livestock

The efficacy of disease control measures is related to the capacity to limit the initial spread of infection during the **high risk period** of an epidemic:

- application of good biosecurity and hygienic standards (difficult to sustain in the long term)
- rapid identification of virus introduction (early detection)
- prompt enforcement of appropriate disease control policies

Contingency planning

The rapid implementation of adequate disease eradication measures is associated to the **level of preparedness** of the veterinary services in the affected country:

a contingency plan should be developed in times of peace

In case of infection the prompt execution of the measures provided for by the contingency plan is critical in limiting the magnitude of the epidemic mainly in **Densely Populated Livestock Areas (DPLAs)**

Contingency plan

A contingency plan

- Describes the **organization of the system** to be implemented for an effective disease control, and
- Identifies the **resources** which must be available in order to make this system operational (**resource manual**)
- Provides updated information on all the **procedures** to be followed and the **actions** to be carried out with suspect and confirmed outbreaks (**operational manual**)

Contingency plan

- Legal powers
- Financial provisions
- The chain of command
- The establishment of national and local disease control centres
- Expert groups
- The resources required for disease emergencies (personnel, equipment and facilities)
- Instructions for dealing compulsorily notifiable exotic diseases
- Diagnostic laboratories
- Plans for emergency vaccination
- Training
- Publicity – disease awareness

Legal powers

Veterinary services must have legal powers to **guarantee** that the **eradication** of a notifiable disease is promptly successful

Reference to the legislation containing the legal powers relevant for disease eradication shall be made in the contingency plan

The legal powers shall encompass:

- The **notification** of suspected exotic disease
- The **access to holdings** keeping animals

Legal powers

- The access to documents and records required for epidemiological investigation
- The **killing** of infected and contact animals
- The **destruction** of carcasses and contaminated materials, and access to sites to be used for this purpose
- The payment of **compensation**
- Sanitation and other procedures at infected premises
- The control of movements and other restrictions (e.g. establishment of protection and surveillance zones)
- Vaccination

Financial provisions

The costs of an epidemic can be huge

H7N1 HPAI epidemic in Italy 1999-2000

413 outbreaks

≈ **16** million birds stamped out

€ **100m** direct costs

€ **500m** total costs

H5N2 HPAI epidemic in USA 2014-2015

279 outbreaks

≈ **50.5** million birds stamped out

\$ **1.6b** direct costs

\$ **3.3b** total impact for the USA economy

Financial provisions

It shall be ensured that a Country has the **budgetary powers** to cover the costs of an epidemic:

- Personnel
- Capital equipment and consumable items
- Laboratory work
- Culling, destruction of carcasses/contaminated material, and sanitation
- Compensation payments to owners of animals
- Emergency vaccination, if needed

The cooperation of farmers is fundamental and it can be relied on only if compensation for depopulated animals is paid promptly

Chain of command

A **clear-cut chain of command** shall be established. It should be:

- Understood by all who are involved with disease eradication
- **Clearly described in the contingency plan**

The chain of command can be different in various countries according to the organization of the veterinary services

The CVO should be ultimately in charge of eradication operations and he/she should establish and coordinate the **National disease control centre**

National disease control centre (NDCC)

The **NDCC** must direct and verify the operations of the **Local disease control centres (LDCCs)**

Responsibilities of **NDCC** include:

- Definition and overall direction of control strategies
- Ensuring that the **LDCCs** implement them promptly and effectively
- Deployment of staff and other resources
- Provision of information to National and International authorities and organizations (**transparency**)
- Liaison with diagnostic laboratories, and liaison with the media

Local disease control centre(s)

LDCC(s) shall be established in the affected area(s)-> responsible for the **enforcement of eradication and surveillance measures** within their territory

A veterinarian shall be directly in charge of the centre with the powers to:

- Designate a holding as an “infected premises” and deploy the necessary staff, materials and equipment

Local disease control centre(s)

- Arrange **valuation and culling** of infected and contact animals, disposal of carcasses and contaminated material and sanitation procedures
- Advise on delineation of protection and surveillance zones and **impose movement restrictions**
- Close markets for live animals and abattoirs as necessary
- Liaise with police and other authorities

Disease control centre(s)

NDCC and LDCCs must be adequately staffed and equipped:

- Suitable means of communication
- Maps and other sources of information (access to livestock database, geographical information systems – **GIS**, etc.)
- Updated lists of organizations, staff and other persons who must be contacted
- **Local disease control centres** must have direct availability to all the resources required for disease emergencies (personnel, equipment and facilities)

Resources for disease emergencies - personnel

One of the most critical resource factors is the immediate availability of **trained and experienced personnel** → lists of the staff available for a disease emergency shall be established and maintained

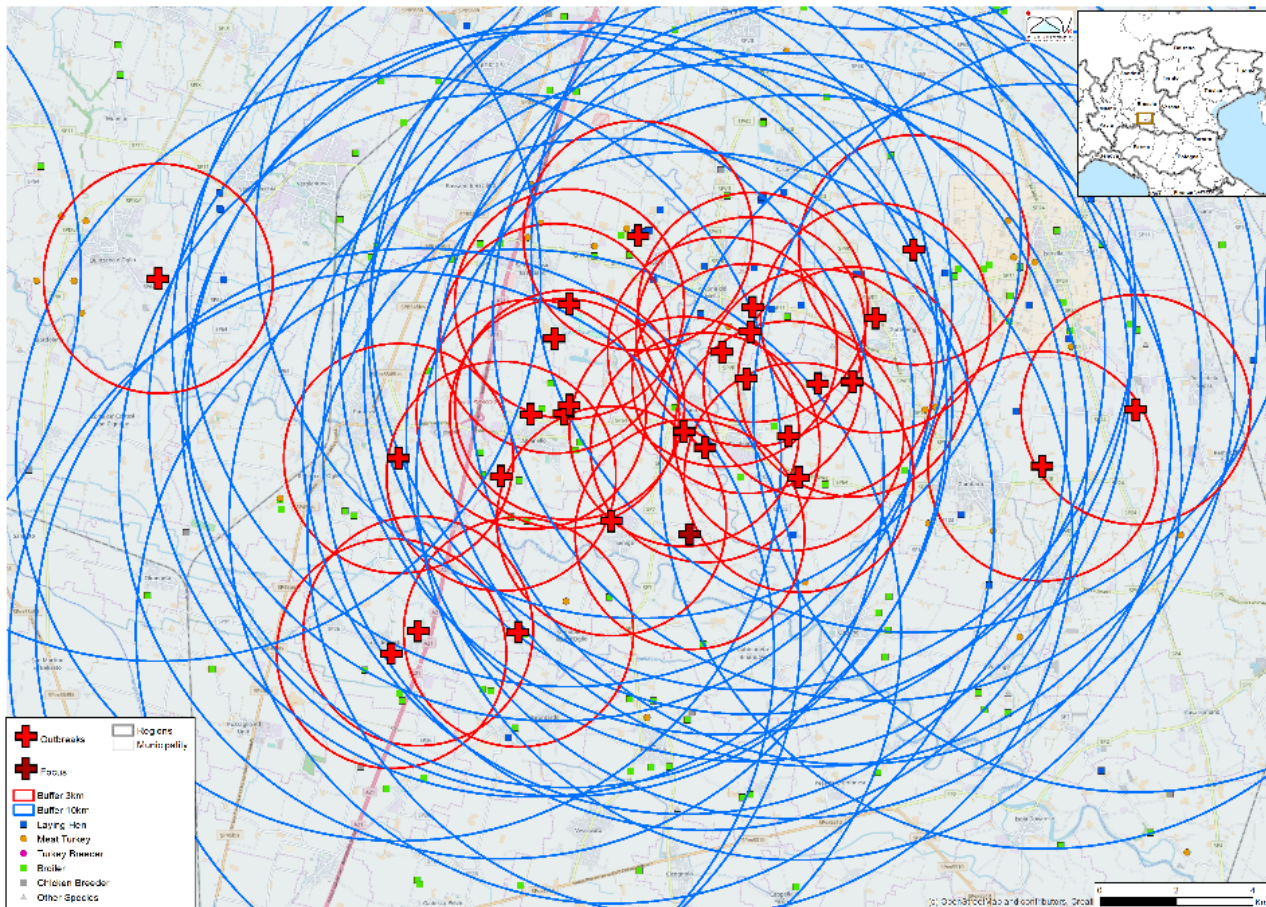
Standing arrangements/contracts for **culling and disposal of carcasses**, and cleansing and disinfection of infected premises

- Culling crews and all equipment and materials to rapidly enforce stamping out measures
- Rendering plants (capacity)
- Equipment and staff for cleansing and disinfection
-



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DPPA – Outbreak eradication and restriction areas



Resources for disease emergencies - equipment

The effective and prompt eradication of epidemic disease requires the **immediate availability** of appropriate equipment such as:

- Protective clothing (**zoonotic infection**)
- Autopsy and sampling equipment
- Disinfectants effective against exotic disease viruses
-

LDCC(s) shall have available office equipment including:

- Preprinted proformas such as formal notices of restrictions, **epidemiological questionnaire(s)**, etc.

Instructions for dealing with exotic diseases

The **operational manual** contains a set of instructions and **detailed procedures** for dealing with disease outbreaks

When a disease is reported the action to be taken:

- In the event of a suspected case (e.g. submission of samples to laboratories)
- Where disease is confirmed (e.g. notification of local authorities, agricultural associations, etc.)

Instructions for dealing with exotic diseases

Procedures at an 'infected premises'

- Isolation of the premises
- Valuation and compensation
- Culling of animals
- Carcasses and contaminated material disposal
- Sanitation
- Restocking

Instructions for dealing with exotic diseases

Epidemiological inquiry and movement tracing

- A **standardised system** should be used

Creation of restriction zones around the outbreak site

- Census of all livestock holdings
- Regular surveillance of all livestock holdings
- Movement controls
- Prohibition of markets, shows, etc.

■

Diagnostic laboratories

Disease control centres must have immediate and continuous access to a **diagnostic facility** for exotic diseases

An **EU network of National Reference Laboratories** coordinated by the EU-Reference Laboratory is in place for each exotic disease

The contingency plan shall contain information on the available resources and the diagnostic capacity
(**Laboratory contingency plan**)

Epidemic disease control policies

Control policies are not mutually exclusive:

- Enhanced biosecurity
- Stamping out and pre-emptive culling
- Movement restrictions
- Monitoring and surveillance
- **Emergency vaccination**

There is a clear need to implement prevention and eradication strategies based on a **combination of measures** that may include the use of vaccination

Emergency vaccination

The implementation of an effective **emergency vaccination programme** is related to the level of preparedness

The emergency vaccination programme must:

- be part of the national contingency plan
- include **decision making patterns** in different scenarios in order to allow a rapid decision on whether to vaccinate or not in the face of an epidemic

Training

Staff shall be **regularly trained** in procedures for detecting and eradicating exotic diseases

Publicity and awareness

Awareness of the disease shall be maintained within veterinary profession, agricultural community, etc., to guarantee a **prompt notification** of the possible occurrence of an exotic disease

Conclusions

Contingency planning is not the production of a “fancy” manual but the organization of a coordinated **system** that can become **fully and promptly operational** in case of a disease outbreak

In order to fulfil this objective the plan shall be:

- widely distributed to stakeholders
- regularly updated
- repeatedly tested by means of external audits and **simulation exercises**



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Regional Workshop on Animal Disease Preparedness

Thierry van den Berg

Laboratory quality control

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Definition

Laboratory quality control is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory.

Quality control is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions.

Laboratory quality control material is usually run at the beginning of each shift, after an instrument is serviced, when reagent lots are changed, after calibration, and whenever results seem inappropriate

Main requirements for **NRLs** in the **Reg. 625/2017**

- **Competent Authorities** responsible for designating a **NRL** for each **EURL** (Total network in EU >1300) (art 100)
- **Assist Competent Authorities** in outbreaks! (art 101)
- **Ensure the dissemination** to the competent authorities and official laboratories of information that the European Union reference laboratory supplies
- **NRLs to comply with:**
 - ISO 17025 (art.100 and 37)
 - obligations to participate successful in trainings & proficiency tests with EURLs (art. 101);
 - Coordinate activities of official laboratories (art 101)
- **NRLs to be equipped with biosecurity standards (art 100)**
- **Conduct training courses for Official Labs**
- **NRLs subjects to audits by Competent Authorities in the Member States (art. 39)**

Definitions

- “The aim of quality control is simply to ensure that the results generated by the test are correct. However, quality assurance is concerned with much more: that the right test is carried out on the right specimen, and that the right result and right interpretation is delivered to the right person at the right time”
- **Quality Control** - QC refers to the measures that must be included during each assay run to verify that the test is working properly.
- **Quality Assurance** - QA is defined as the overall program that ensures that the final results reported by the laboratory are correct.
- **Quality Assessment** - quality assessment (also known as proficiency testing) is a means to determine the quality of the results generated by the laboratory. Quality assessment is a challenge to the effectiveness of the QA and QC programs.



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Norms

R & D



- **GLP**, GCP
- **ISO 9001**

Production



- ISO 9001
- GMP
- HACCP

Control



- **ISO 9001**
- **ISO 17025**
- **ISO 17043**
- **ISO 15189**
- **ISO 17020**

Management



- **ISO 9001**
- **ISO 14001**
- EMAS
- OHSAS

Important norms for laboratories

ISO 17025 (LABs): General requirements for the competence of testing and calibration laboratories

ISO 9001 (R&D): is the standard that outlines the requirements an organization must maintain in their quality system

ISO 17043 (PTs): specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes.

ISO 14001 (Environment): international standard that specifies requirements for an effective environmental management system (EMS).



Processes

Accreditation /certification is a dynamic process, not a switch on/off

Lab activities and management can be grouped in 10 processes:

General management (all norms)

Continue improvement (all norms)

Evaluation of expert dossier (ISO 9001)

Follow-up of an epidemiological project (ISO 9001)

Chemical, microbiological, molecular labanalyses (ISO 14001, ISO 17025, ISO 15189)

Organisation of Proficiency Tests (ISO17043)

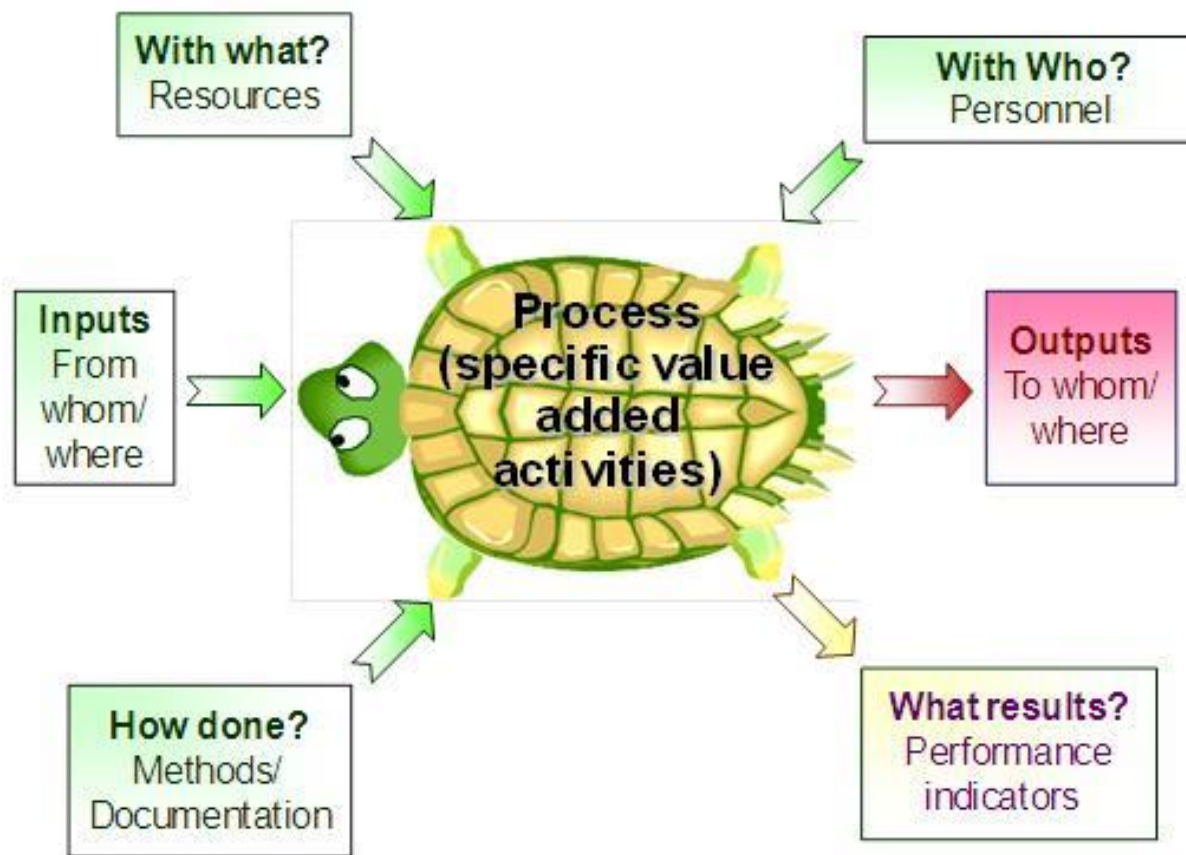
Management of external services (all norms)

HRM (all norms)

ICT (all norms)

Documentation (all norms)

Process Auditing “Turtle Diagram”





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**“I have some paperwork to catch up. If I’m not back
in two days, organize a search and rescue team!”**



"What makes you think I have something to hide?"

Audits

Quality control, or QC for short, is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements".

This approach places an emphasis on three aspects (cfr ISO 9001):

1. Elements such as controls, job management, defined and well managed processes, performance and integrity criteria, and identification of records
2. Competence, such as knowledge, skills, experience, and qualifications
3. Soft elements, such as personnel, integrity, confidence, organizational culture, motivation, team spirit, and quality relationships.

Inspection is a major component of quality control, where physical product is examined visually (or the end results of a service are analyzed).

	Pre-analytical	Analytical	Post-analytical
INTERNAL QUALITY CONTROL: Set of procedures undertaken by the staff to ensure quality of reports	Investigation Specimen Collection technique Storage and transportation Quantity Labeling Laboratory	Proficiency of personnel Reagents stability, integrity and efficiency Equipment reliability Specificity & sensitivity of selected test Procedural reliability using standard operating procedures Use of appropriate controls Documentation Assessment	Recording and reporting Interpretation Turnaround time
EXTERNAL QUALITY ASSESSMENT: a system of objectively checking laboratory results by means of an external agency	External quality assessment scheme Rechecking On-site visits Combination of any two or more of the above		
ACCREDITATION: Process of inspection of laboratories and their licensing by a third party to ensure conformity to pre-defined criteria	Laboratory license		

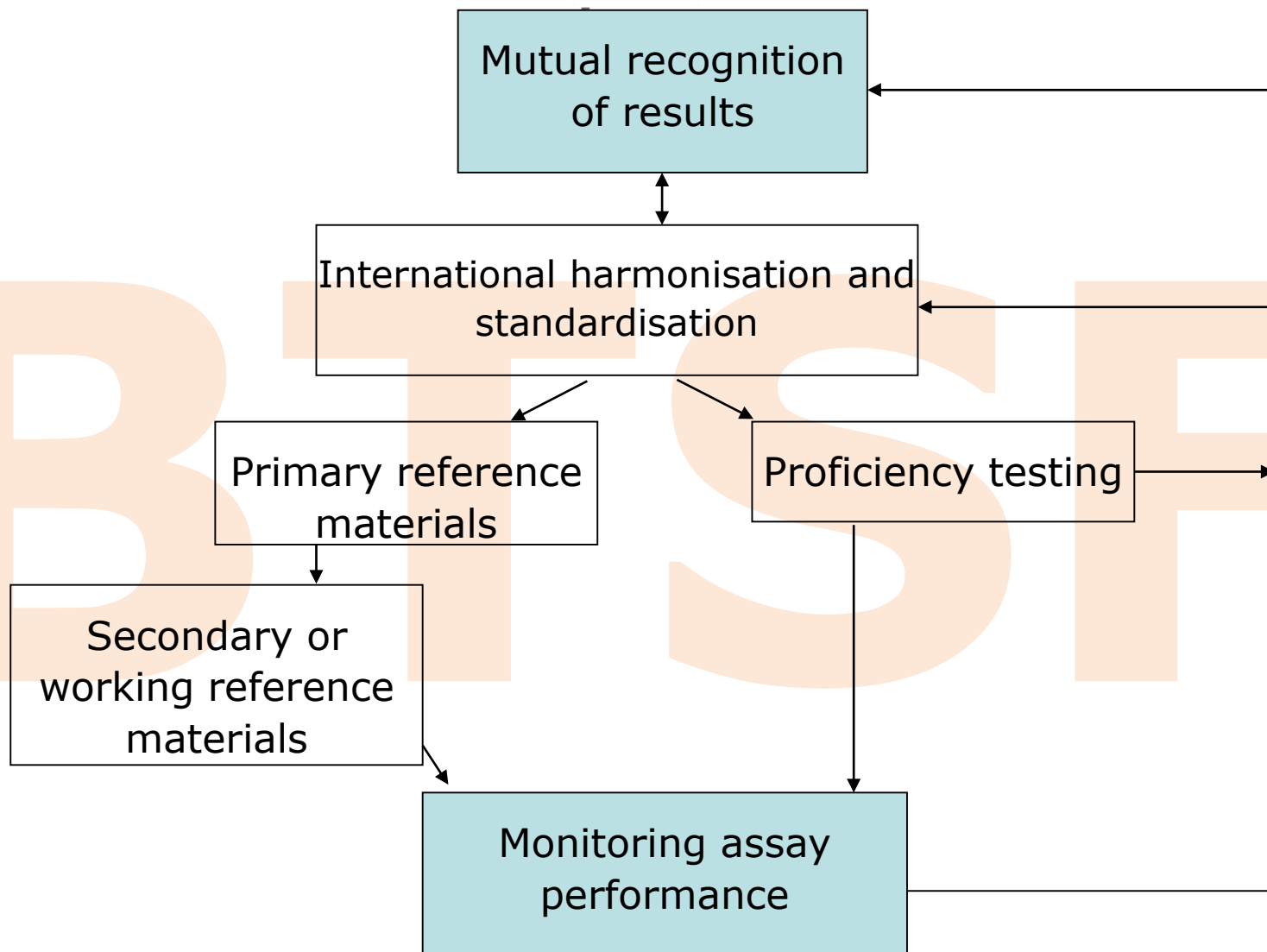
Focus on the laboratory

Validation

=

**the evaluation of a process to
determine its fitness for a
particular use**

("Fit for purpose ")



Stages Of Assay Validation

PART I

- - Feasibility studies => initial estimates of repeatability, analytic sensitivity/specificity
- - Assay development and standardisation => selection of reagent concentration, protocol parameters, repeatability studies, determination of analytic sensitivity/specificity
- - Determining assay performance characteristics => diagnostic sensitivity (300 samples) and specificity (1000 samples), standards of comparison ("gold standard"), precision and accuracy, cut-off selection

PART II

4. Monitoring validity of assay performance
=> charting method using data generated by reference materials
5. Maintenance and enhancement of validation criteria
=> proficiency testing

OIE Manual CHAPTER 1.1.04 : intro

“The principles of validation discussed in this chapter will focus primarily on methods to detect antibody in sera using an ELISA as an example. However, these same principles are applicable to validation of tests for other analytes in sera or tissues.”

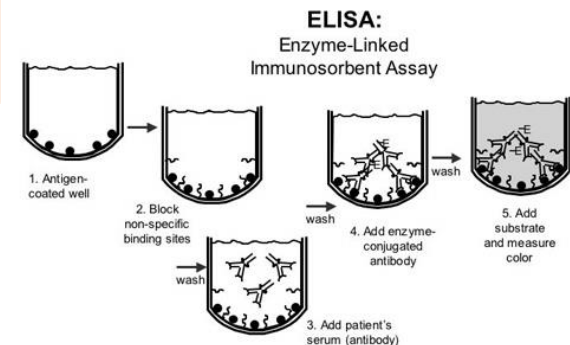
Enzyme linked ImmunoSorbant Assay

Cheap

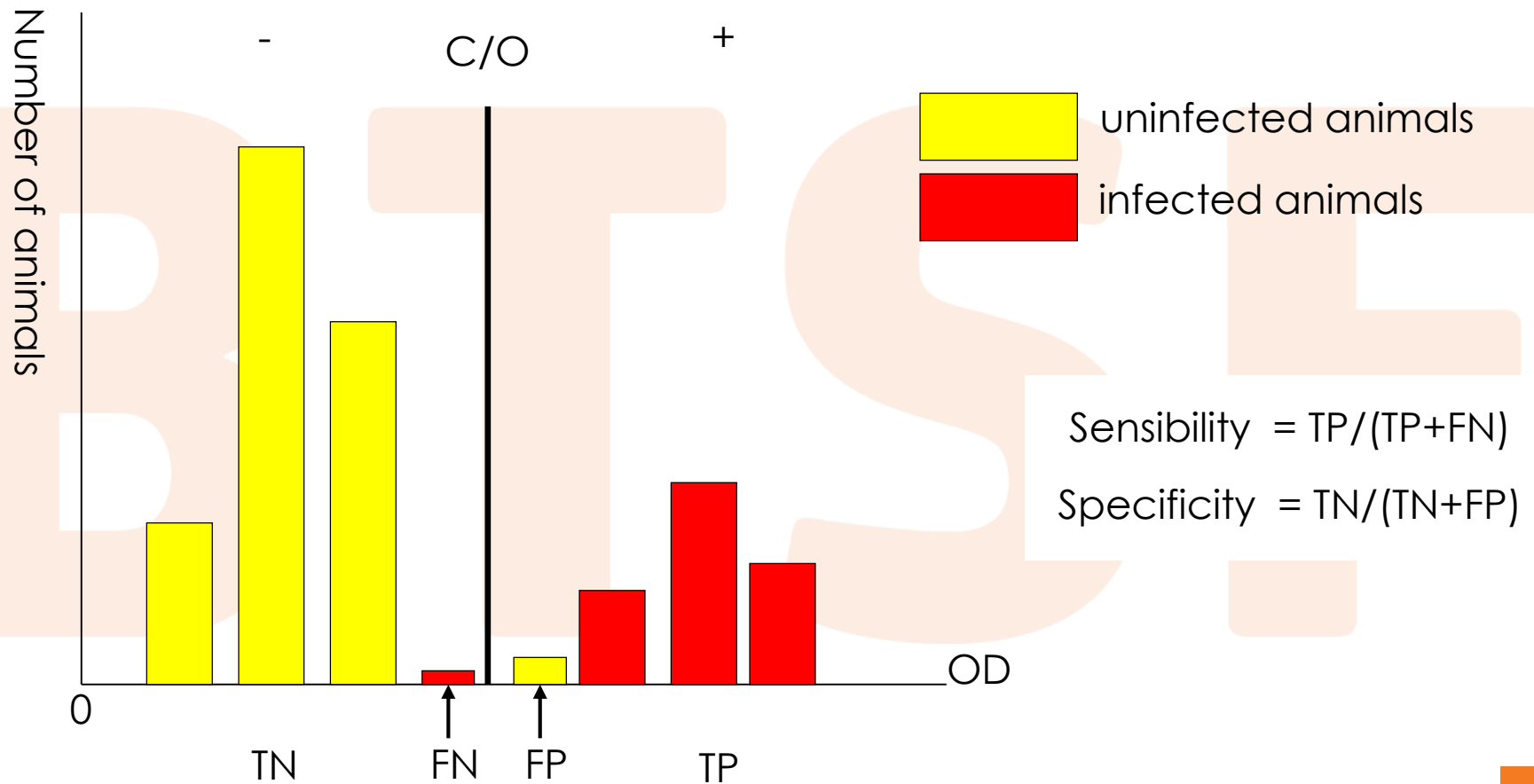
Fast results

Automatisation (robots)

Large scale



Determining Assay Performance Characteristics



What Is Quality Control (QC)?

Measures taken to monitor the quality of the test itself

Example: QC for Rapid Testing includes:

- Testing of samples with known results to verify if the procedure is working properly
- Interpreting the presence or absence of control bands/lines within the device itself

If an error occurs, do not release or report results until you have corrected the error.

Internal and External Quality Control

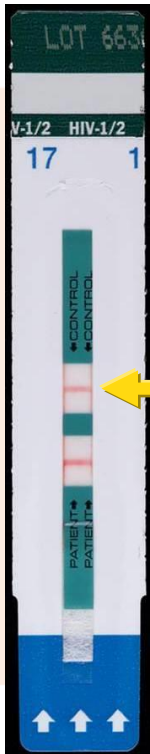
Internal Control

Included in testing device or as part of the kit

Control
Band

External Control

Known positive and negative samples that are used to validate the reliability of the test system – prepared by Eu or NRL or commercially



Variables that affect the quality of results

- The educational background and training of the laboratory personnel
- The condition of the specimens
- The controls used in the test runs
- Reagents
- Equipment
- The interpretation of the results
- The transcription of results
- The reporting of results

Errors in measurement

True value - this is an ideal concept which cannot be achieved.

Accepted true value - the value approximating the true value, the difference between the two values is negligible.

Error - the discrepancy between the result of a measurement and the true (or accepted true value).

Sources of error

Input data required - such as standards used, calibration values, and values of physical constants.

Inherent characteristics of the quantity being measured - e.g. CFT and HAI titre.

Instruments used - accuracy, repeatability.

Observer fallibility - reading errors, blunders, equipment selection, analysis and computation errors.

Environment - any external influences affecting the measurement.

Theory assumed - validity of mathematical methods and approximations.

Random Error

An error which varies in an unpredictable manner, in magnitude and sign, when a large number of measurements of the same quantity are made under effectively identical conditions.

Random errors create a characteristic spread of results for any test method and cannot be accounted for by applying corrections. Random errors are difficult to eliminate but repetition reduces their influence.

Examples of random errors include errors in pipetting and changes in incubation period. Random errors can be minimized by training, supervision and adherence to standard operating procedures.

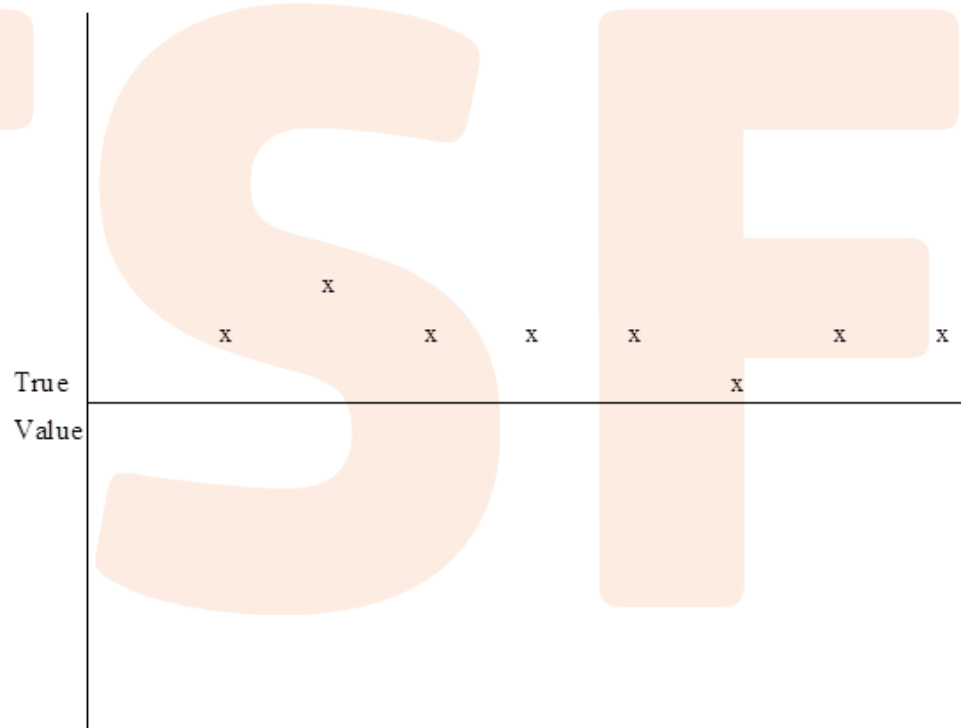


Systematic Error

An error which, in the course of a number of measurements of the same value of a given quantity, remains constant when measurements are made under the same conditions, or varies according to a definite law when conditions change.

Systematic errors create a characteristic bias in the test results and can be accounted for by applying a correction.

Systematic errors may be induced by factors such as variations in incubation temperature, blockage of plate washer, change in the reagent batch or modifications in testing method.



Proficiency testing

- According to the ISO definition, *Proficiency testing* (PT) also known as *External quality Assessment* (EQA) or *EQ Control* (EQC) or *Third line testing* refers to:
 - a system of objectively checking laboratory results by means of an external agency
 - including comparison of a laboratory's result at intervals with those of other laboratories
- the main objective being the establishment of trueness

Generating Secondary Or Working Reference Materials

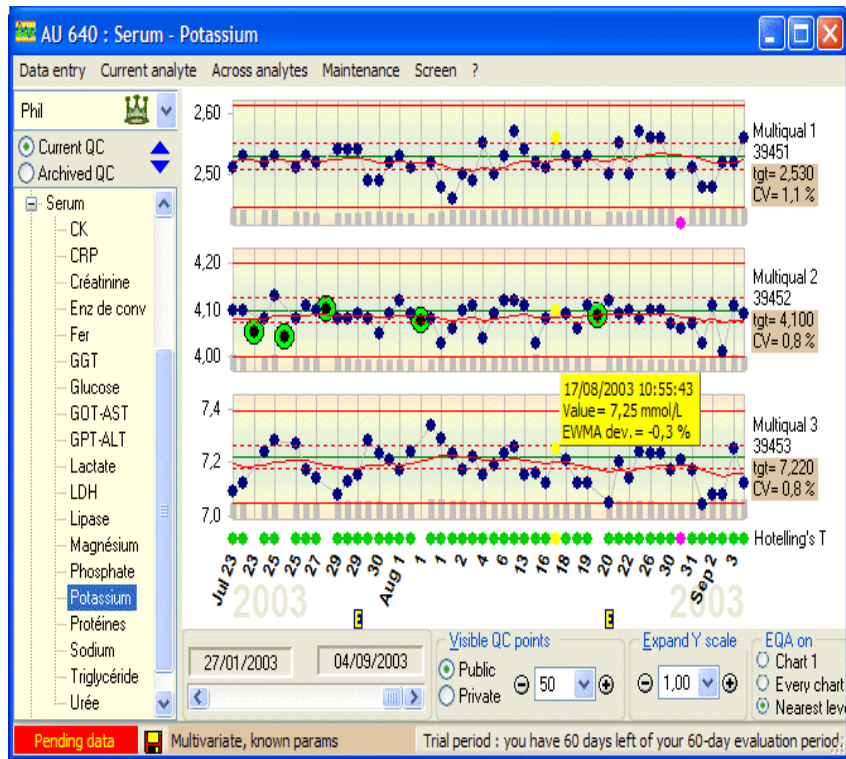
In Practice

Preparing National and Working Reference Materials

e.g. SPCE ELISA for the detection of antibodies against FMDV

1. Vaccination of calves against a serotype of FMDV
2. 1) Titration of their sera in ELISA and, for comparison, in VNT
3. 2) Expression of results as percentage of inhibition
4. 3) Selection of certain dilutions that give PI comparable to those obtained by the primary reference sera
5. 4) Making single dilutions in NBS and test again in ELISA
6. 5) Adding a pool of negative sera as negative control
7. 6) Selection of those dilutions that give practically identical PI as the primary sera and test them 3 times in ELISA
- 7) Aliquot the desired dilutions and test them, again 3 times, in ELISA before routine use
- 8) Import all normalised control values in a quality control chart

Advantages of Quality Control Charts

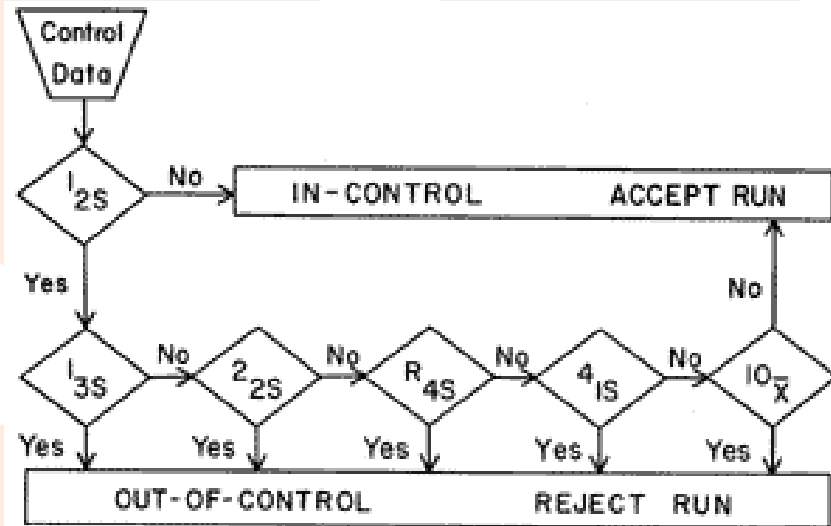


- Visualisation of assay performance in time (Shewhart charts)
- Continuous monitoring of assay
- Helpful tool in deciding to accept or to reject a run
 - Multi-rule procedure
- Westgard rules (1:2s, 1:3s, 2:2s, R:4s, 4:1s, 10:x)
- Evaluation of staff competence
- Assay in or out of statistical control
- International mutual recognition of results

Decision Criteria

Accept or reject an analytic run?

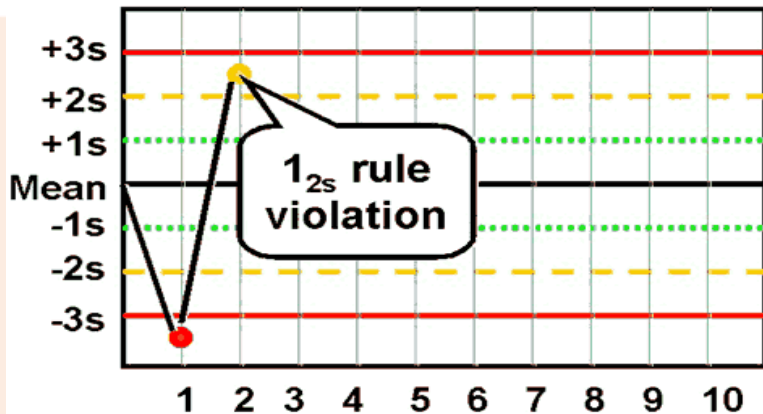
- 1:2s warning → detailed inspection of the data
 - 1:3s random error → reject run
- 2:2s within the same control or across levels → systematic error
- R:4s within the same control or across levels → systematic error
- 4:1s within the same control or across levels → systematic error
- 10:x within the same control or across levels → systematic error (shift of the mean)



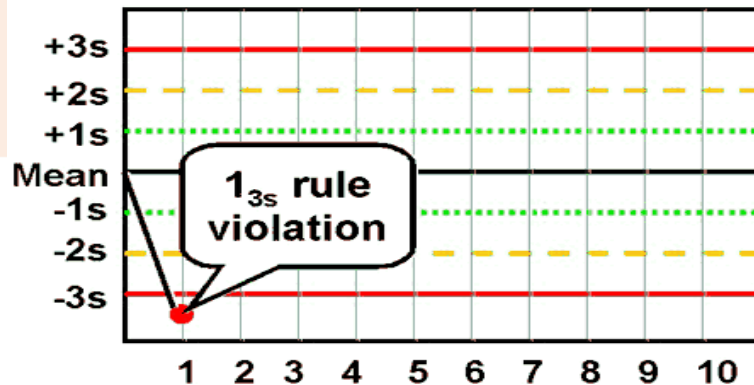
Westgard rules

- The formulation of Westgard rules were based on statistical methods. Westgard rules are commonly used to analyse data in Shewhart control charts.
- Westgard rules are used to define specific performance limits for a particular assay and can be use to detect both random and systematic errors.
- There are six commonly used Westgard rules of which three are warning rules and the other three mandatory rules.
- The violation of warning rules should trigger a review of test procedures, reagent performance and equipment calibration.
- The violation of mandatory rules should result in the rejection of the results obtained with patients' serum samples in that assay.

Accept or Reject?

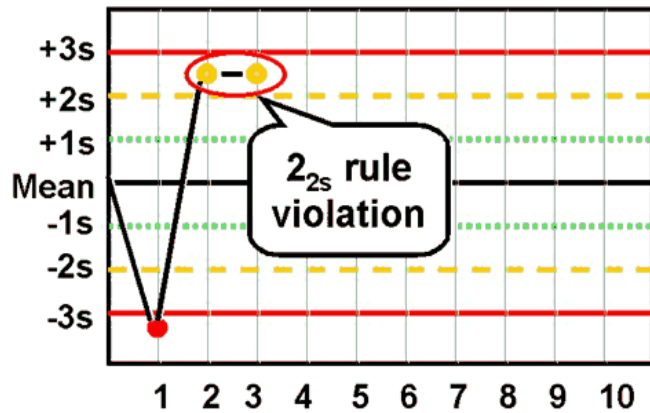


The control observation exceeds the 2s limit. Warning of possible problems

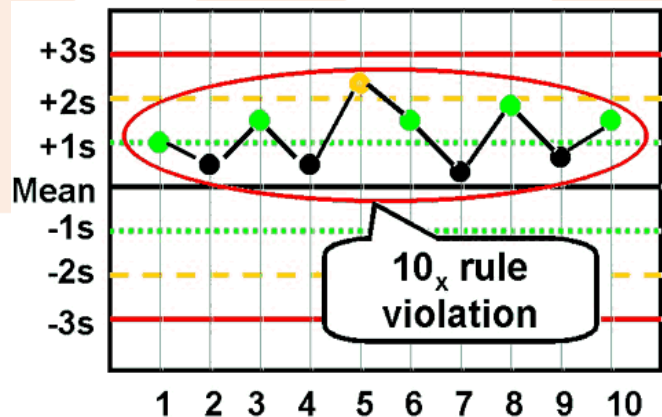


Reject run, the control observation exceeds the $-3s$ limit. A random error has occurred

Accept or Reject?

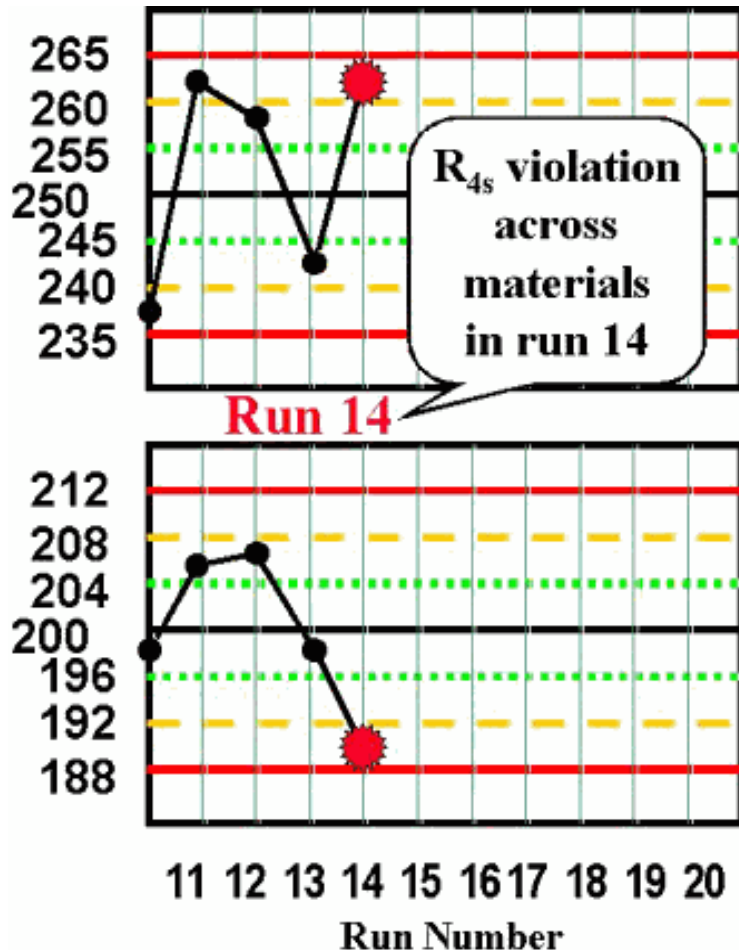


Reject run, a systematic error has occurred. Two consecutive point of the same control observation exceed the 2s limit



Reject run, a systematic error has occurred. 10 successive points fall on the same side of the mean. A possible shift of the mean?

Accept or Reject?

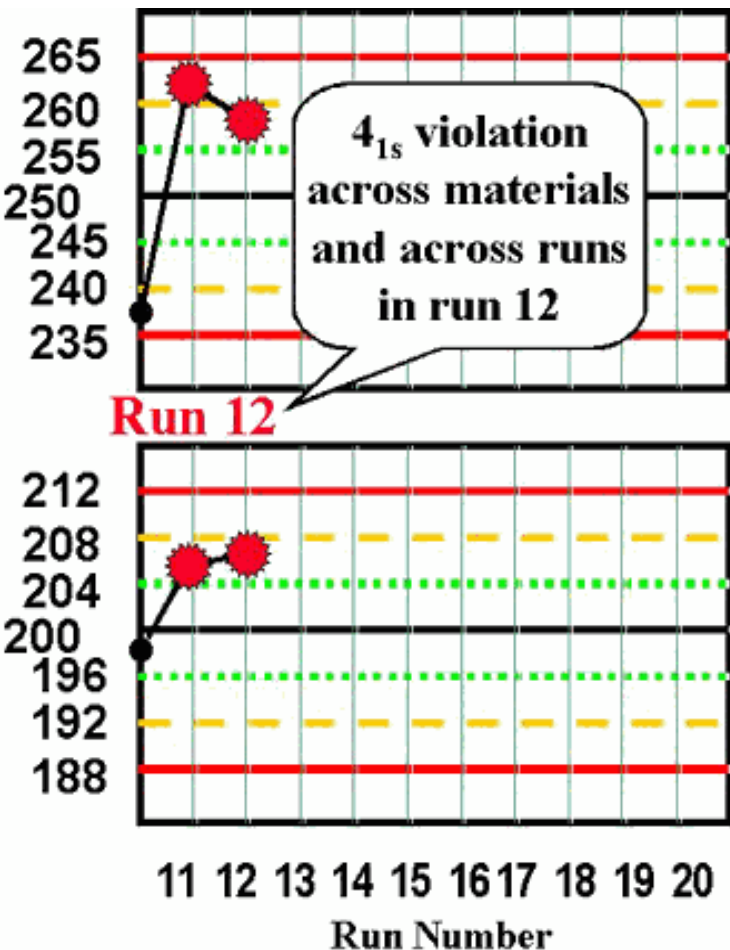


The first control observation exceeds the 2s limit, while the second exceeds the -2s limit. The difference/range between both observations exceeds 4s.

Reject run due to likelihood of random error

(across levels)

Accept or Reject?



Across control materials 4 consecutive points exceed the 1s limit. A systematic error is probably occurring throughout the concentration range covered by the controls. Run should be rejected.

Quality Control Without Control Chart Software Programme

e.g. Monitoring the performance of VNT assay

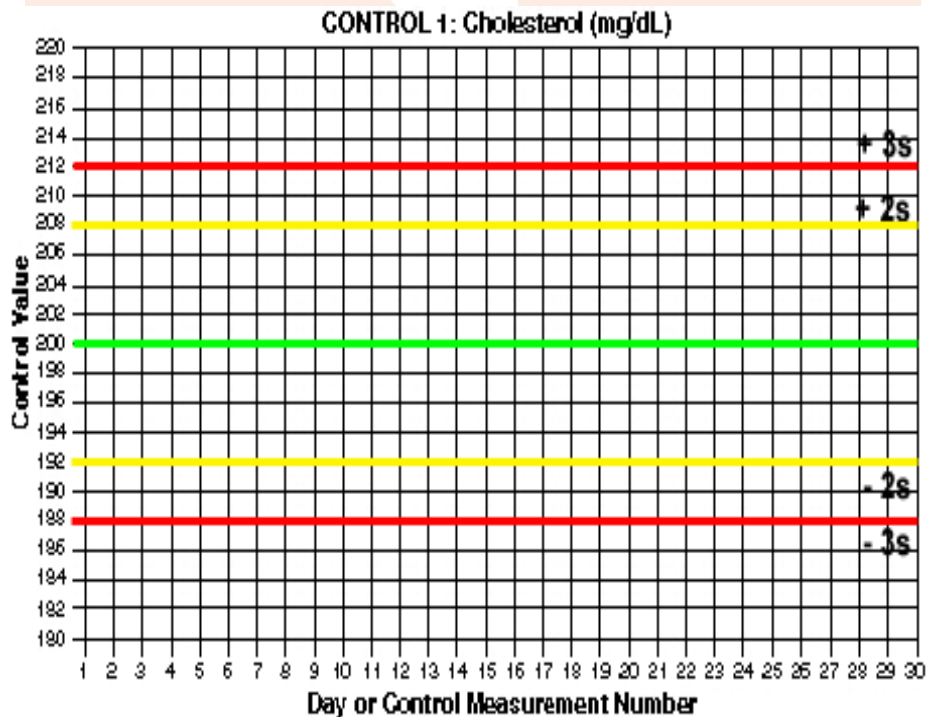
1. Titration of the positive control serum (PC)
2. Write down the daily titre of the PC in a table
3. Periodically visualise these titre logs on a chart (using e.g. Microsoft Excel)

Analyse the chart using the 1:2s, 1:3s, 2:2s, R:4s, 4:1s
and 10:x rules

→ BUT: time-consuming + retrospective

Note: before analysing these titres at least 20 PC titres need to be obtained in order to calculate a reliable mean and standard deviation!!!

Making of an In-house QC Chart



1. Select appropriate control materials (e.g. secondary/working standards)

Characterise method performance by collecting a minimum of 20 measurements

Calculate the mean and standard deviation of those data

4. Select the number of control measurements (e.g. 4 per control)

Select the control rules applied (e.g. 1:2s and 1:3s)

Calculate the control limits
Analyse analytic run results

Advantages and Disadvantages of Control Charts

Advantages

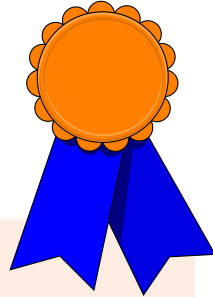
1. *Monitoring assay performance in time*
2. *Valuable tool in obtaining accreditation*
3. *Visualisation*
4. *Evaluation of staff competence*
5. *Multi-rule*
6. *Helpful tool in deciding to accept an analytic run*

Mutual recognition of results

Disadvantages

1. *Expensive software programme*
2. *Risk of rejecting analytic runs that are in statistical control*
3. *Not applicable to test such as VN (nominal test results)*

Keys to successful quality control



- Adequately trained, interested and committed staff.
 - Common-sense use of practical procedures.
 - Willingness to admit and rectify mistakes.
- Effective communication.



Take-home messages

A quality assurance (QA) programme is essential for improving the reliability, efficiency and use of laboratory services in order to achieve the required technical quality in laboratory diagnosis.

The process of quality assurance should be continuous and monitored

Quality assurance is the responsibility of all laboratory technicians and supervisors.

It is useful periodically to calculate indicators to evaluate the performance of the laboratory.

It is not sufficient in QC simply to identify errors or weaknesses in laboratory services; remedial action must be taken to permanently remove them.



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“I think we’re in good enough shape to start making the same mistakes again.”

B

F



The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.



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Better Training for Safer Food BTSF

• *European Commission
Consumers, Health, Agriculture and Food Executive
Agency
DRB A3/042
L-2920 Luxembourg*



Regional Workshop on Animal Disease Preparedness

Silvia BELLINI

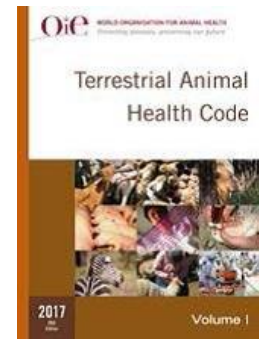
Surveillance

**Better Training
For Safer Food**



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Content



- Introduction (OIE)
- General principles on surveillance in the Terrestrial Animal Health Code
- Surveillance in the disease specific chapters of the Terrestrial Animal Health Code (ASF)

What is Surveillance?

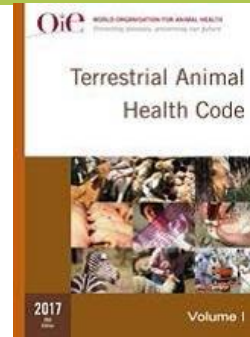
(OIE: Terrestrial Animal Health Code, 2017)

OIE Terrestrial Animal Health Code Definition

“Means the systematic ongoing collection, collation and analysis of information related to animal health and the timely dissemination of information so **action** can be taken”



Essential part of any disease control programme



Introduction and objectives

Aims of Surveillance:

- demonstrating absence / presence of disease or infection
- detecting as early as possible exotic or emerging diseases

Prerequisites for reliable information:

- comply with Chapter 3.1. (Veterinary Services);
- surveillance data complemented by other sources (scientific publications, research data)
- transparency of surveillance activities (Chapter 1.1. - Notification of diseases, infections and infestations, and provision of epidemiological information)

The general recommendations of chapter 1.4 may be refined by the specific approaches described in the disease chapters.

Surveillance (OIE)

- The most common type of surveillance: **passive surveillance**
- Vet Services learn of the occurrence of a disease through notification: abattoir, vets in the field, farm producers, labs
- Passive surveillance remains the cornerstone of surveillance systems in all OIE member countries
- It is the most likely way in which new or emerging diseases will be detected

However:

Most surveillance systems incorporate, to a greater or lesser extent, elements of active surveillance, depending on

- 1) Prioritisation of the disease by Vet Services,
- 2) Characteristics of the disease

Surveillance: Wildlife

The presence of a disease in wildlife does not mean it is necessarily present in domestic animals. Wildlife may be included in a surveillance system because they can serve:

- as reservoirs of infection
- as indicators of disease risk to humans and domestic animals.

..in practice surveillance is specifically required for:

Disease freedom (Country- Zone):

- Initial declaration
- Maintenance

Compartmentalization:

- Internal and
- external surveillance

Outbreak surveillance



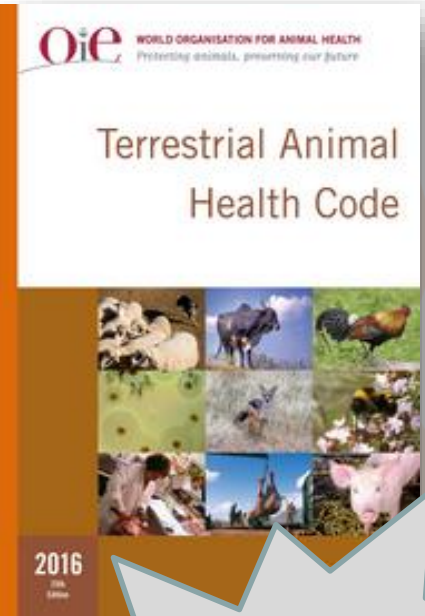
To be effective surveillance systems should adapt to the changing situations

OIE International Standards

Content Volume 2

Specific chapters on diseases:

- Susceptible species, definition of infection, incubation period (determining quarantine period and other risk mitigation procedures)
- *Surveillance*
 - Determining status of a country, zone or compartment (establishment; suspension; recovery)
 - Recommendations for imports, depending on statuses, for the different commodities (live animals, genetic material, products of animal origin)



e.g : ASF
(chapter
15.1)

Terrestrial Animal Health Code: Chapter 15.1. Infection with African swine fever virus

Specific Article on Surveillance: 15.1.27



- Introduction to surveillance (Article 15.1.27.)
- General conditions and methods for surveillance (Article 15.1.28.)
- Surveillance strategies (Article 15.1.29.)
- Surveillance for recovery of free status (Article 15.1.30.)
- Surveillance for ASFV in wild and feral pigs and African wild suids (Article 15.1.31.)
- Surveillance for arthropod vectors (Article 15.1.32.)

The impact of ASF varies in different regions of the world

The **surveillance strategy** needs to be tailored to the situation and take into account:

- Prevalent type of pig production system
- Presence of wild and feral pigs
- Presence of African wild suids
- Presence of Ornithodoros ticks
- ASF situation in adjacent territories
- ASFV genotype



Free status



Early Detection



Eradication/Endemicity

ASF Surveillance

An increased likelihood of infection in particular localities or subpopulations exists, targeted sampling could be appropriate. This may include:

- Specific high-risk feral pigs populations
- Pigs reared outdoors
- Farms which feed swill
- Areas in which the disease has been previously detected
- Evidence of involvement of ticks
- ...



ASF Surveillance

Target Animals in the EU

Domestic

Pigs:

- commercial farms
- backyards

Wild Boar

■ Surveillance Methods:

(a) clinical, (b) virological, (c) serological

Based on the situation

ASF Surveillance



Due to the characteristics of ASF: High Morbidity and Lethality

Passive Surveillance
Key role in Early Detection



any cases where clinical signs or lesions are suggestive of ASF should be investigated without delay



Clinical Surveillance

Is the most effective tool for detecting ASF [Mortality (94.5-100%)]. However, due to the clinical similarity with other *diseases*, it should be supplemented by serological and virological *surveillance*.

DOMESTIC PIGS

In Commercial Holdings

- *Strict health monitoring programme of pig holdings (pigs sick/dead examined and tested)*

In Backyards

- *Vet inspection on pig slaughtering for own consumption (pigs with lesions/symptoms examined and tested)*

Virological Surveillance

It is important for early detection, differential diagnosis and for systematic sampling of target populations. It should be conducted:

- ✓ to investigate clinically suspected cases
- ✓ to monitor at risk populations
- ✓ to follow up positive serological results
- ✓ sentinel animals (to confirm eradication after stamping-out)

Serological Surveillance

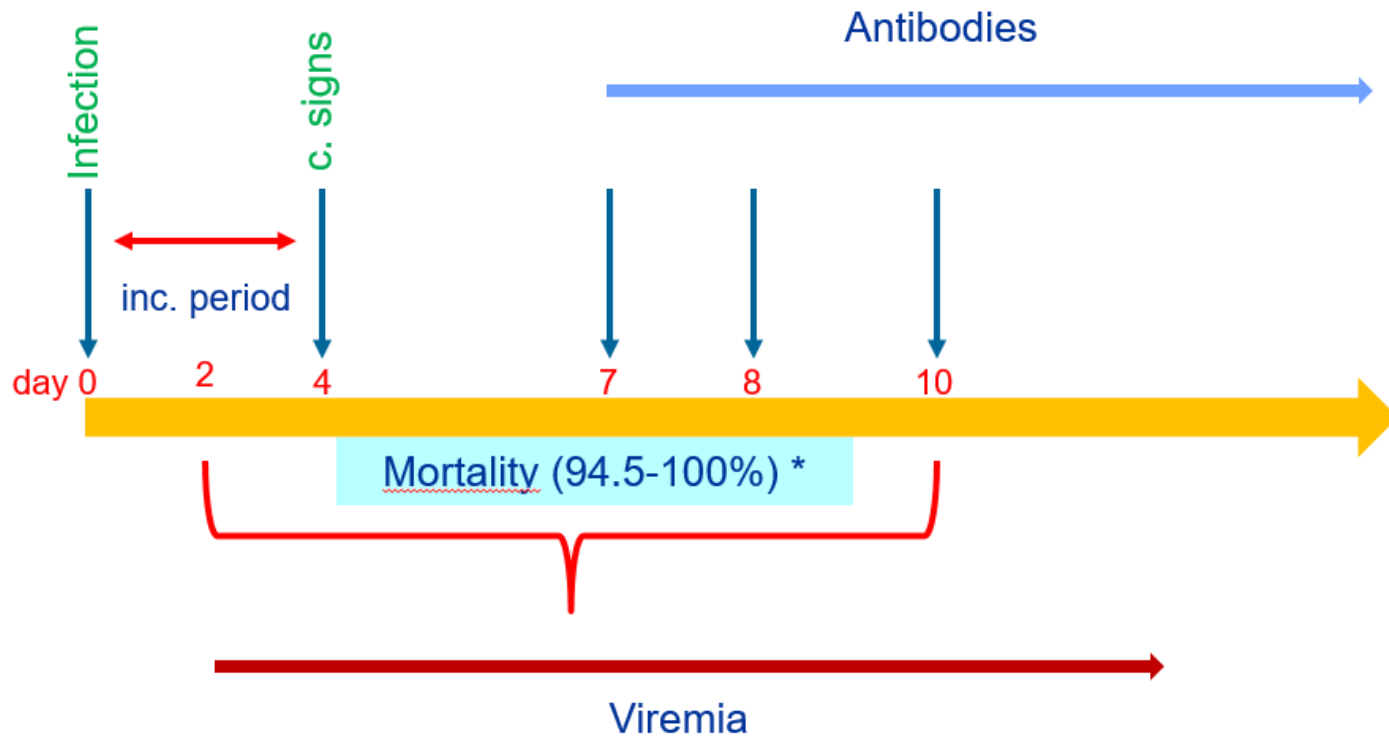
Serological surveillance aims at detecting antibodies against ASFV.

Positive ASFV antibody test results can indicate an ongoing or past outbreak, if some animals recover they may remain seropositive for life.

Serology is not suitable for Early Detection



ASF pathogenesis



*Gallardo C., et al. 2014; Blome S., et al 2012..

Surveillance in Domestic Pigs (Example)

Based on the biological properties of ASFV

In commercial farms independently of their size following tests are carried out on a monthly basis:

- 10 randomly selected pigs for the presence of ASF antibodies (ELISA test)
- 5% of dead pigs for PCR testing (organ material) ← OK
- 4% of the slaughtered animals at the abattoir: PCR tested.

Backyard pigs are inspected during home slaughtering by a veterinarian. In case of suspicion organ samples are taken for ASF testing.

Sero-prevalence: 25-30%

Healthy Animals (??)

Article 15.1.31. Terrestrial Code Surveillance for ASFV in wild and feral pigs and African wild suids (1)

- The **objective is to demonstrate** that *infection* with ASFV is **not present** in **wild and feral suids or, if** known to be **present**, to estimate the geographical distribution of the *infection*.
- The **geographic distribution and estimated size** of wild and feral suid populations should be assessed
- the **limits of the area** over which wild and feral pigs range should be defined.
- The surveillance programme may include animals found dead, road kills, animals showing abnormal behaviour and hunted animals,
- The surveillance programme may also include **awareness campaigns targeted at hunters and farmers.**

Article 15.1.31. Surveillance for ASFV in wild and feral pigs and African wild suids (2)

There may be situations where a targeted *surveillance* can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

- areas with past history of ASF;
- sub-regions with large populations of *wild* or *feral* pigs or African *wild* suids;
- border regions with ASF affected countries or *zones*;
- interface between *wild* and *feral* pig, and domestic and *captive wild* pig;
- areas with farms with free-ranging and outdoor pigs;
- areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
- other risk areas such as ports, airports, garbage dumps and picnic and camping areas.



Article 15.1.32.: **Surveillance for arthropod vectors**

Vector surveillance aims at defining the type and distribution of ticks of the genus *Ornithodoros*.

The Veterinary Authority should have knowledge of the presence, distribution and identity of *Ornithodoros*

When vector surveillance is necessary, a sampling plan in accordance with Chapter 1.5. should take into account: the biology and ecology of species, in particular, the favoured habitat (burrows and structures associated with pig production). The plan should also take into account the distribution and density of pigs in the country or zone.

Sampling methods include CO₂ trapping and flagging, and vacuuming of burrows or structures.



Surveillance in the EU affected countries

Due to the characteristics of ASF: Morbidity, Lethality



Passive Surveillance (**all country**)

Key role in early detection: domestic pigs and wild boar

Feral pigs

Territories under restriction

- Testing of all the animals sick or found dead (PASSIVE)
- Serological and virological testing of shot animals (ACTIVE)

Domestic pigs

Territories under restriction

- Strict health monitoring programme of pig holdings (pigs sick/dead examined and tested for ASF - CD 2003/422/EC)
- Each week, virological testing of the first 2 dead pigs
- Vet inspection on pig slaughtering for own consumption

Period Jan 2014 – July 2017: 257,305 tests in Baltic countries and Poland (85,697 in domestic pigs, 173,594 in wild boar). EFSA (2017): Epidemiology of ASF in eastern EU.

Results of surveillance activities (example)

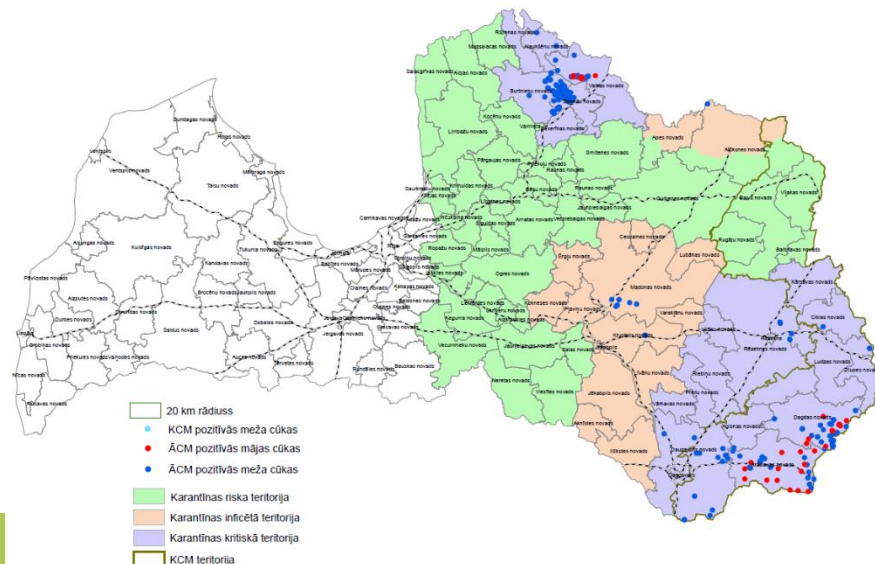
Wild Boar

On 1.04.14, the population density ranged from 12,82 to 4,2 WB/10 km². A decrease in WB was reported in 2015, max in Burtnieku county (from 11,35 to 0,6 WB/10 km²).

Despite the decrease, ASF cases were still occurring in that Unit.

Surveillance 2015 (January/May)

- 119 WB found dead, 98 virus pos. (82, 4%) [PASSIVE]
- 487 WB hunted, 3 virus pos. (0,62%) [ACTIVE]



An Effective Passive Surveillance

Requires: **REPORTING**

*the trust of pig owners that report the disease to the
Veterinary Authorities:*



..rapid diagnosis, eradication



AWARENESS CAMPAIGN



AWARENESS CAMPAIGN

Focused on:

- ✓ Explaining the risks
- ✓ Explaining the role of bio-security: domestic pigs, during hunting
- ✓ Involve hunters in the strategy
- ✓ Production of info material: farmers, hunters, borders, airport, ports
- ✓ Training



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*Thank you very much for your
attention!*



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Regional Workshop on Animal Disease Preparedness

Tsviatko Alexandrov

Better Training For Safer Food

*Stakeholders involvement
and enhanced passive
surveillance*

Content

- High risk periods
- Surveillance in practice
- Stakeholders
- Awareness
- Conclusions



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What is that cannot stay hidden.....



High risk periods

1st

The period between the introduction of an infection and the first detection of the infection

Efficiency of surveillance

2nd

The period between the first animal has been detected as infected and the establishment of measures to prevent virus spreading

Outbreak management

Surveillance in practice

Active surveillance	Passive surveillance
<ul style="list-style-type: none">• regular active veterinary surveillance• Usually targeting to detect 5% prevalence with 95 % confidence	Trainings and awareness targeted to farmers, vets, all stakeholders



**Focused on
detection of
clinical signs**

BT, 2014

CSF, 2008

FMD, 2011

All first outbreaks reported by farmers!

SGP, 2013

LSD, 2016

HPAI, 2005, 2016 -2018

NCD



Networking during Pre-epidemic, Epidemic and Post-epidemic

- Ministries (Agriculture, Financial, Internal affairs etc.),
- Agencies
- Regional and municipal epidemiological Commissions
- NDCC and LDCC
- Farmers associations
- Hunting organization
- other



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Example: FMD outbreak, Bulgaria 2011

The minister of culture

The minister of finances



Police



Fire brigade



ЗАБРАНЕНО
ФОТОГРАФИРАНЕТО
НА СЪСЕДНА ТЕРИТОРИЯ

NO PHOTOGRAPHY PERMITTED
IN NEIGHBOUR TERRITORY

No admittance!
Infectious animal
disease!

Влизането
забранено!
Заразна болест
по животните!

Stakeholders at greatest importance for passive surveillance

- Farmers
- Hunters
- Animal transport drivers
- Other.....

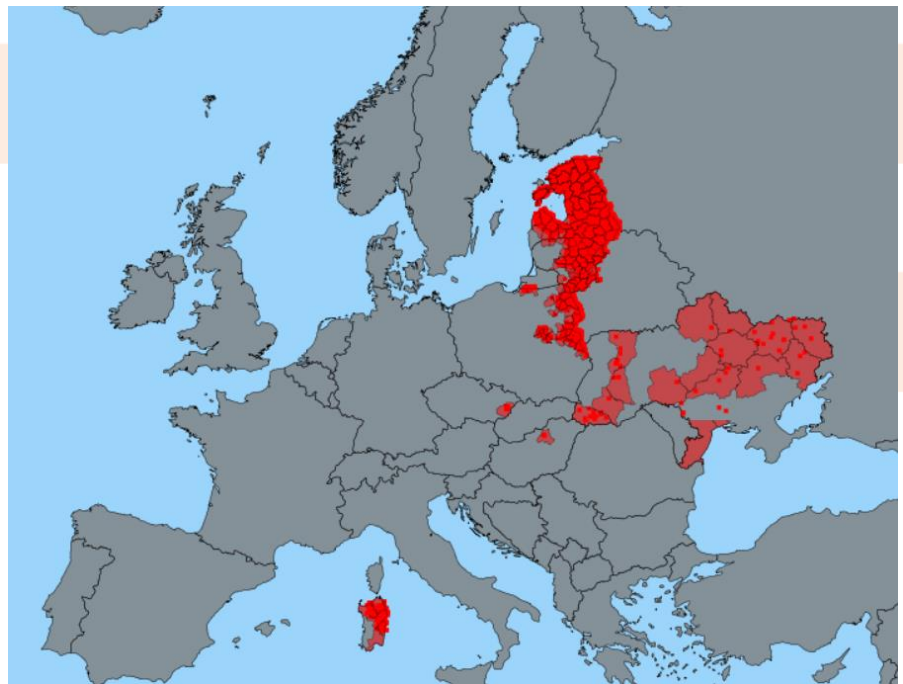


Crucial role and responsibilities from Animal Health & Welfare perspective

Hunters

Surveillance and control of:

- ASF,
- CSF,
- FMD,
- BT,
- Rabies
- AI
- Other.....



ASF cases and affected regions in wild boar in Europe, 2014 – 1st May 2018 (Source: ADNS)

Example: FMD in wild boar, Bulgaria 2011

Until 2011

- No evidence of wildlife involvement in the recent major epidemics in Europe 1920s-2007
- It was assumed wildlife will have limited role in domestic FMD outbreaks (spillovers of limited consequence)

However..... !!!! FMD in Bulgaria - 2011

- Detected first in hunted wild boar
- Lesions in wild boar detected by hunters and reported
- 11 villages affected
- Free status lost and ban for trade for year and a half



Tools for stakeholders' involvement (1)

- Legal obligations
- Controls
- Prescriptions
- Penalties

Tools for stakeholders' involvement (2)

“**Awareness** is the ability to directly know and perceive, to feel, or to be cognizant of events. More broadly, it is the state or quality of being conscious of something”

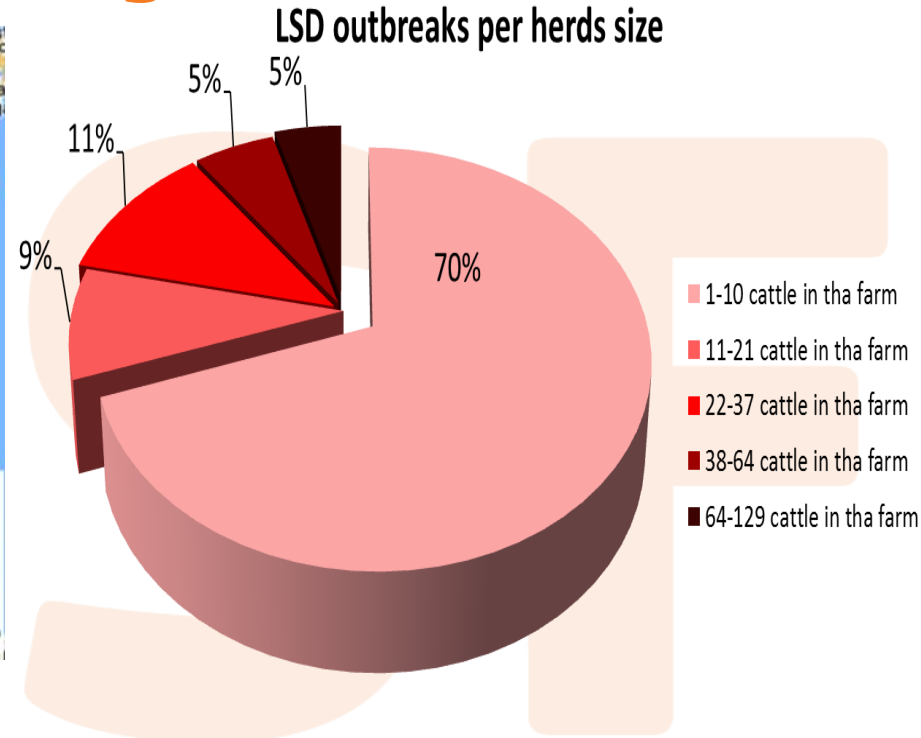
From Animal Health point of view **awareness** helps for:

- **Improve of passive surveillance**
- Higher level of biosecurity
- Control measures
- Decision making



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LSD epidemic in Bulgaria in 2016



- 217 outbreaks – most of them detected and reported by farmers
- Small herds (up to 10 animals) with **low biosecurity** mainly affected

Awareness

Why?

1. Do we really need to campaign?

Yes, Increasing public awareness of animal health care is a core element of any successful animal disease control and prevention strategy

2. Can we get what we want by other means ?

Disease control is impossible without good cooperation with stakeholders

3. Awareness is critically important to :

- *Engage the public in combating the animal diseases*
- *Facilitate the cooperation between industry (stakeholder organizations) and government*
- *Ensure higher preparedness*
- *Maximize the case detection*
- *Achieve animal health status*

Awareness

Tools

- **Trainings** (Real time, Desktop, Workshops, BTSF, Simulation exercises, Webinars, Cascade trainings)
- **Meetings** (face to face ..)
- **Leaflets, posters, booklets**
- **Media, radio**
- **website**

Шап по чифтокопитните животни Foot-and-mouth disease



Фигура 1. Обилно отделяне на слюнка

БОЛЕСТТА

Шапът е най-силно боляване по домакипитни животни.

Болеват:

- говеда и биволи
- овце и кози
- домашни и дивни
- елени, сърни
- други

Клинично болестта

- висока температура
- обилно отделяне на слюнка
- мехурести изригвания (лезии) (фиг. 2), езика (лезии) (фиг. 3), езика (лезии) (фиг. 4), езика (лезии) (фиг. 5), езика (лезии) (фиг. 6).



Фигура 2. Лезии по езика и устната кухина



Фигура 3. Лезии по езика

НАЧИН НА ЗАРАЗЯВАНЕ

Източник на инфекция са болните животни, които отделят мляко, изпражнения и разпространяват се:

- чрез контакт между животни;
- механично, чрез фураж, инвентар, постеля и др.

Телефони за контакт:
e-mail: AHWFC@bfsa.bg
<http://www.bahh.govt.bg/>

Българска агенция по безопасност на храните, гр. София, 1606, бул. "Пенчо Славейков" № 15А

Заразен нодуларен дерматит Lumpy skin disease



Фигура 1. Слизести изтечения от очите



Фигура 2. Възловидни изменения по кожата на цялото тяло



Фигура 3. Разявлени изменения по кожата

БОЛЕСТТА

Заразният нодуларен заразен вирусна болестта е заразна вирусна болестта, характерна за всички животни, характерна за всички животни, характерна за всички животни.

Болестта води до намалена млечност, вреди на кожата и нанася големи губи, вследствие ограничаване на движението и невъзможност да се преживи животът, от засегнатите региони.

НАЧИН НА ЗАРАЗЯВАНЕ

Предаването и разпространението става механично и други насекоми така и чрез директен контакт между болни и здрави животни с вирусна фуражи, е не, превозни средства могат да бъдат източници.

КЛИНИЧНО ПРОЯВЛЕНИЕ

По-тежко боледуват млади говеда, в пика на животни. Характерна е жена от депресия, зачервяване и слизисти изделения (фиг. 1), които може да водят до конюнктивит, а в тежките случаи до слепота. Обикновено заболяването е видимо уголемени.

Българска агенция по безопасност на храните, гр. София, 1606, бул. "Пенчо Славейков" № 15А

Шарка по овце и кози

БОЛЕСТТА

Шарката по овцете и козите е силно заразно вирусно заболяване.

Клинично при овцете и козите болестта протича с:

- треска и депресия;
- генерализиран изриг от папули (възловидни образувания) по кожата на цялото тяло;
- пневмонични огнища в белите дробове.

Кожните изменения (лезии) се наблюдават по главата и обезкосмените части на тялото — коремната област, основата на опашката, вимето, гениталиите, вътрешните части на крайниците.

Главата изглежда уголемена и деформирана.

Протичането на болестта може да завърши със смърт.

НАЧИН НА ЗАРАЗЯВАНЕ

Източник на инфекция са болните животни.

Предаването на болестта става с:

- директен контакт между болни и здрави животни;
- контактирани с вируса фуражи, оборудване, превозни средства, постеля.

ПРЕДПАЗНИ МЕРКИ

Избягвайте:

- контакт с животни от други стада;
- посещение на други животновъдни обекти;
- размяна и споделяне на животни, инвентар, превозни средства с други животновъдни обекти.

Телефони за контакт: 02 915 98 20; 02 915 98 42
e-mail: AHWFC@bfsa.bg
<http://www.bahh.govt.bg/>

ВНИМАНИЕ!

Всяко съмнение за Шарка по овцете и козите, трябва незабавно да се съобщава на официален ветеринарен лекар. По този начин може да спасите хиляди животни и да предотвратите огромни икономически загуби за страната! Обявяването на болестта е задължително и е от съществено значение за ограничаване на по нататъшното ѝ разпространение!

Българска агенция по безопасност на храните, гр. София, 1606, бул. "Пенчо Славейков" № 15А

Decision Number SANTE/EM/AH/2017/10527/EXOTIC DISEASES/BG



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Фиг. 1. Диво прасе, заболяло от шап. Мехурче по рилото. (© FLI)



Фиг. 2. Мехурче в между пръстовото пространство на копито на диво прасе (© FLI)



Фиг. 3. Шапна лезия върху копито на диво прасе (© FLI)



Фиг. 4. Шапна лезия върху копито на диво прасе (© FLI)



Фиг. 5. След инфекциозно заздравяване и деформация на копитата на диво прасе



Ако видите някои от тези изменения при диви чифтокопитни животни, незабавно информирайте най-близкия ветеринарен лекар до мястото, където ловувате. По този начин може да спасите хиляди животни и да предотвратите огромни икономически загуби за страната!



ВНИМАНИЕ!

Африканска чума по свинете

Африканската чума по свинете (АЧС) е много опасна епидемия по животните и е разпространена в голяма част на Източна Европа. Междувременно тази епидемия е достигнала Чешката република и е само на 80 км от австрийската държавна граница. За хората болестта е абсолютно безвредна, но избухването в Австрия би имало катастрофални въздействия за селскостопанските предприятия!

Със спазването на определени предпазни мерки може да се противодейства, тази епидемия по животните да не се довлече от засегнатите страни в Австрия. Заетите в селското стопанство могат да имат много важен принос!

- Вирусът на АЧС е много дълго устойчив в продуктите от свинско месо. Ако свинете ядат замърсена храна, те ще се заразят с тази епидемия по животните. Не изхвърляйте остатъци от храна в природата – дивите прасета биха могли да я поемат!
- Храненето на домашните прасета с остатъци от храна в Австрия е забранено!
- Особен риск произтича от собственото производство на салами и шпек от районите на избухване. Вземайте за Австрия само съответно контролирани стоки!
- Ако Вие самите сте притежател на прасе или ловец: Почиствайте облеклото, обувките и принадлежностите, които са били носени в районите на избухване, основно – вирусът на АЧС е много устойчив и може напр. лесно чрез мръсни ботуши да бъде предаден
- Ако сте заети в предприятия държатели на животни в Австрия, то използвайте във всеки случай собствени облекло за обора и ботуши! Ако е възможно, избягвайте контакт с отглежданите свине
- Ако намерите умрели диви прасета, не ги докосвайте а информирайте веднага Вашия работодател





European

Workshop on Animal H x + v

fesass.eu/fr/actualite/31374/workshop-animal-health-how-can-we-make-wildlifeand-livestock-live-together

Site officiel - fesass.eu

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Organisation Activités Publications

A+ A- [social icons]

- Bienvenue**
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- Publications
- Liens

Actualités > Workshop on Animal Health : How can we make wildlife and livestock live together ?

Workshop on Animal Health : How can we make wildlife and livestock live together ?

180313 MEP DANTIN 2



Recherche

Contactez-nous

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 37 rue de Lyon
 75 000 Paris
 Tél : 32 27 59 44 07
 → Contact email



Mot du Président

Le calendrier de travail de la Commission européenne en matière de réglementation de la Santé Animale s'annonce particulièrement chargé pour 2018 et 2019. La Commission doit adopter les textes clés pour l'application de la Loi de Santé



Windows taskbar with icons for search, file explorer, PowerPoint, mail, and other applications. System tray shows time 20:50 and date 03.05.2018.

Conclusions

Stakeholders involvement

- should be long term and continuous!
- helps to create a broad societal commitment to engaging in disease control
- is of crucial importance for successful Animal diseases control and prevention strategy
- should be planned in each routine control programme



The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.

Thank you!



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Better Training for Safer Food BTSF

• *European Commission
Consumers, Health, Agriculture and Food Executive
Agency
DRB A3/042
L-2920 Luxembourg*



Regional Workshop on Animal Disease Preparedness

Stefano Marangon

*Presentation of a practical
experience of surveillance -
Risk-Based Surveillance for
Avian Influenza*

Better Training For Safer Food

**Tokyo, Japan
12-15 June 2018**

Background – “AI free” Definition

OIE Terrestrial Animal Health Code

Article 10.4.2.

The avian influenza status of a country/zone/compartment can be determined on the basis of the following criteria:

- 1) avian influenza is notifiable in the whole country.....
.....
- 2) **appropriate surveillance is in place** to demonstrate the presence of infection in the absence of clinical signs
.....
- 3) consideration of all **epidemiological factors** for avian influenza occurrence and their historical perspective

AI Surveillance in the European Union (EU)

Decision 2010/367/EU on "

"

Avian Influenza Surveillance

Poultry

- Passive surveillance
- Active surveillance
- Representative sampling (to demonstrate freedom)
- **Risk Based Surveillance**

Wild birds

- Passive surveillance (RBS)

AI surveillance in EU

Domestic poultry – Objectives

- To complement early detection systems
- To inform the competent authority of circulating AIV with a view to controlling the disease

Risk-based surveillance (RBS)

Risk-based surveillance - The most efficient way to find a disease is to survey the animal populations that are most likely to be affected

Risk-based surveillance means “looking for something where it is mostly likely to be found” (FAO, 2014)

(Decision 2010/367/EU)

2.1. *Risk-Based Surveillance (RBS)*

RBS shall be the preferred method for the carrying out of surveillance for avian influenza in a targeted and resource efficient way.

Member States choosing that method shall specify the relevant risk pathways for infection of poultry flocks and the sampling frame for poultry holdings identified as being at a higher risk of becoming infected with avian influenza.

Criteria and Risk Factors for AI RBS

Introduction

- Proximity to wetlands
- Proximity to wintering/nesting sites for migratory waterfowl
- Free-range farms
- Low levels of biosecurity

Spread

- Poultry species reared
- Presence of more than one species
- Farm density

These criteria and risk factors are **NOT EXHAUSTIVE**

Depending of the individual animal health situation in the Country concerned, they may need to be **WEIGHTED DIFFERENTLY**

Risk Based Surveillance - Issues

Differences between Countries

Differences in poultry production sector

- Production types and types of premises
- Distribution and density of poultry farms
- Organization of poultry production
- (e.g. vertical integration, industrial/rural, free-range)

Different environmental risk factors

- Composition and dynamics of wild water bird populations
- Proximity of poultry farms to wetlands
- Possible persistence of AI virus in the environment

Data availability, accuracy and management

- Poultry farms registry
- Rural, ornamental, pet birds
- Census/AIV monitoring of wild birds

**A
standardised
RBS
approach is
almost
impossible**

BTSEF

AI Risk Based Surveillance Case-study - Italy

Risk based surveillance – Definition of AI risk at an *area-level*

AIMS

factors

- Farm Density
- Poultry production type
- Contacts with wild waterfowl
- Previous occurrence of AI cases

risk

active

PROCEDURE

Estimation of **risk levels** per province (NUT 3) for each separate risk factor

Summing the 'individual' risk levels to obtain an '**overall**' risk level

Reclassification of the overall risk level into High, Medium, and Low (supervised and filtered by an **expert opinion** approach)

Risk-based surveillance – Definition of risk factors

- Farm Density
 - Densely Populated Poultry Areas (**DPPA**)
- Species and production type
 - Higher susceptibility (e.g. turkeys)
 - Long lived poultry (e.g. layers and breeders)
- Contacts with wild waterfowl
 - Proximity to wetlands considered as proxy for presence of wild waterfowl nesting/resting sites
- Previous occurrence of AI cases
 - Number of **LPAI** and **HPAI** cases in the last five years

Risk-based surveillance – Inclusion of risk factors

Identification of densely populated poultry areas (DPPAs)

Data derived from the **National Farm Registry**

- Number of poultry farms in each Italian province

laying hens
outdoor laying hens
broilers
breeders
fattening turkeys
turkey breeders
quails and quail breeders

guinea fowl and guinea fowl breeders

fattening ducks

duck breeders

fattening geese

goose breeders

farmed game birds (gallinaceans) and breeders

ratites

.....

Geographical distribution of commercial poultry farms

- The DPPA located in the Po valley accounts for up to 70 % of the Italian poultry production, with more than 3,300 industrial poultry farms and about 95 million bird places





Available online at www.sciencedirect.com



The Veterinary Journal 181 (2009) 171–177

The
Veterinary Journal

www.elsevier.com/locate/tvj

Risk factors for highly pathogenic H7N1 avian influenza virus infection in poultry during the 1999–2000 epidemic in Italy

Luca Busani ^{a,b,*}, Maria Grazia Valsecchi ^c, Emanuela Rossi ^c, Marica Toson ^a,
Nicola Ferrè ^a, Manuela Dalla Pozza ^a, Stefano Marangon ^a

^a *Istituto Zooprofilattico delle Venezie, viale dell'Università 10, 35020 Legnaro, Padova, Italy*

^b *Istituto Superiore di Sanità, viale Regina Elena, 299, 00161 Rome, Italy*

^c *Unit of Medical Statistics, Department of Clinical Medicine and Prevention, University of Milano-Bicocca, Via Cadore 48, 20052 Monza, Italy*

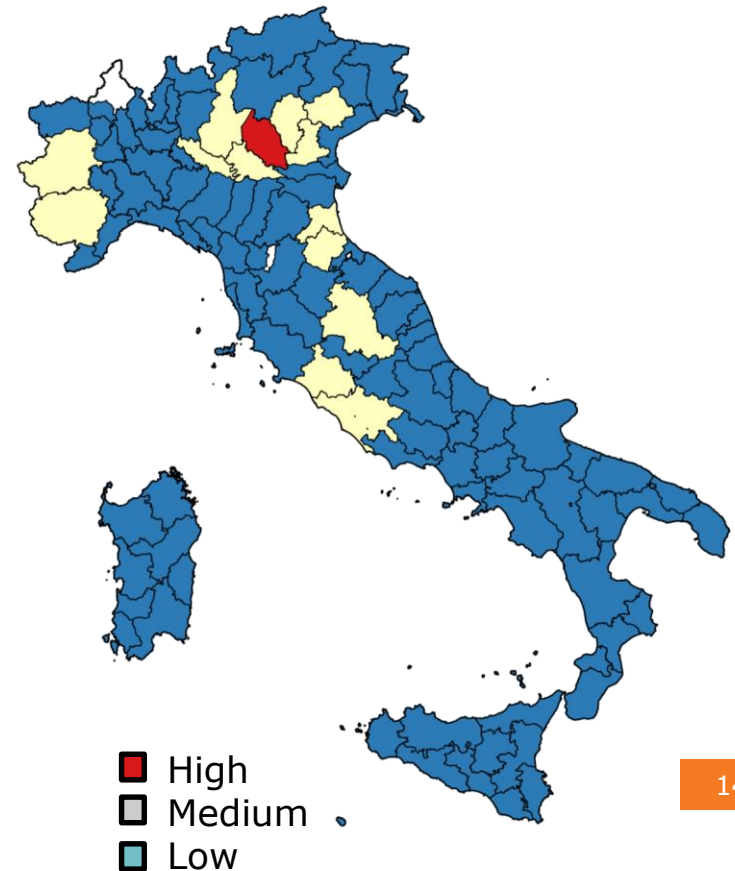
Accepted 13 February 2008

National Surveillance Plan – Inclusion of risk factors

Densely Populated Poultry Areas

- Data derived from the National Animal Registry
 - **Number** of poultry farms per province
 - Weighted for **Species/Production type**

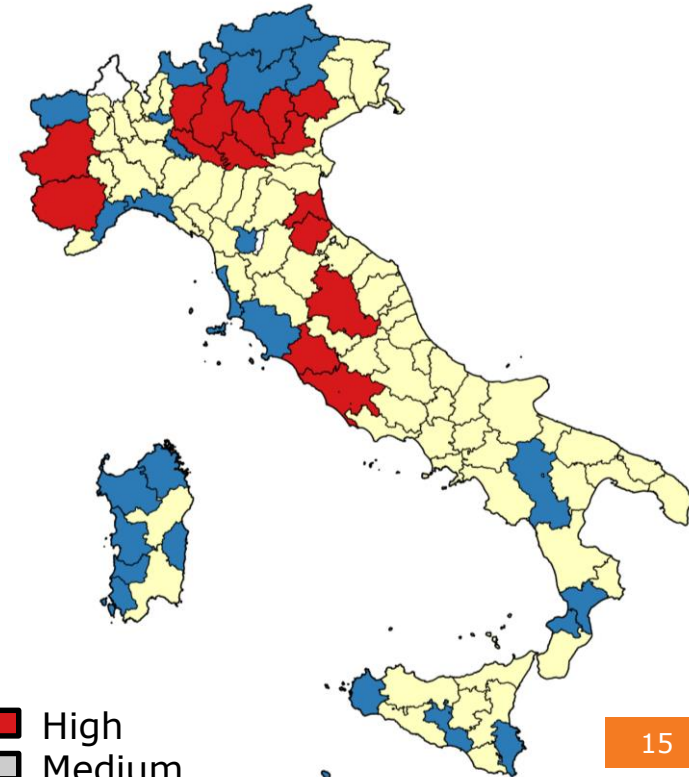
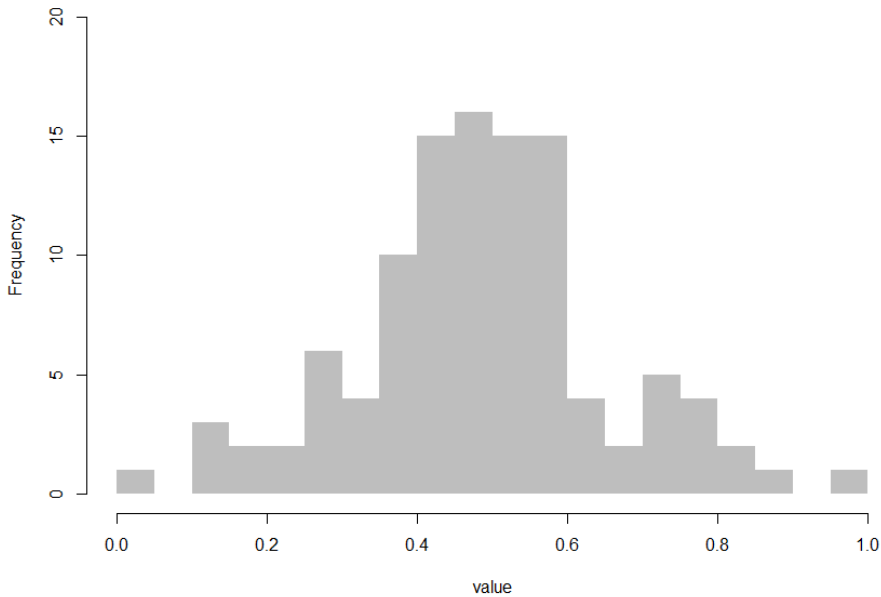
Production type	Cumulative % infection (A)	Weighting (A/max(A))
Fattening Turkeys	35.3	1.00
Laying Hens	31.2	0.88
Breeders	19.2	0.54
Broilers	4.9	0.14
Other Species	4.9	0.14
Growers	-	1.00



DPPAs – RF weighting

The value indicating the risk level per province is then normalised and standardised to 1

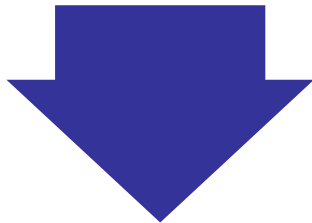
Map showing the normalised level of risk per province



- High
- Medium
- Low

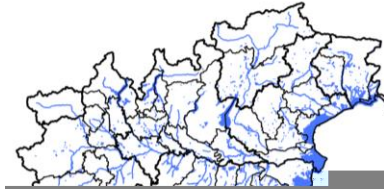
Proximity to wetlands – RF inclusion

- Census of (migratory) wild waterfowl is not regularly updated
- The proximity to wetlands was used



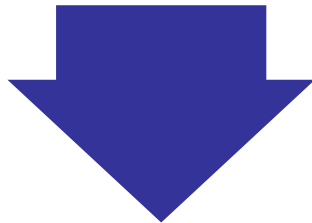
- The total area (sq km) of wetland per province was used as proxy as a measure of “potential attraction” for wild waterfowl

Geographical distribution of wetlands (RAMSAR)



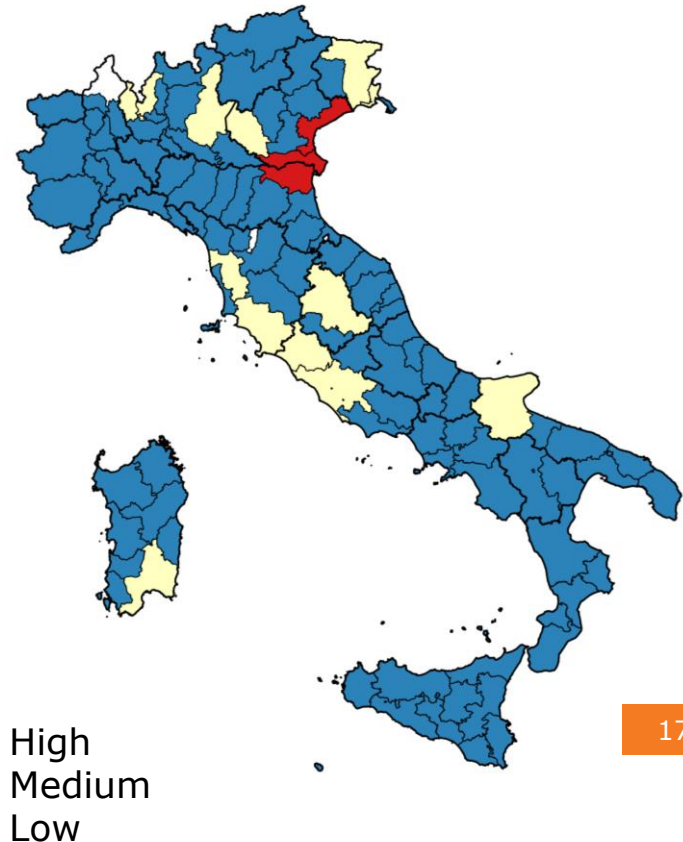
Proximity to wetlands – RF weighting

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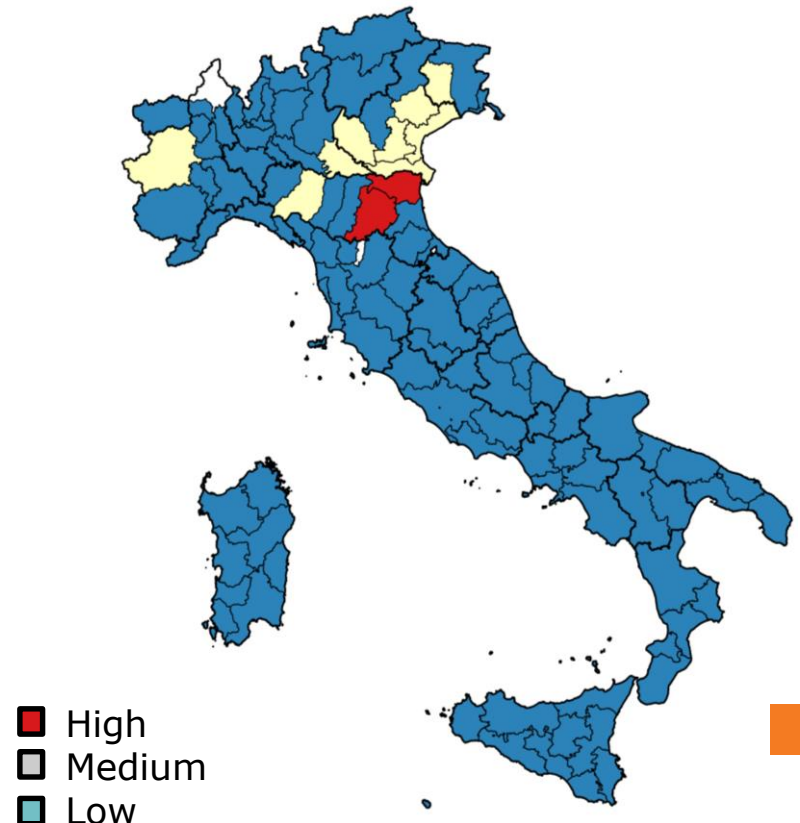
Level of risk associated to presence of wetlands per province



2012-2016 Epidemiological situation – RF weighting

- Number of LPAI and HPAI outbreaks per province in the last five years
- Collected and evaluated separately
 - HPAI is generally detected through passive surveillance
 - Active surveillance has the main goal to promptly detect LPAIV exposure
- The number of outbreaks per province is standardised to 1

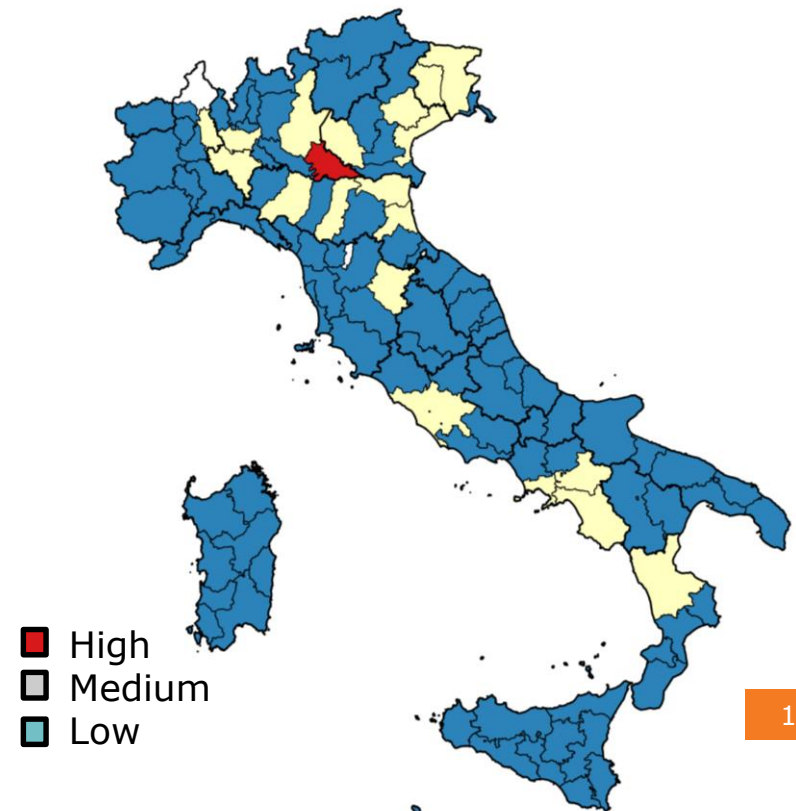
Number of HPAI cases per province



2012-2016 Epidemiological situation – RF weighting

Number of LPAI cases per province

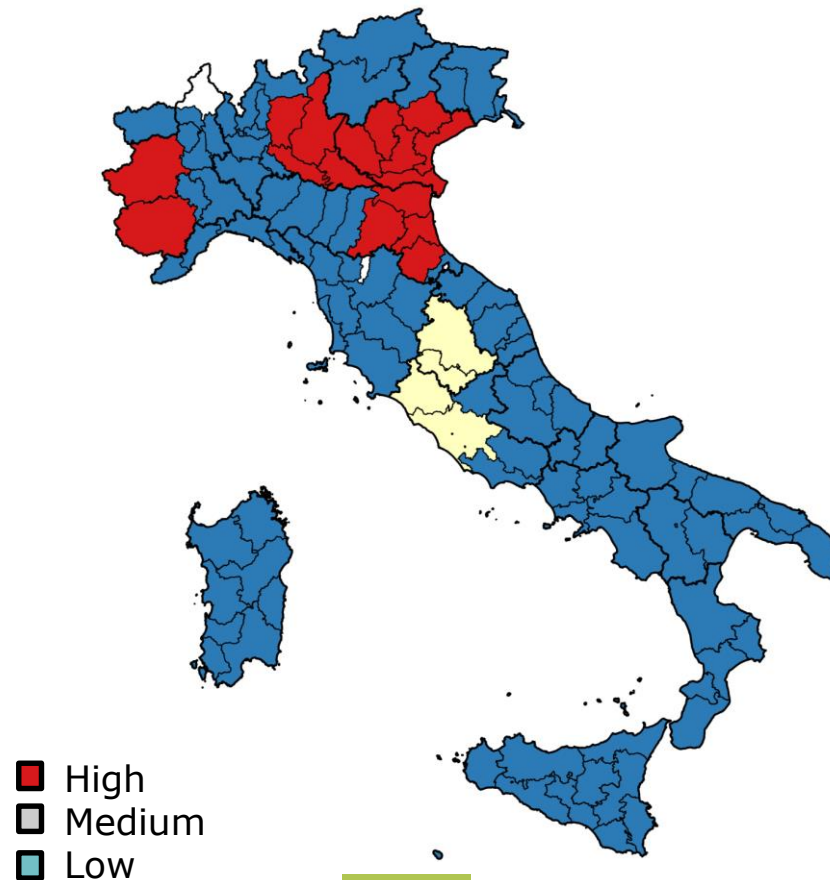
- Number of LPAI and HPAI outbreaks per province in the last five years
- Collected and evaluated separately
 - HPAI is generally detected through passive surveillance
 - Active surveillance has the main goal to promptly detect LPAIV exposure
- The number of outbreaks per province is standardised to 1



Definition of the overall risk level

- All of the data related to each risk factors are **scaled to 1**, and **summed together**, to obtain the overall AI risk per province
- The risk is further classified into **three classes**, according to a Jenk classification (Natural Breaks)
 - High risk
 - Medium risk
 - Low risk
- The results are then re-evaluated on the basis of an expert opinion
- The final classification is transmitted to National/Regional Veterinary Authorities, for any observations and comments

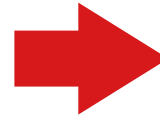
Risk map - Areas subjected to active surveillance



Risk-based surveillance

High risk areas

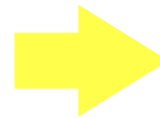
- Veneto
- Lombardy
- Emilia Romagna
- Piedmont



Active surveillance on all commercial poultry farms (excluding broilers) and passive surveillance

Medium Risk areas

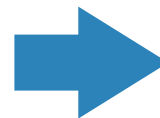
- Lazio
- Umbria



Active surveillance on a representative sampling basis and passive surveillance

Lower risk areas

- Remaining areas



Only passive surveillance

Active surveillance in high risk areas Target population and sampling scheme

Commercial poultry farms (except broilers) are **serologically** tested

Number of samples per poultry farm

- Expected within farm prevalence: $\geq 30\%$ (Confidence Level: 95%)
- 10 blood samples per holding, but at least 5 blood samples per shed

Sero-positive farms -> investigation and follow-up sampling for virus detection

Ducks, geese and quails: at least 20 samples (cloacal and tracheal swabs) per holding are **PCR** tested

Active surveillance in medium risk areas

Target population and sampling scheme

Active surveillance on a **representative sample of poultry farms** (except broilers)

- Expected between farms prevalence: 5%
- Geese and Ducks farms: 99% confidence level (90 farms per area)
- Other poultry farms: 95% confidence level (60 farms per area)

Number of samples per poultry farm

- As in high risk areas

Active surveillance plan

Timing and type of tests

Fattening turkeys

- Before loading for slaughter

Laying hens/breeders

- Biannual
- Before movements
- Before loading for slaughtering

Ducks and geese, quails, and game birds

- Biannual

Gallinaceous birds

- Screening → ELISA type A
- Confirmation → HI (H5 and H7)

Ducks, Geese, Quails

- PCR

AI passive surveillance

AI is a **compulsorily notifiable** disease

- Clinical signs for AI must be notified

Early warning – Passive surveillance for **exclusion diagnostics**

- Increased mortality (e.g. in layers a mortality $\geq 0.5\%$ daily for two succeeding days - for other species slightly different threshold)
- Birds showing general clinical signs for other pathogens and AI cannot be excluded
- Drop in feed, water intake, egg production
- **Sampling for exclusion diagnostics shall be performed**

Summarising...

RBS is preferable to a representative sampling approach:

- Increases the chance to early detect AI introduction and spread
- Optimizes the use of resources

RBS approaches largely vary according to different Risk Factors (and sampling/testing schemes):

- Different situations may demand different RBS approaches



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Better Training for Safer Food
BTSF

ASF on farm in China near Russian border

13 June 2018

Pathways

- Animal movement
- Swill feed
- Vectors (ticks)
- Contact with contaminated humans
- Fomite (straw, equipment etc.)

Biosecurity Protocol at Farm Level

- Check animal confinement e.g. fencing
- Contact between domestic and wild pigs
 - Prevent where necessary
- Human access to affected farm
 - Restrict if possible
- Check type of feed used e.g. swill or commercial feed
- Replacement stock
 - Avoid infected sources
- Straw and other fomites

Biosecurity Protocol at Regional Level

- Surveillance
 - Enhance both passive and active
- Animal movement
 - Impose restrictions
- ASF status
 - Confirm existence of virus
- Pork and pork products
 - Restrict importation into region
- Animal feed
 - Restrict importation from infected areas

Biosecurity Protocol at Country Level

- Surveillance
 - Enhance both passive and active
- Animal movement
 - Impose restrictions
- Live pig importation
 - Impose restrictions
- Pork and pork products
 - Restrict importation into country

Preparedness - Current Situation

- Live animal importation
 - Able to check record of importation
 - Able to quarantine animals from involved country
 - Able to appropriate destroy and dispose
- Pork and pork product
 - Able to check record of importation
 - Able to safely destroy products
- ASF diagnosis
 - **Not able to conduct**
- Farm depopulation and decontamination
 - Able to conduct

Outbreak control – farm level

- Create restriction zone around infected farm
- Trace animal contacts to and from infected farm
- Trace movement of animal transportation vehicle
- Test for ASF in restriction zone
 - Send samples to reference laboratory for confirmation of infection

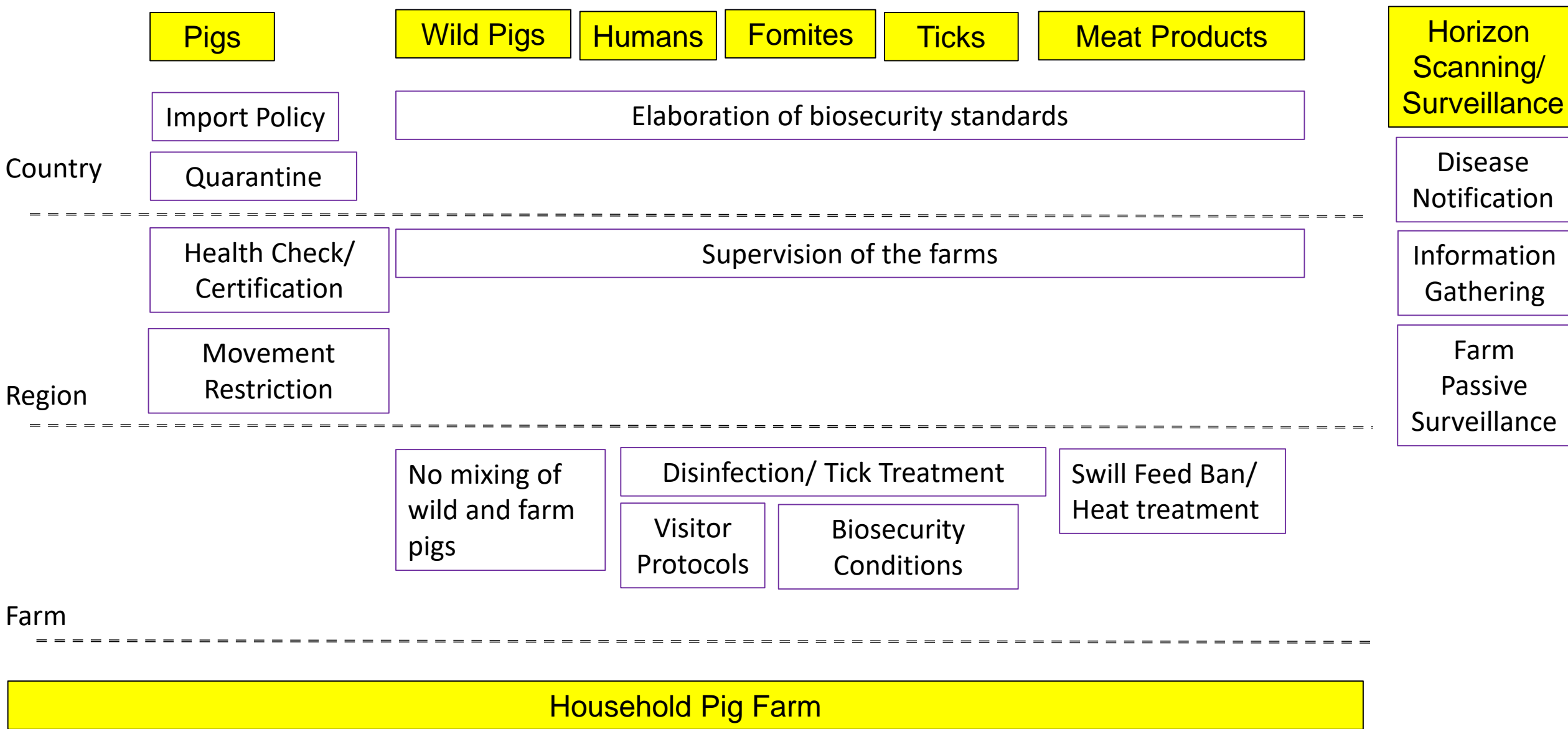
Preventive measures

- Recommend regionalization in involved country
- Enhanced certification process of imports
- Conduct awareness campaign
 - For farmers and traders

General

- Check legislation and regulation
- Report or communication to OIE
- Diagnostic capacity
 - Create capacity i.e. import testing kit and train lab personnel

Identification of pathways and the relevant preventive measures



Risk of disease incursion

Pathway	Country factor	Regional factor	Farm factor	Risk
Pigs	Low	Low	Low	LOW
Pork (Feed / Swill)	Low	Low	Low	LOW
Wild Pigs	High	High	Moderate	HIGH
Humans	Low	Low	Low	LOW
Fomites	Low	Low	Low	LOW
Ticks	High	High	Moderate	HIGH

Level of Preparedness

Increase the level biosecurity.

Wild boar surveillance, ask cooperation to hunters, buffer zone (building fence)

Strengthened surveillance in certain area (identified as high risk area)

Warning, disseminating information

Review the current system, functioning well. Providing emergency kit.

Emergency outbreak

- Laboratory in place to conduct confirmatory test
- Ready to disseminate outbreak information stakeholders inside outside country
- terminate the export

- Contingency plan

Movements and shipping restriction, disinfection, culling, incineration and burying, monitoring farms