Technical meeting
4-6 December 2013
Beijing

VACCINATION AS A CONTROL TOOL AGAINST HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

Developing guidance on vaccines and vaccination against HPAI from lessons learned

Standards for AI vaccines and vaccination

OIE position and activities

Joseph Domenech and Gounalan Pavade

Technical meeting on Vaccination
as a control tool against HPAI
OIE/FAO Network of Expertise on Animal Influenza (OFFLU)
4-6 December 2013, Beijing, People's Repubic of China

A. Horizontal approaches

Improving animal health is a global public good

Veterinary Services are at the heart of animal health systems tasked with preventing and controlling animal diseases

(See OIE definition VS)

The role of OIE in transforming sciences into practice and policy making

Through the publication of standards, guidelines and recommendations

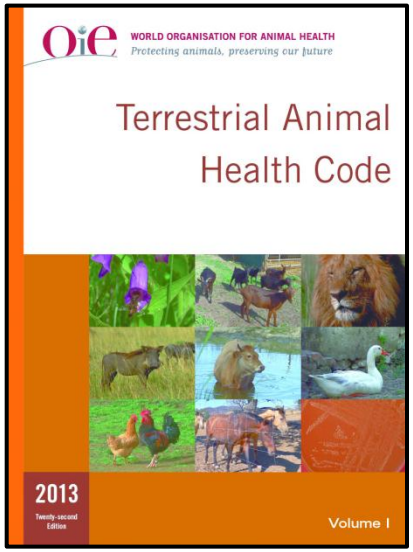
Which will be translated in tools, methods, strategies and policies, laws & regulations

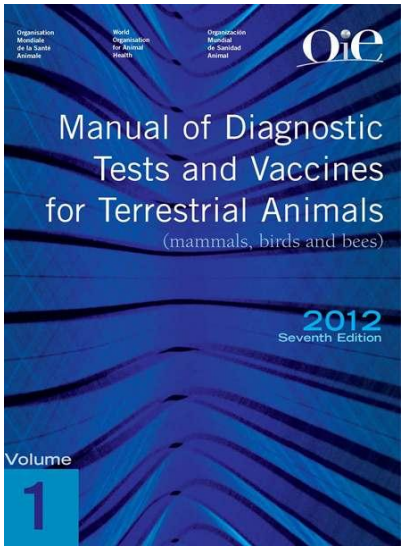
OIE standard setting process

- Specialized Commissions: Scientific Com., Biol. Stand. Com...
- Ad Hoc Groups and Working Groups

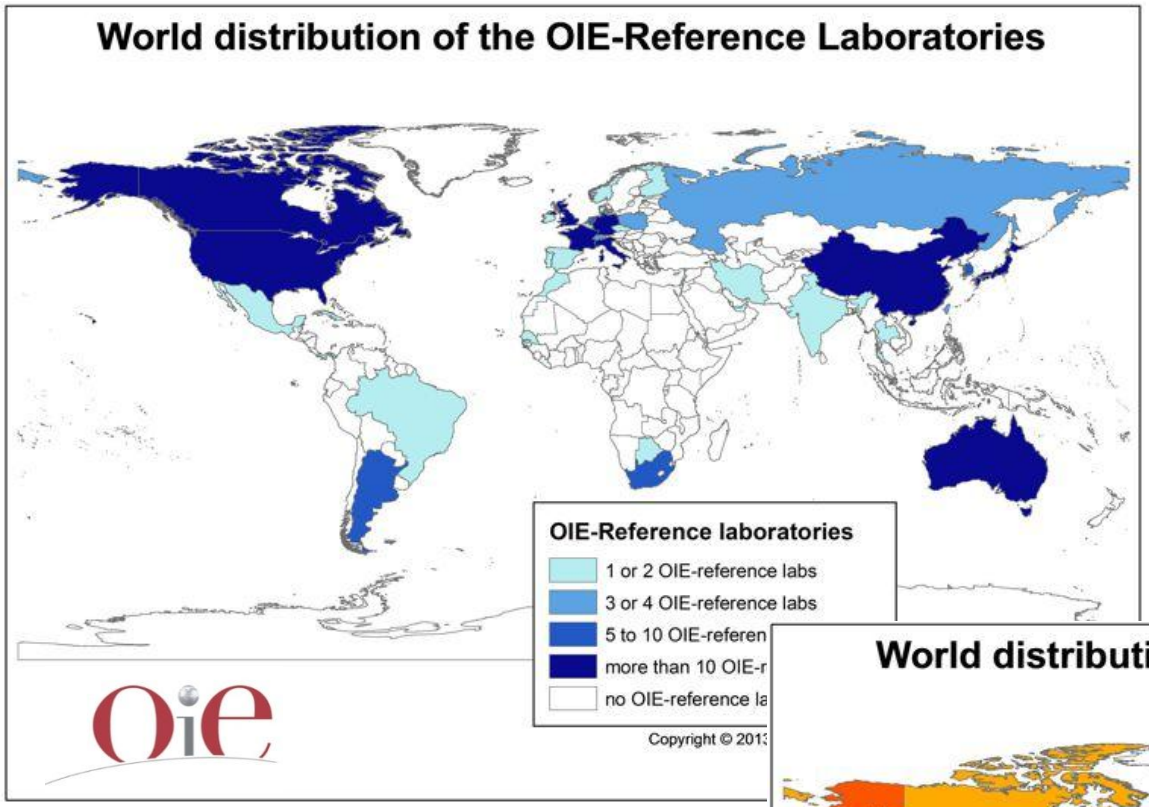
Proposed Standards sent to all OIE Delegates

- Comments from all OIE Delegates
- Consultation of major partners
- Second round of discussions with Commissions...



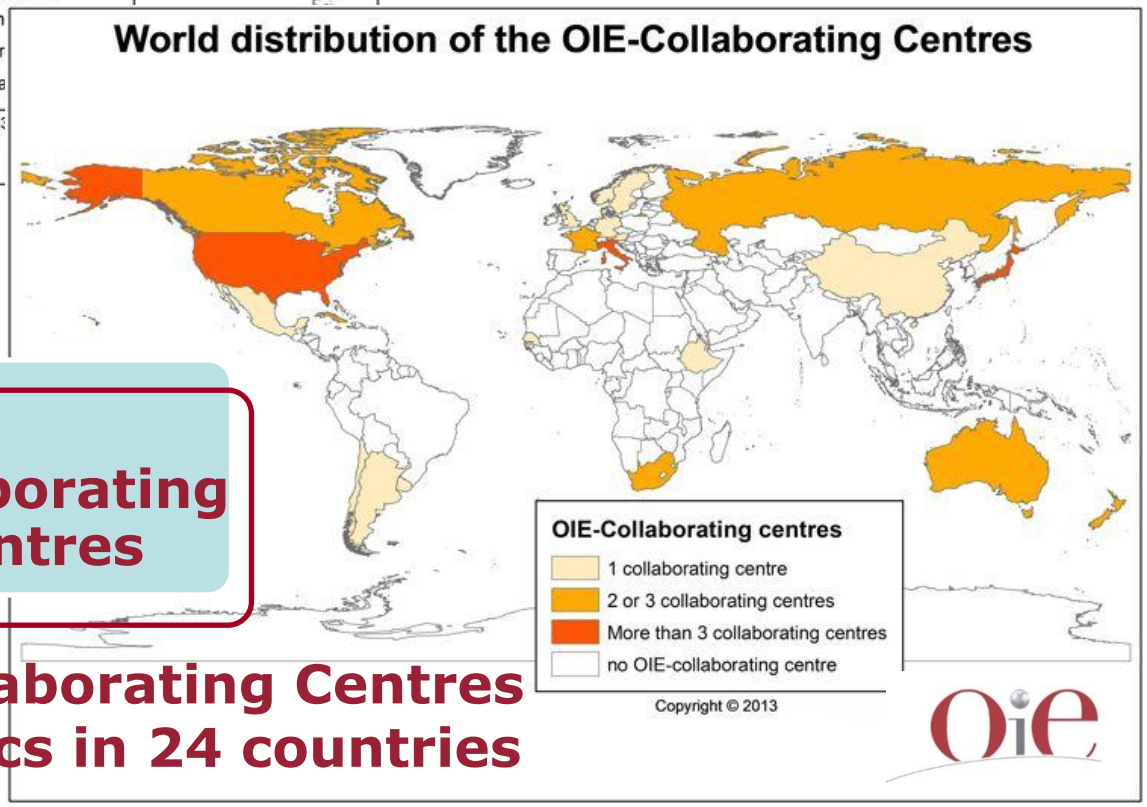


General Session May Adoption: vote of all Delegates during the World Assembly



Reference Laboratories

241 laboratories,
116 diseases/topics
in 37 countries

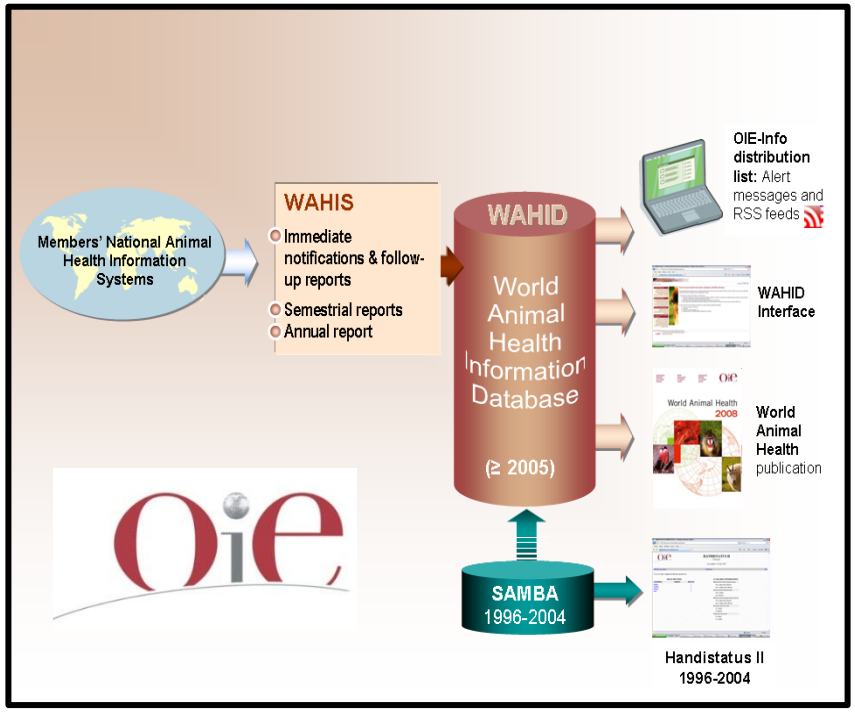


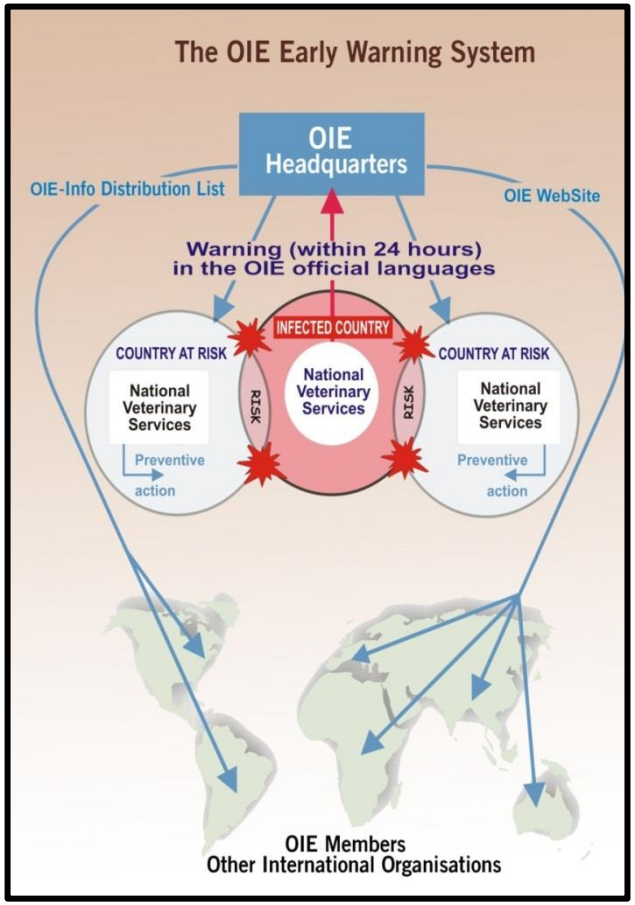
OIE Reference Centers May 2013

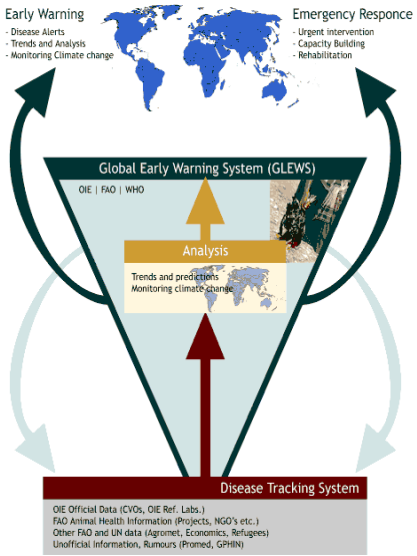
Collaborating Centres

43 Collaborating Centres
42 topics in 24 countries

Disease information - Reporting



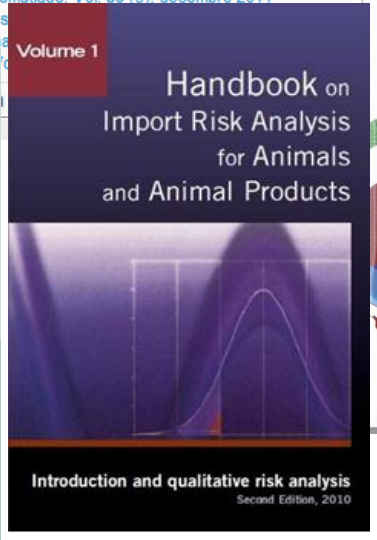


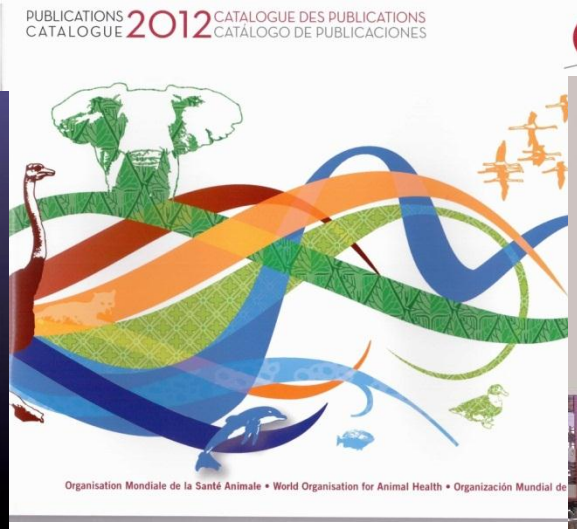


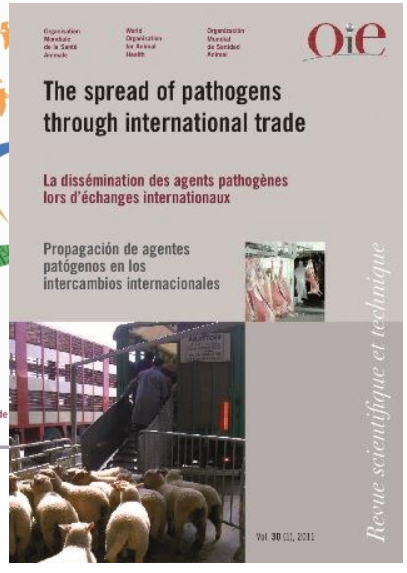
Global Early Warning System (GLEWS)

Publications www.oie.int

Global Strategies for Animal Disease Control, (3) 2013







International Conferences

OIE Global Conference on Wildlife, Paris (France) 23-25 February 2011

Permanent institutional cooperation

FAO - Food and Agric. Org.

WHO - World Health Organization

CODEX ALIMENTARIUS International Food Standards

WTO - World Trade Or

IPPC - Int.Plant Prot.

World Bank

CABI - CAB Int.

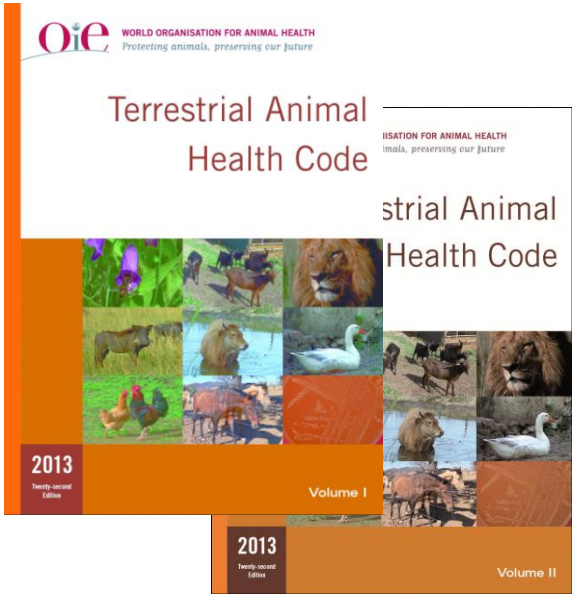
ILRI – Int. Livestock Res. Inst.

FAO - OIE GF TADS

Global Framework for the Progressive Control of Transboundary Animal Diseases

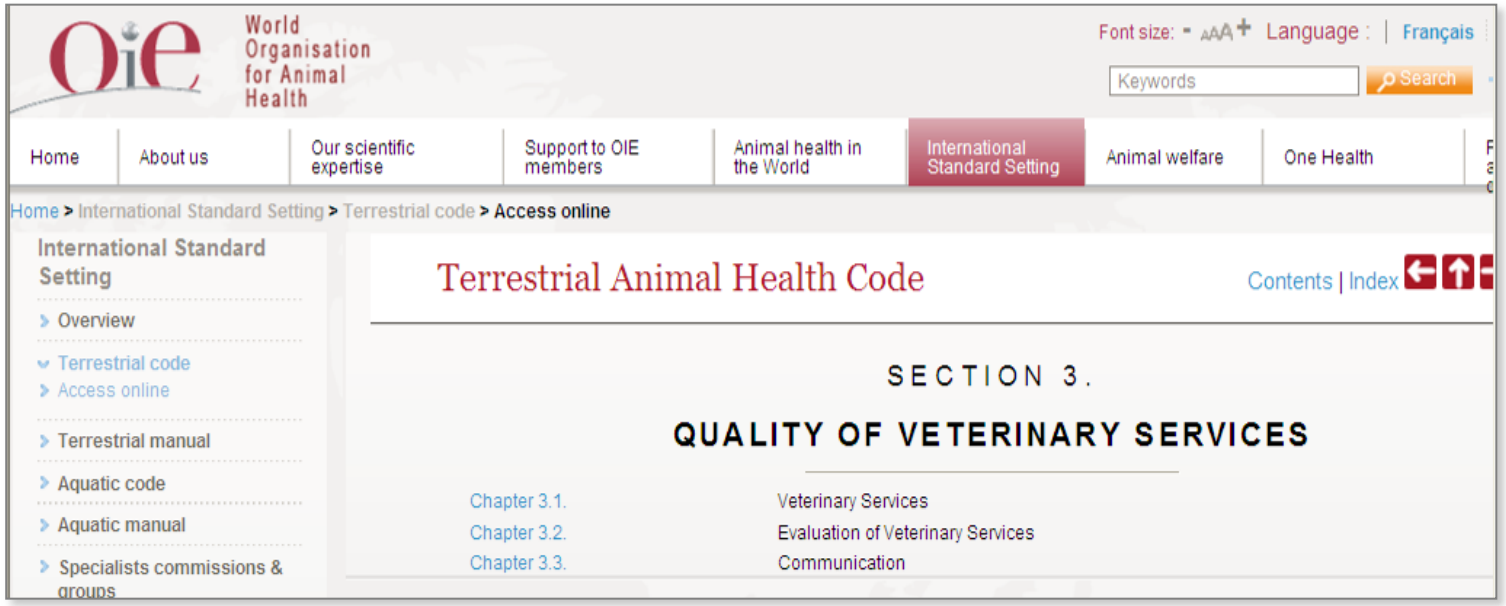
And cooperation with Regional public organisations and private sector bodies (more than 50 agreements)

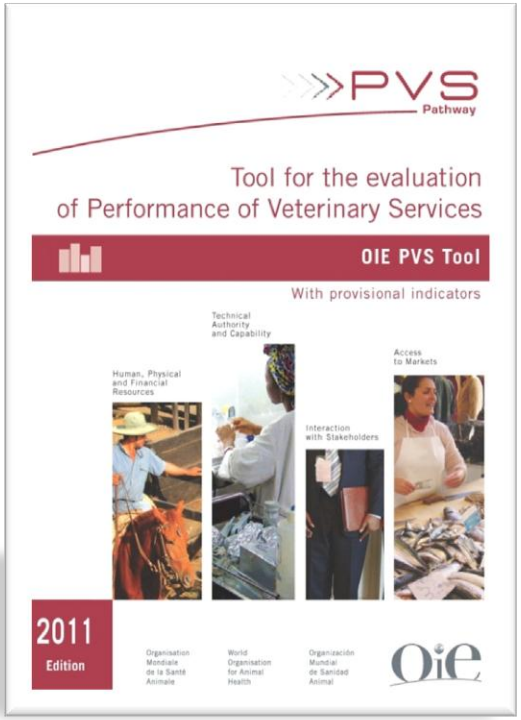
OIE assistance to countries

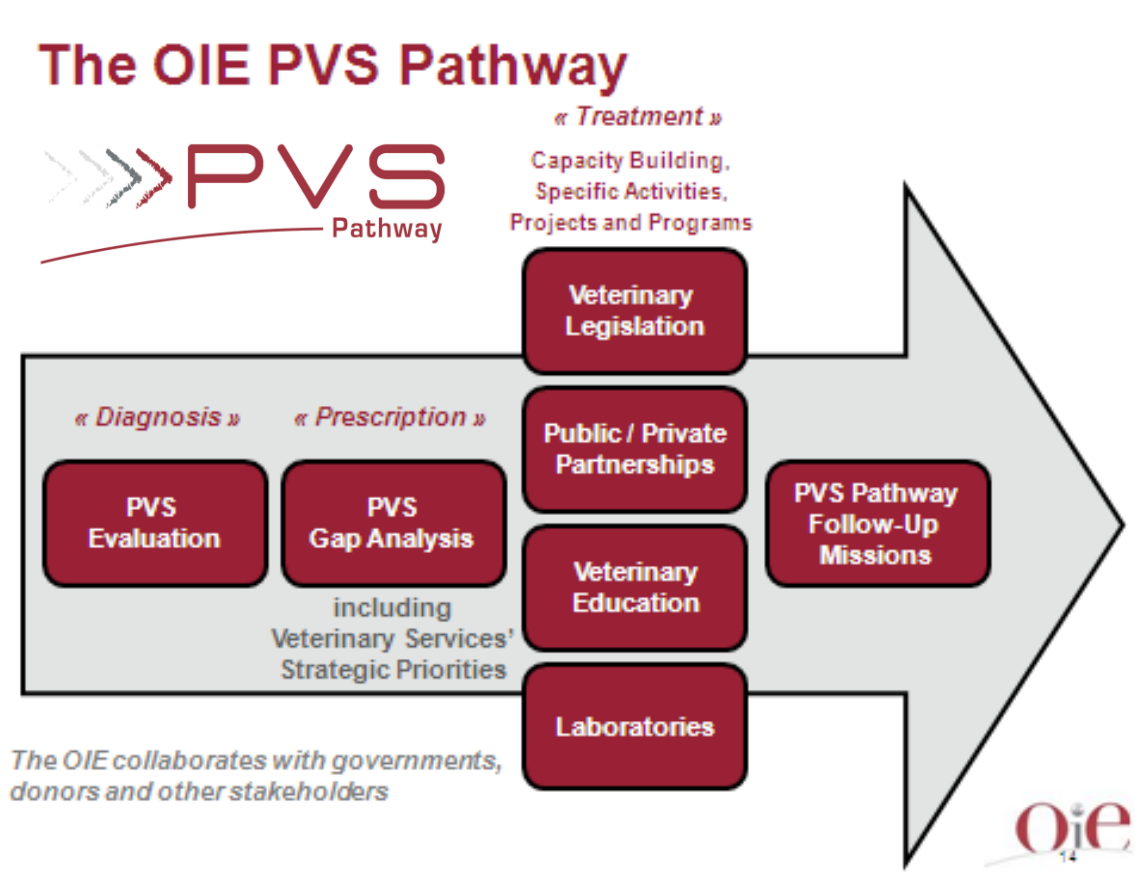


OIE Terrestrial Animal Health Code

- Chapter 3.1. Veterinary Services
- Chapter 3.2. Evaluation of Veterinary Services







PVS Evaluation

PVS Gap Analysis

OIE PVS Legislation missions,
Veterinary Education (twinnings)
Veterinary Stat Body (twinnings)
Laboratory PVS Gap Analysis,
One Health PVS mission.
PVS Pathway Follow-up Eval.
Round tables with donors.

A continuous Process to improve the compliance of VS with international standards

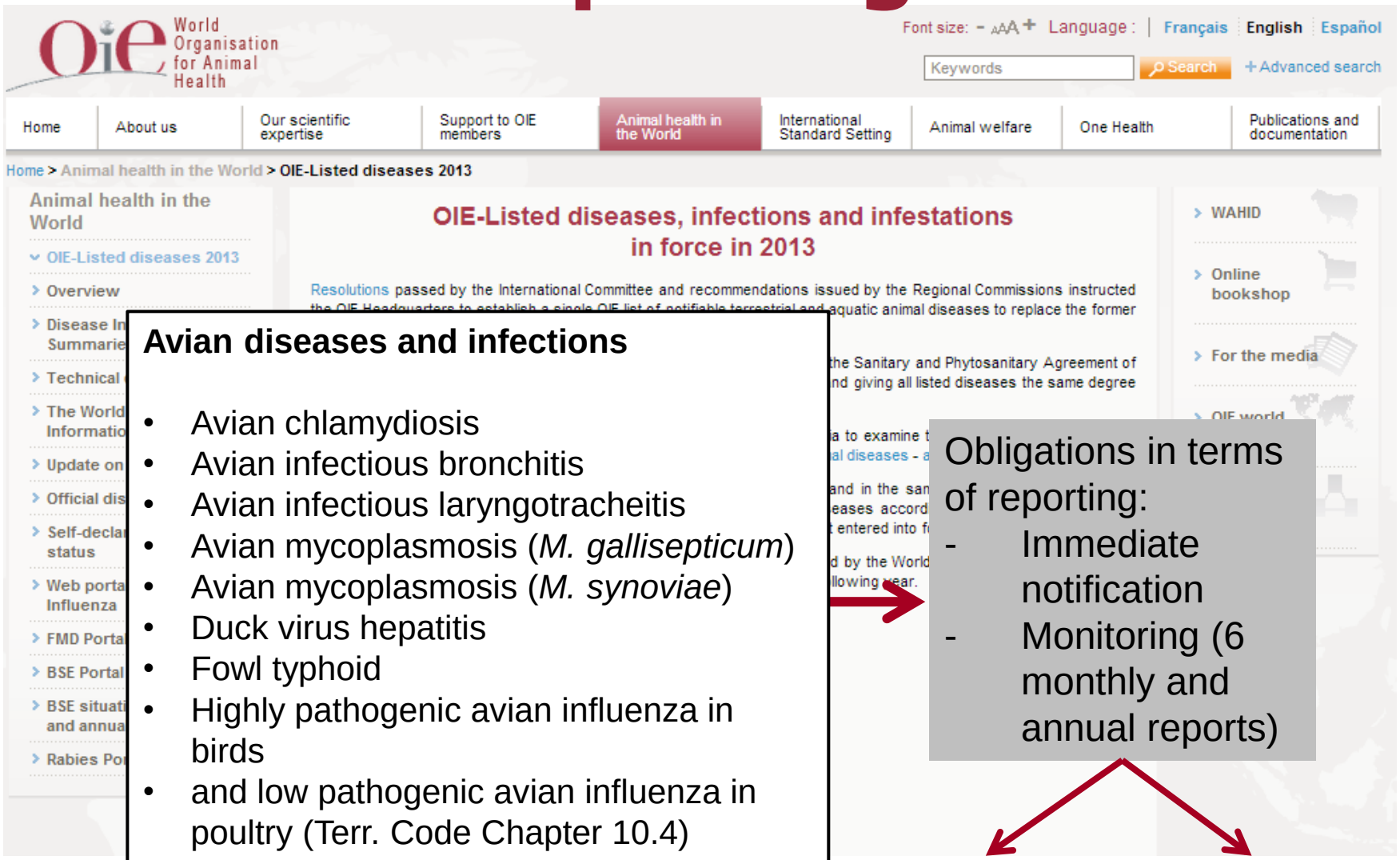
OIE

B. Disease specific approaches

OIE International standards and guidelines on Infection with Avian Influenza Virus

OIE standards and recommendations act as the front-line of prevention and control against the spread of disease and related challenges.

Reporting



Avian diseases and infections

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*M. gallisepticum*)
- Avian mycoplasmosis (*M. synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Highly pathogenic avian influenza in birds
- and low pathogenic avian influenza in poultry (Terr. Code Chapter 10.4)
- Infectious bursal disease (Gumboro dis.)
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis

Obligations in terms of reporting:

- Immediate notification
- Monitoring (6 monthly and annual reports)

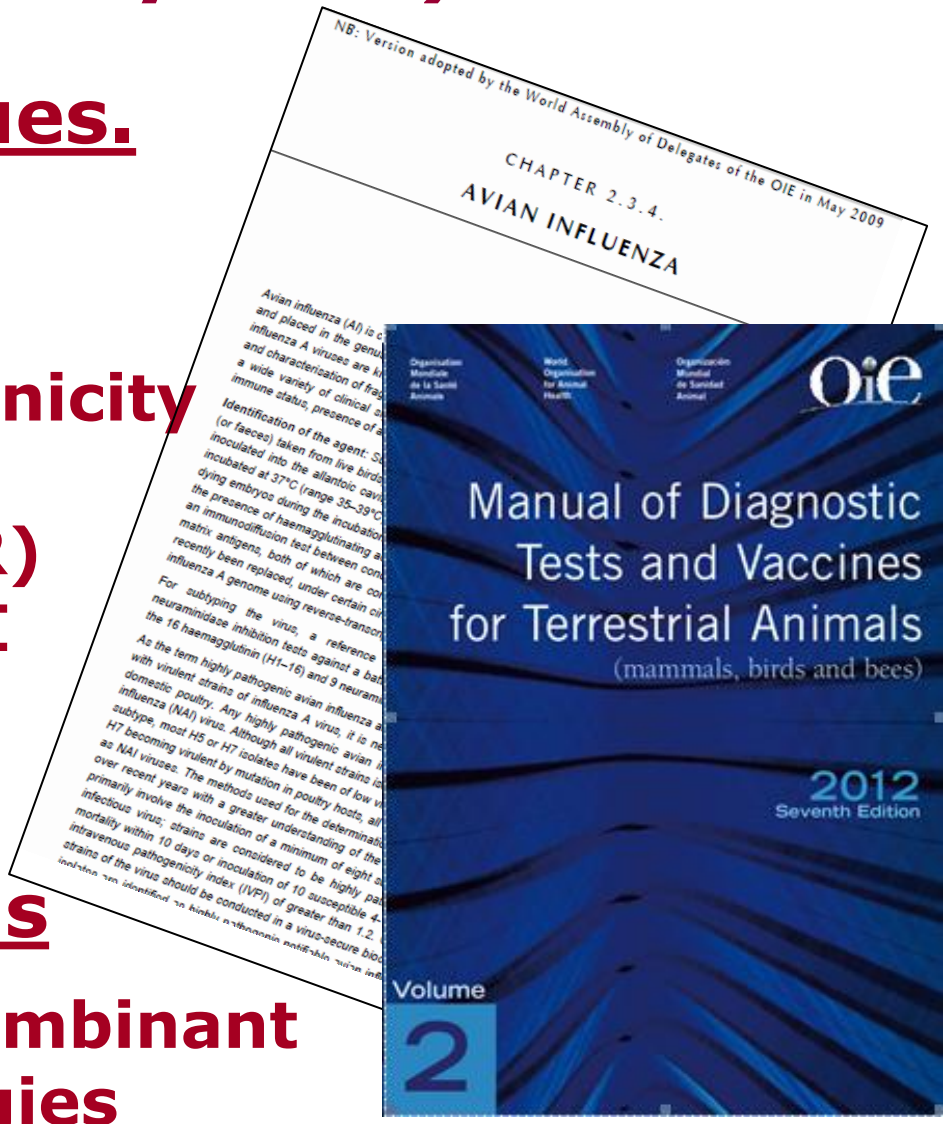
WAHIS II

WAHIS-wild

Manual of Diagnostic Tests and Vaccines Chapter 2.3.4. on Avian Influenza (revised May 2009)

- **Diagnostic techniques. prescribed test:**
  - Agent identific. and assessment of pathogenicity
  - Antigen detection and RNA detection(RT-PCR)
  - Serology: AGID, HA/HI ELISA…
- **Vaccine and Biological Standards**

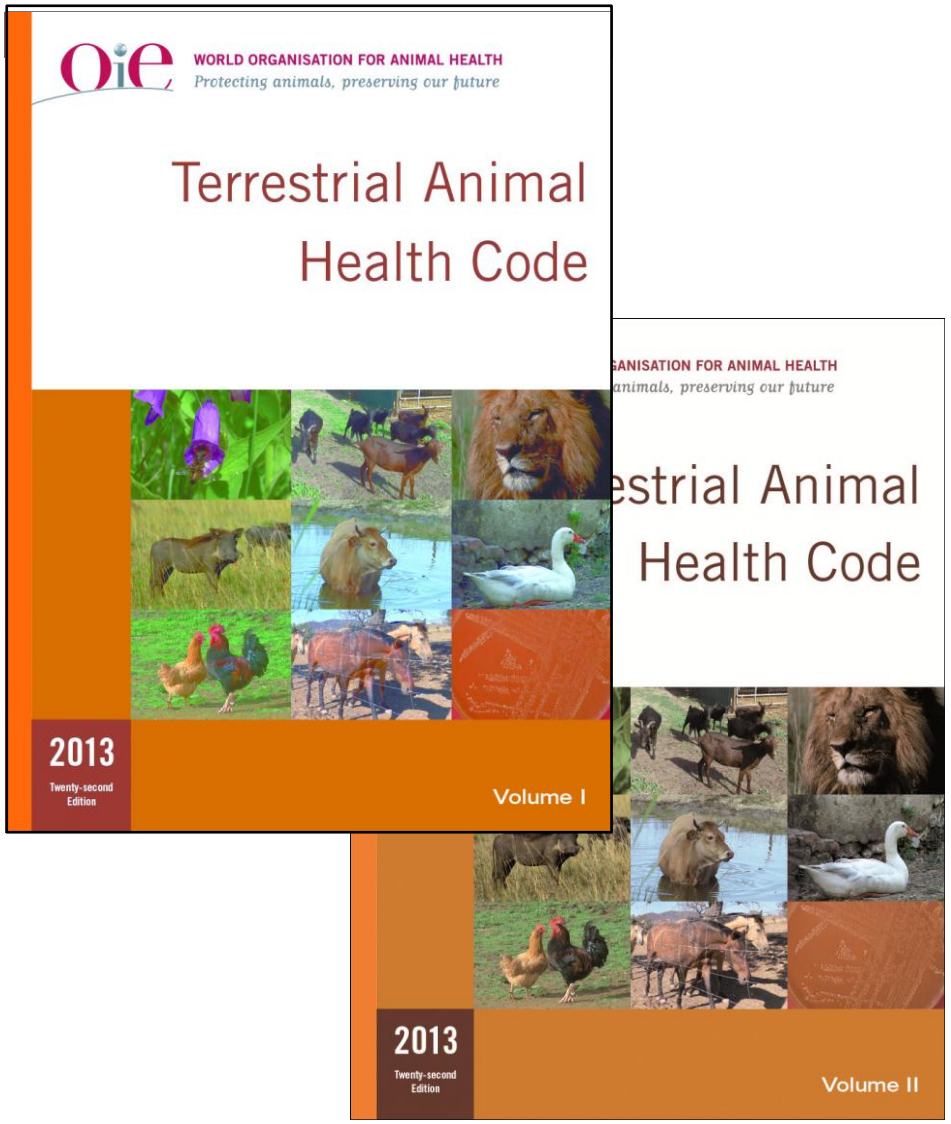
  Conventional and recombinant vaccines, DIVA strategies



OIE Terrestrial Animal Health Code, 2013

Chapter 10.4. Infection with Avian Influenza Virus

Science based and regarding import of commodities risk analysis approaches



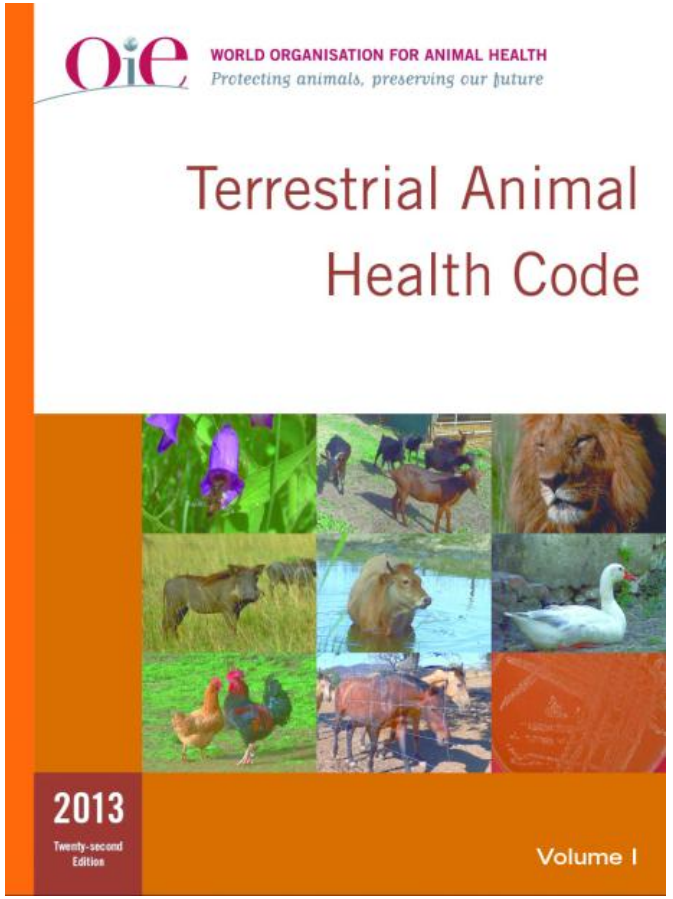
Horizontal Chapters

- Diseases notification (1.1)
- List of notifiable diseases (1.2)
- Diagnostic tests for notif. Dis. (1.3)
- Disease Surveillance (1.4)
- Self/Official declaration of status (1.6)
- Import risk analysis (2.1)
- Quality and Eval. of Vet. Serv. (3.1, 3.2)
- Veterinary legislation (3.4)
- Zoning and Compartmentalization (4.3, 4.4)
- Imp/export. procedures (5.1, 5.2)
- Biosecurity proc in poultry production (6.4)
- Slaughter and killing (7.5, 7.6)

Disease Specific Chapters (vertical)

AI Chapt. 10.4 contains articles on:

- Case definition, species
- Criteria for sanitary statuts: country, zone or compartiment
- No risk commodity
- Recommandation for import of live animals and commodities
- Pathogen inactivation
- Specific disease surveillance



Slides in black: not to be read but included in the PPT for information

Chapter 1.1. Notification of diseases , infections, infestations and epidemiological information

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the Headquarters:

1) in accordance with relevant provisions in the disease-specific chapters, notification through the World Animal Health Information System (WAHIS) or by fax or e-mail, within 24 hours, of any of the following events:

a) first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment;

b) re-occurrence of a listed disease, infection or infestation in a country, a zone or a compartment following a report declared the outbreak ended;

c) first occurrence of a new strain of a pathogen of a listed disease, infection or infestation in a country, a zone or a compartment;

d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a listed disease, infection and infestation prevalent within a country, a zone or a compartment;

Article 1.1.3. (cont.)

e) an emerging disease with significant morbidity or mortality, or zoonotic potential;

f) evidence of change in the epidemiology of a listed disease, infection or infestation (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2) weekly reports subsequent to a notification under point 1 above, to provide further information on the evolution of the event which justified the notification. These reports should continue until the disease, infection or infestation has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country; in any case, a final report on the event should be submitted;

3) six-monthly reports on the absence or presence, and evolution of listed diseases, infections or infestations and information of epidemiological significance to other Member Countries;

4) annual reports concerning any other information of significance to other Member Countries. Although Member Countries are only required to notify listed diseases, infections and infestations and emerging diseases according to points 1 to 4 above, they are encouraged to inform the OIE of other important animal health events.

Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations on the OIE list

Article 1.2.2

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the agent (via live animals or their products, vectors or fomites) has been proven.
AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.
AND

3)
a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.
OR
b) The disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or a zone.
OR
c) The disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations.
AND

4) A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.
OR

5) The disease or infection is an emerging disease with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other diseases or infections.

Article 1.2.3.

The following are included within the category of avian diseases and infections:

- ***Avian chlamydiosis***
- ***Avian infectious bronchitis***
- ***Avian infectious laryngotracheitis***
- ***Avian mycoplasmosis (Mycoplasma gallisepticum)***
- ***Avian mycoplasmosis (Mycoplasma synoviae)***
- ***Duck virus hepatitis***
- ***Fowl typhoid***
- **Infection with avian influenza viruses and infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds**
- ***Infectious bursal disease (Gumboro disease)***
- ***Newcastle disease***
- ***Pullorum disease***
- ***Turkey rhinotracheitis.***

Chapter 1.6. Procedures for self declaration and for official recognition by the OIE

Article 1.6.1. General principles

Member Countries may wish to make a self declaration as to the freedom of a country, zone or compartment from an OIE listed disease. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim.

The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF). But countries may request official recognition by the OIE as to the risk status of a country or zone with regard to these 6 diseases

The OIE does not grant official recognition for other diseases.

Chapter 3.1. Veterinary Services

5 articles on:
- Fundamental principles of quality
- Evaluation of its Veterinary Services where the initiating Member Country is an actual or a prospective importer or exporter of commodities
- Procedures for the evaluation of the Veterinary Services: OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool).

Chapter 3.2. Evaluation of Veterinary Services

14 articles describing the scope, the evaluation criteria for the organisational structure and material resources, legislation and functional capabilities, animal health controls, veterinary public health controls. They also address the performance assessment and audit programmes, the participation in OIE activities and the evaluation of the veterinary statutory body
This article outlines appropriate information requirements for the self-evaluation or evaluation of the Veterinary Services of a country.

Chapter 3.4. Veterinary Legislation

13 articles on:
- Objectives, definitions, principles, methods for drafting the texts,
- Definition of the competent authority, veterinarians and para professionals,
- Outline of legislation for laboratories, production sector, animal diseases and welfare, medicines and biologicals, human food production chain, import-export and certification

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Chapt.6.4. Biosecurity procedures in poultry prod.

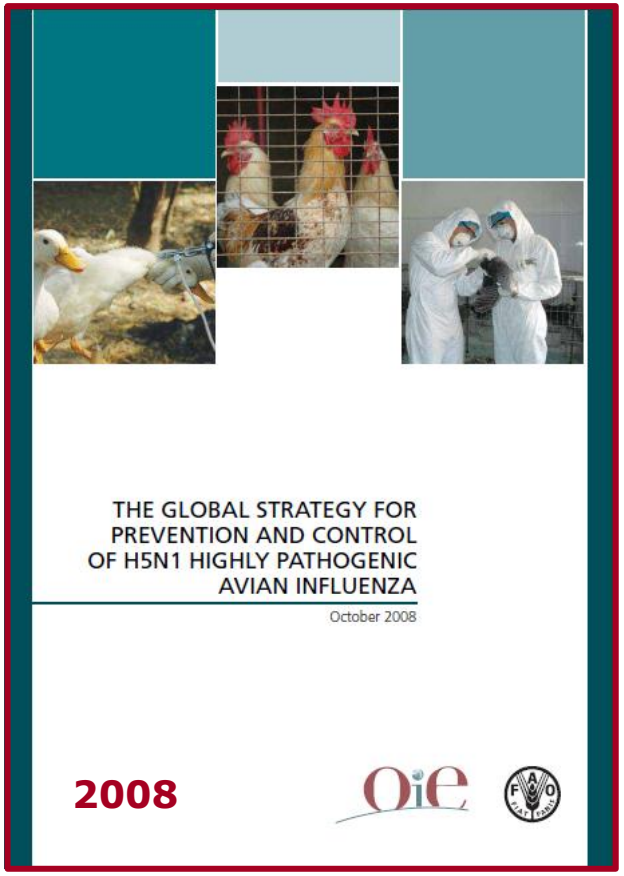
7 articles on:
- Definitions, purpose, scope
- Recommendations: on the location and construction of poultry establishments, applicable to the operation of poultry establishments, for prevention of further dissemination of infectious agents of poultry, to prevent the dissemination of infectious agents to and from live bird markets

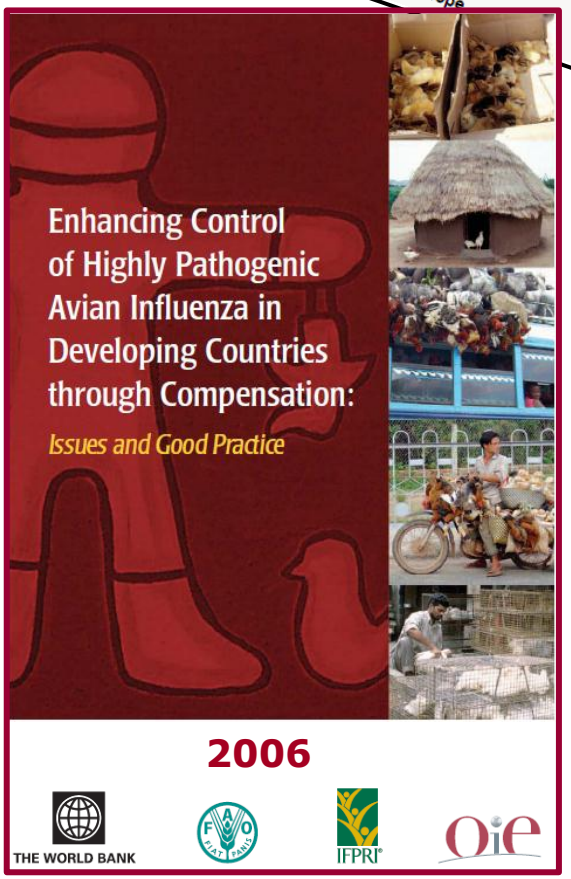
Chapter 10.4.
Infection with Avian Influenza Virus

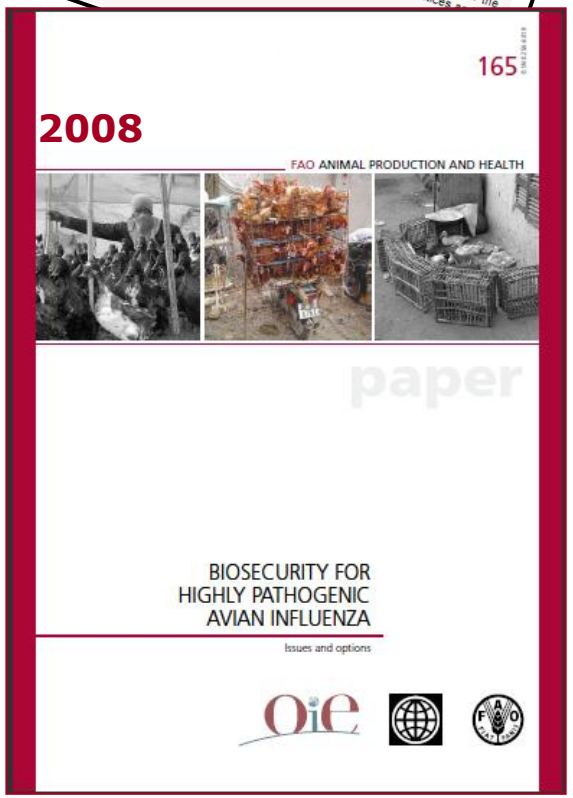
33 articles including :

- 1 article on general provisions: pathogenicity abd criteria for notific., incub., case definition…
- 6 articles for importing safe commodities after destruction of the virus
- 3 article on determination of self AI status for a country/zone/compartment
- 14 articles on recommendations for importing of commodities
- 2 articles on inactivation of the virus
- 7 articles on surveillance

The articles on surveillance define the principles and provides a guide for the surveillance of AI in accordance with Chapter 1.4. applicable to Member Countries seeking recognition of country or zonal freedom from CBPP or seeking reestablishment of freedom following an outbreak.







Guidelines, Strategies and Standards

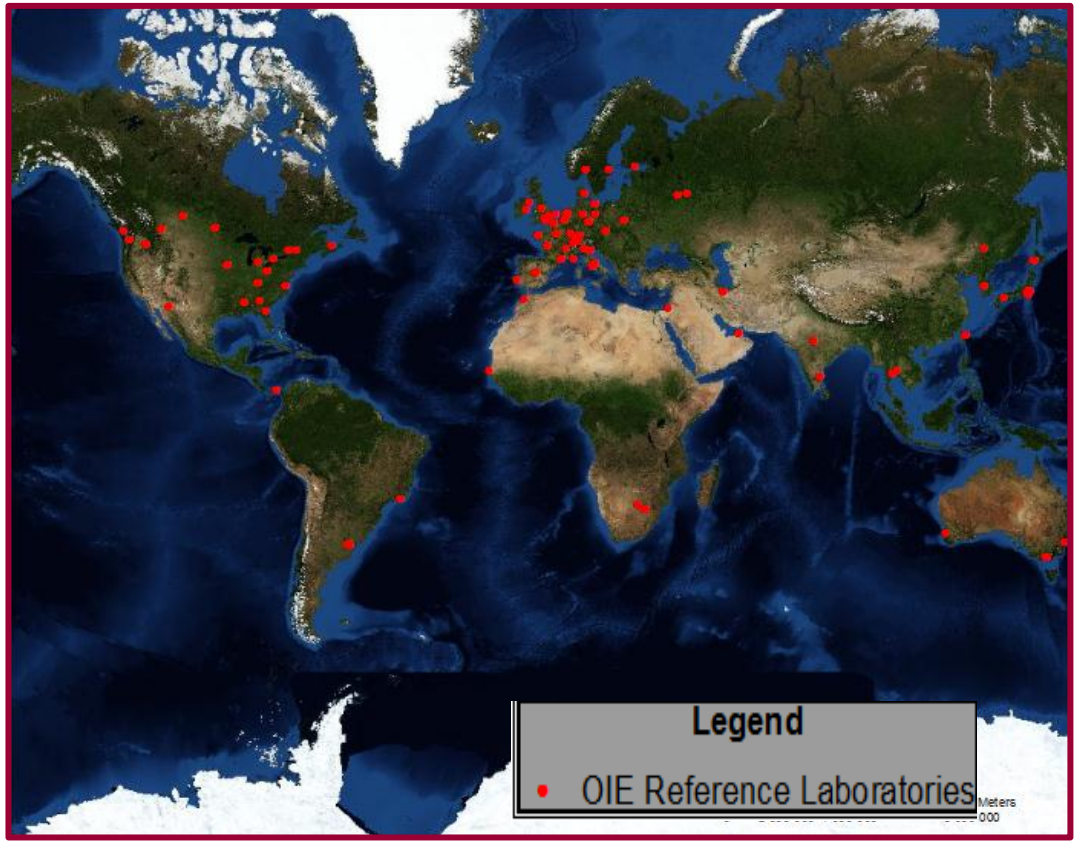
OIE-FAO Network of Expertise on Animal Influenza

Experts working to protect health and livelihoods through global cooperation

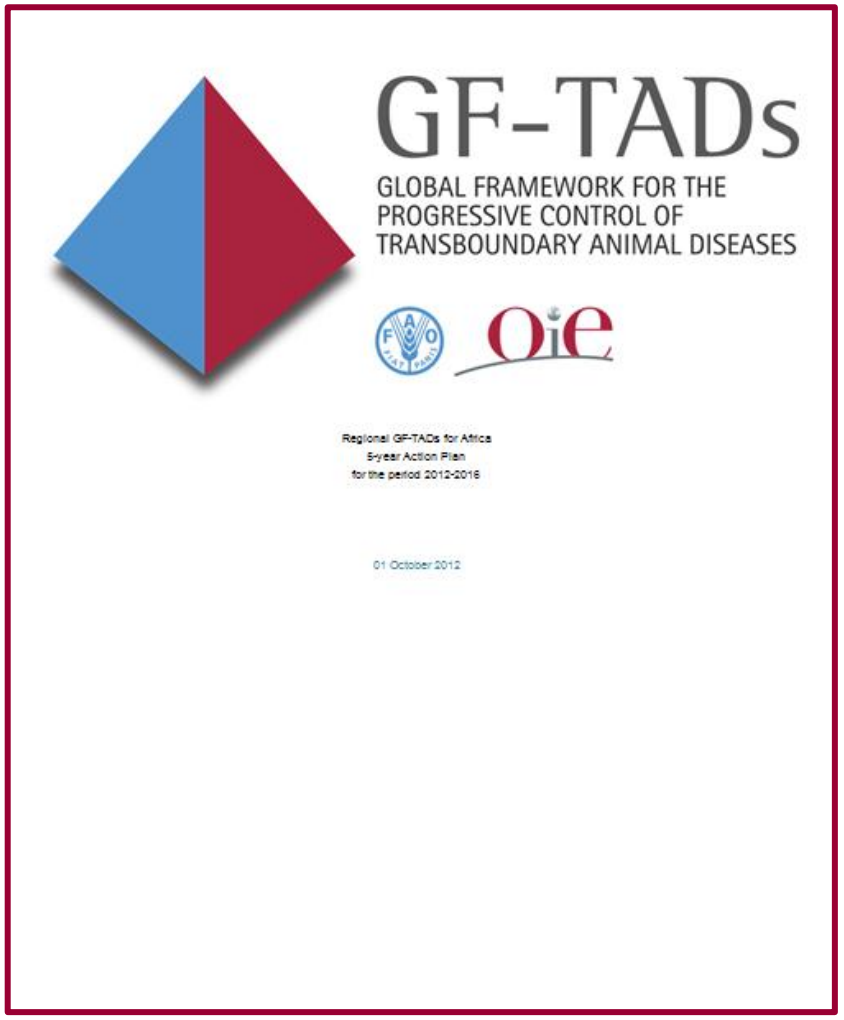
www.offlu.net

HPAI and LPAI OIE Reference Laboratories

- Dr Frank Wong, CSIRO, Geelong, Australia
- Dr John Pasick, Winnipeg, Canada
- Dr Hualan Chen, Harbin, China
- Dr Timm C. Harder, Riems, Germany
- Dr Chakradhar Tosh , Bhopal, India–
- Dr Ilaria Capua, Padova, Italy
- Prof. Hiroshi Kida, Sapporo, Japan
- Prof. Ian Brown, Weybridge, UK
- Dr Mia Torchetti, Ames, USA



5 Years Action Plan
Global and regional GF-TADs



HPAI is one of the priority diseases in Europe, Asia, Americas, and Middle East

As well as at the Global level

Vaccination

AVIAN INFLUENZA VACCINATION

---> OIE information document

---> Verona Recommendations*

Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

MEETING OF THE

OIE *AD HOC* GROUP ON VACCINATION STRATEGIES FOR AVIAN INFLUENZA

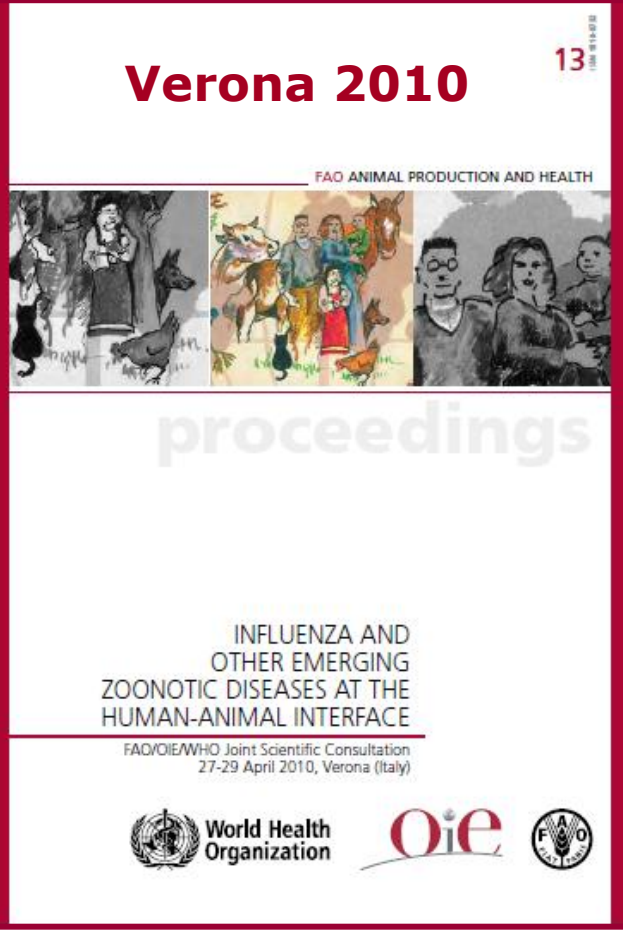
Paris, 3-4 October 2006

OIE information document on avian influenza vaccination

Acknowledgements

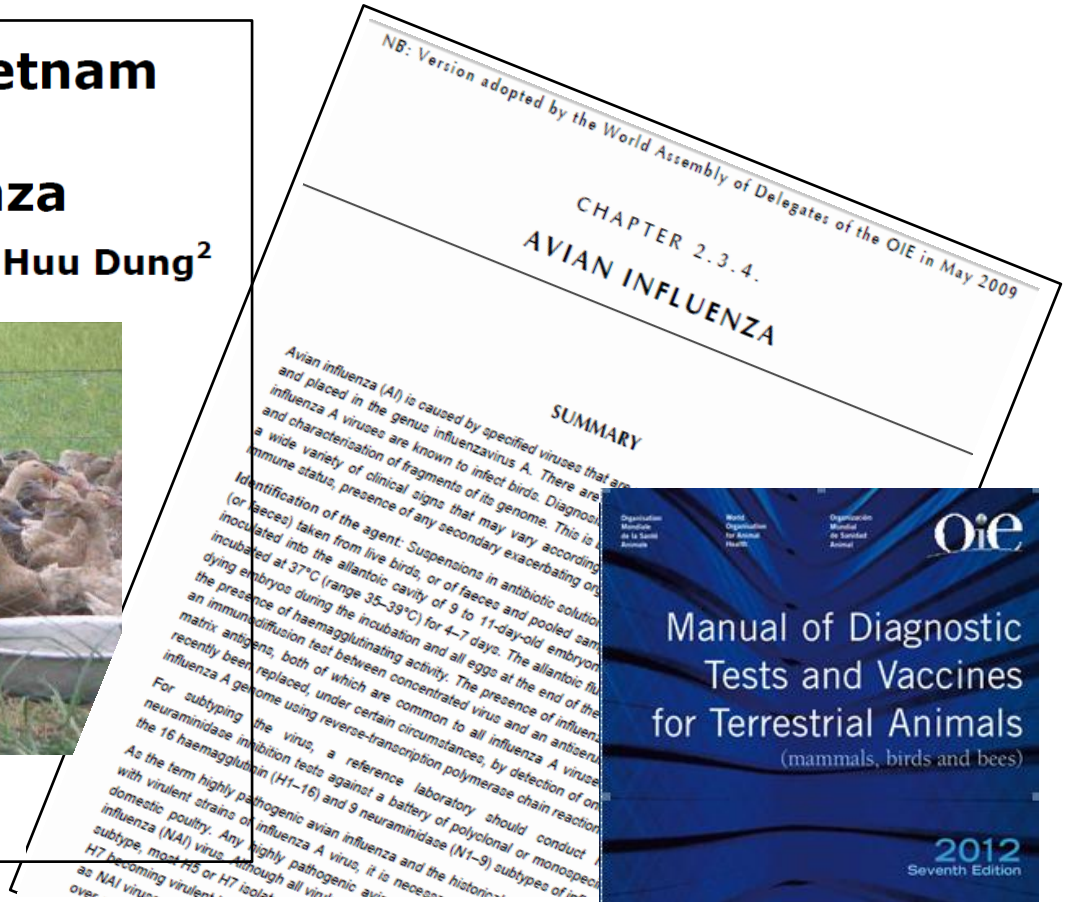
This document was prepared with the support of FAO and the valuable input of the OIE *ad hoc* group on AI vaccination guidelines, which first met in March 2006. Members of the *ad hoc* group are: Dr Annemarie Bouma (The Netherlands), Dr Hualan Chen (China), Dr Baltus Erasmus (South Africa), Dr Peter Jones (International Federation on Animal Health), Dr Stefano Marangon (Italy) and Dr Joseph Domenech (FAO).

Verona 2010



Vaccination of poultry in Vietnam against H5N1 highly pathogenic avian influenza

A Case Study by Dr Les Sims[1] and Dr Do Huu Dung[2]


NB: Version adopted by the World Assembly of Delegates of the OIE in May 2009

CHAPTER 2.3.4.

AVIAN INFLUENZA

SUMMARY

Avian influenza (AI) is caused by specified viruses that ar... and placed in the genus influenzavirus A. There are... influenza A viruses are known to infect birds. Diagnosi... and characterisation of fragments of its genome. This is... a wide variety of clinical signs that may vary according... immune status, presence of any secondary exacerbating or...

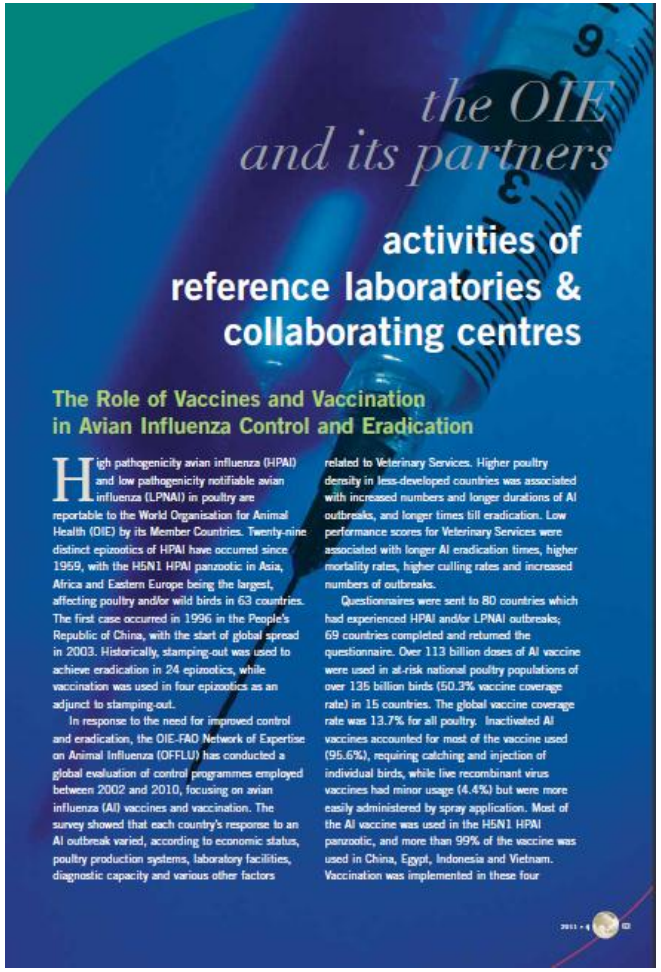
Identification of the agent: Suspensions in antibiotic solutio... (or faeces) taken from live birds, or of faeces and pooled sam... inoculated into the allantoic cavity of 9 to 11-day-old embryon... incubated at 37°C (range 35–39°C) for 4–7 days. The allantoic flu... dying embryos during the incubation and all eggs at the end of the... the presence of haemagglutinating activity. The presence of influen... an immunodiffusion test between concentrated virus and an antiseru... matrix antigens, both of which are common to all influenza A viruses... recently been replaced, under certain circumstances, by detection of on... influenza A genome using reverse-transcription polymerase chain reaction...

For subtyping the virus, a reference laboratory should conduct... neuraminidase inhibition tests against a battery of polyclonal or monospecif... the 16 haemagglutinin (H1–16) and 9 neuraminidase (N1–9) subtypes of in...

As the term highly pathogenic avian influenza and the historic... with virulent strains of influenza A virus, it is necessa... domestic poultry. Any highly pathogenic avi... influenza (NAI) virus. Although all viru... subtype, most H5 or H7 isola... H7 becoming virulent... as NAI viruses...

In Manual 2.3.4. Part C. REQUIREMENTS FOR VACCINES AND DIAGNOSTIC BIOLOGICALS

It is important that vaccination alone is not considered the solution to the control of NAI or LPAI subtypes if eradication is the desired result. Without the application of monitoring systems, strict biosecurity and depopulation in the face of infection, there is the possibility that these viruses could become endemic in vaccinated poultry populations



Rev. sci. tech. Off. int. Epiz., 2011, **30** (3), 839-870

Assessment of national strategies for control of high-pathogenicity avian influenza and low-pathogenicity notifiable avian influenza in poultry, with emphasis on vaccines and vaccination

D.E. Swayne [1, 2]*, G. Pavade [1], K. Hamilton [1], B. Vallat [1] & K. Miyagishima [1]

(1) World Organisation for Animal Health (OIE), 12 rue de Prony, Paris 75017, France
(2) World Organisation for Animal Health (OIE) Collaborating Centre for Research on Emerging Avian Diseases, Exotic and Emerging Avian Viral Diseases Research Unit, Southeast Poultry Research Laboratory, Agricultural Research Service, United States Department of Agriculture, 934 College Station Road, Athens, Georgia 30605, United States of America
*Corresponding author

Special thanks to OFFLU, the joint OIE and Food and Agriculture Organization of the United Nations (FAO) animal influenza network of experts and FAO staff for assistance during this research study

Submitted for publication: 29 September 2011
Accepted for publication: 21 October 2011

OFFLU 2012

OFFLU avian influenza vaccine guidance

Continued evaluation and updating of vaccine seed strains to protect against emergent variant field virus strains

Rev. sci. tech. Off. int. Epiz., 2009, **28** (1), 293-305

Experiences with vaccination in countries endemically infected with highly pathogenic avian influenza: the Food and Agriculture Organization perspective

J. Domenech [1], G. Dauphin [1], J. Rushton [1], J. McGrane [2], J. Lubroth [1], A. Tripodi [1], J. Gilbert [3] & L.D. Sims [4]

Current OIE conclusions on vaccination against HPAI

- Vaccination works if implemented appropriately (vaccination coverage…). It raises the level of protective flock immunity and increases the resistance to infection. It reduces viral replication and viral shedding.
- Needs appropriate vaccine (vaccine matching, Quality control), vaccination methods (cold chains, trained vaccinators…), Post Vacc Monitoring
- It is not an easy tool
- Vaccination cannot eradicate the disease/virus if used alone
- Importance of other methods: biosecurity in farms, live bird markets…, control of movements, stamping out…

- Knowledge of the prevailing epidemiological situation is of critical importance as well as of the poultry production system in place which influences the risk of virus introduction and spread.
- Logistical constraints have also to be known for adequate planning of field interventions.
- Need of effective veterinary Services
- Role of surveillance/early detection/early warning/immediate response (contingency and emergency planning…)
- Private-Public Partnership

- Specific problem related to backyard farming production systems (small village holders)
- Vaccination strategies: country or zonal massive vaccination, targeted vaccination (high risk areas/zones, important impact…), emergency vaccination, commercial farms vaccination (private good)
- Surveillance of circulating strains and identification of new possible field variants (virus characterization, vaccine matching studies…)
- Issue of new vaccines protecting 1 day old chicken and more effective in all duck species?
- Combination of various poultry vaccinations to be considered

Thank you for your attention