International regulations and standards for avian influenza, including the vaccine standards of the World Organisation for Animal Health

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Summary
For avian influenza the World Organisation for Animal Health (OIE) has laid down international standards on notification, trade, diagnosis, surveillance and the production and use of vaccine. These standards are science- and risk-based to ensure safe trade in poultry and poultry products without unjustified barriers. The European Union, with its 27 Member States, has in place harmonised legislation in line with OIE standards. Early detection, rapid diagnosis, notification and high quality Veterinary Services are crucial for ensuring a rapid response to avian influenza outbreaks and for swiftly reducing the risk of virus spread via trade. Depending on the situation, vaccination may also be a very important tool for disease control. The use of high quality vaccines and post-vaccination monitoring are essential for the successful implementation of vaccination. Compliance with international standards is of paramount importance for protecting animal and human health in the global crisis of the highly pathogenic avian influenza of the H5N1 subtype.

Keywords

Introduction
Strategies for the control and eradication of highly pathogenic avian influenza (HPAI) should target the animal host. This involves the following key actions: early detection, early warning, rapid confirmation of suspects, rapid response, and rapid and transparent notification. The classical control methods are stamping out infected animals and increasing biosecurity. Depending on the epidemiological situation vaccination can be an important additional tool.

International standards are of paramount importance in global crises such as the one we are facing currently with HPAI H5N1 virus (HPAIV). International standards lead to a harmonised approach, which is essential for the control of transboundary animal diseases such as avian influenza. Using these standards the negative economic and social consequences will be mitigated by assuring safe international trade. International standards also harmonise the diagnostic and control tools to be used, and define the necessary quality levels of the Veterinary Services that are in the forefront of combating animal diseases.
International standard-setting bodies

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization recognises the following three international standard-setting bodies: the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the International Plant Protection Convention. The OIE is defined as the international standard-setting body for animal health and its mandate is to improve animal health worldwide.

The OIE has established standards on notification, trade issues and surveillance of the most important animal diseases. The OIE Terrestrial Animal Health Code (referred to hereafter as the Terrestrial Code) aims to assure safe international trade in terrestrial animals and their products. This is achieved by giving standards that detail the health measures to be used by the Veterinary Services of the importing and exporting countries. Such measures aim to avoid the transfer of pathogenic and/or zoonotic agents without imposing unjustified trade restrictions.

Accompanying the Terrestrial Code is the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (referred to hereafter as the Terrestrial Manual) which provides a harmonised approach to disease diagnosis by describing internationally agreed laboratory diagnostic techniques. To be able to compare the results of different laboratories in different countries the diagnostic techniques stipulated in the Terrestrial Manual should be used, and quality control systems should be implemented in the laboratories. High quality diagnostic work gives countries greater confidence in the animal health status of trading partners. The Terrestrial Manual also sets out general guidelines on quality principles for the production and use of vaccines against specific animal diseases. Besides the official standards in the Terrestrial Code and the Terrestrial Manual, the OIE also develops information documents on different subjects for its Member Countries and Territories containing useful recommendations which are not (yet) part of either the Terrestrial Code or the Terrestrial Manual. International standards can be seen as a global public good. OIE standards have been developed based on risk assessments of the commodities being traded and the latest scientific information available. These standards are continually being updated and are endorsed by all OIE Member Countries and Territories during the annual OIE General Session.

Animal health legislation in the European Union

Beyond the OIE standards, which apply to all 174 OIE Member Countries and Territories, the European Union (EU) has also harmonised its legislation on animal health with a view to common standards allowing safe free trade between its 27 Member States – the ‘Single Market’. EU animal health legislation includes rules for the control of major animal diseases, intra-Community trade and imports from third countries, veterinary checks and animal identification. It is legally binding for its Member States. As regards rules for imports from third countries, EU legislation is in line with OIE standards. Harmonisation of EU legislation was achieved by open negotiation, transparency and mutual trust between the veterinary authorities of Member States and the political representatives. Financial support from the EU for disease eradication and control programmes also plays an important role in striving for a high level of animal health and food safety.

All Member States of the EU are members of the OIE. Scientific and governmental experts from Member States and the European Commission contribute actively to the development of the Terrestrial Code, the Terrestrial Manual and other publications of the OIE. For endorsement of the OIE standards the European Commission in co-operation with Member States prepares a common position that is approved by the European Council and submitted to the OIE General Session. The European position is put forward by the Member State holding the EU Presidency or by the delegate of another Member State which is assigned by the European Council.

International standards and European Union legislation relevant for avian influenza

For avian influenza the OIE has defined standards on notification, trade issues and surveillance. Trade standards are in place for poultry and poultry products such as fresh meat, meat products and eggs, but also feathers and down. Guidelines for surveillance of the disease are also in place. However, besides the information in the avian influenza chapters of the Terrestrial Code and the Terrestrial Manual the horizontal non-disease-specific standards in Volume I of the Terrestrial Code are applicable to most diseases and are important for combating avian influenza. The most relevant chapters are listed below (not exhaustive):
OIE international standards and European Union legislation on trade with regard to avian influenza

The avian influenza chapter of the Terrestrial Code (27) was updated at the start of the current crisis and the new standards were endorsed by the OIE delegates during the General Session in May 2005. New definitions for notifiable influenza, in low pathogenicity and highly pathogenic forms, were implemented, together with specific trade recommendations.

Notifiable avian influenza is now defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtype or by any other avian influenza virus with an intravenous pathogenicity index (IVPI) greater than 1.2 or, as an alternative, at least 75% mortality in 4- to 8-week-old chickens infected intravenously. However, NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI).

Highly pathogenic notifiable avian influenza viruses are defined as those having an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, causing at least 75% mortality in 4- to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI. Low pathogenicity NAI viruses are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

Notifiable avian influenza is, by its definition, restricted to being an infection of poultry. Poultry is defined in the Terrestrial Code as ‘all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose’. This definition of poultry includes backyard poultry but excludes wildlife, racing pigeons and zoo animals.
Although HPNAI is restricted to poultry, occurrence of HPAI in wildlife is also notifiable to the OIE, because the general notification guidelines state that all events of epidemiological significance should be reported. It is important to note, however, that these wildlife infections should not have an effect on trade, as the current *Terrestrial Code* defines NAI as an infection of poultry. By making this distinction the OIE encourages reporting of NAI infections in poultry as well as wildlife and, thus, attempts to increase the transparency of the global animal disease situation.

Within the EU the legislation for the control of HPAI has been harmonised since 1992 (9). In the light of experience gained with HPAI outbreaks globally, and in view of the possible emergence of highly pathogenic strains from precursor low pathogenicity viruses of the H5 and H7 subtypes, the EU has recently updated its avian influenza control policy (11). The legislation is in line with the global strategies for avian influenza control as promoted by international organisations such as the OIE and FAO.

The strategy to prevent and control the introduction and spread of avian influenza viruses relies on rapid disease detection and notification, the killing and safe disposal of infected birds and contaminated material (‘stamping-out policy’), movement restrictions for live poultry and their products, epidemiological investigations and cleaning and disinfection measures. The scope of using vaccination against avian influenza to support disease control measures has also been broadened and vaccination can now be used in a wider selection of circumstances.

Disease control measures must not only be implemented for HPAI outbreaks, but also when low pathogenicity avian influenza (LPAI) viruses of H5 and H7 subtypes are detected in poultry and other captive birds, albeit proportionate to the risk posed by these pathotypes. European Union legislation on avian influenza is flexible: on the one hand Member States can apply very stringent measures that can even go as far as blocking any movements of poultry and other domestic species within the whole territory for a maximum of three days in the event of an outbreak, while on the other hand derogations for non-commercial holdings keeping, for example, rare breeds or endangered bird species, provided this is deemed possible after an assessment of the epidemiological situation and the measures applied to prevent virus spread.

In close co-operation with the European Commission, the European Food Safety Authority provides independent scientific advice and clear communication on existing and emerging risks. The Authority has issued several scientific opinions on avian influenza (12, 13, 14, 15, 16, 17) which support a science-based ongoing review of legislation in the light of the most recent scientific knowledge.

In the EU the Chief Veterinary Officers (CVOs) of the Veterinary Services in Member States bear the ultimate responsibility for the implementation of disease control measures. Member States must have contingency plans that will ensure disease preparedness. These plans detail legal provisions, administrative organisation, establishment of local and central disease control centres, instructions for laboratories and veterinarians, and the provision of information to the public. Veterinary authorities must guarantee that sufficient financial and human resources and equipment are available for the rapid control of a major outbreak, if it occurs.

The effectiveness of a Member State’s disease response is of fundamental importance. However, the European Commission plays a vital role in:

- promptly gathering and re-dispatching information on the disease situation via the CVOs network and the Animal Disease Notification System (ADNS) (http://ec.europa.eu/food/animal/diseases/adns/index_en.htm)

- adopting protection measures at Community level in a few hours (safeguard clause) when HPAI is detected in a Member State or third country from where imports of certain poultry commodities arrive. This ensures transparency regarding the disease situation and control measures, as well as an appropriate legal framework for Member States

- convening meetings (even at very short notice when necessary) of the Standing Committee on the Food Chain and Animal Health (SCoFCAH) (18). Information on the disease situation and the control measures taken are presented by the affected Member State to the governmental experts of the other Member State. The measures are reviewed and the European Commission submits proposals for which the Committee gives its opinion for the formal adoption of additional measures by the Commission.

When HPAI H5N1 is suspected or detected in poultry holdings the control measures of the Avian Influenza Directive (11) apply and an additional larger buffer zone is established where further restrictive measures are applied (4). For transparency to Member States and trading partners areas under restriction are published by means of a formal legal act of the European Commission in the *Official Journal of the European Union* (eur-lex.europa.eu).

**Zoning and compartmentalisation**

The OIE has introduced the concepts of zoning and compartmentalisation, since it may be difficult for countries to maintain a disease-free status for the whole territory. A compartment means an animal subpopulation contained in one or more establishments under a common...
biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade. This approach is based on a management system which requires reliable auto-control mechanisms, a high degree of responsibility among food business operators and tight supervision and control by veterinary authorities to allow trade from such compartments even though infection is present in the exporting country. A zone is a geographical region that contains animals with a distinct health status and is defined by natural or artificial barriers. The introduction of these concepts allows countries to regain freedom from HPAI step by step and even to resume trade from the compartments or zones that are free while the country as a whole may still be infected.

Imports of live poultry and poultry products from third countries into the EU are only authorised from third countries of which the health status of poultry has been positively assessed and where adequate control prevention and surveillance measures for avian influenza are in place. The EU makes extensive use of zoning, if the assessment of the epidemiological situation, the control measures taken and the guarantees provided by the concerned third country allow trade bans to be limited to the part of that country where the infection is located. Other risk mitigating measures for imports of animal products are also applied, e.g. the requirement of additional treatments suitable for virus inactivation. The EU is fostering the implementation of compartmentalisation. Rules for its application within the EU are currently being finalised. The integrated poultry industry lends itself well to this approach and it is therefore the intention to first introduce this concept for AI. As a further step, the criteria for Member State compartmentalisation will also apply in importing third countries.

**Surveillance for avian influenza**

The *Terrestrial Code* chapter on avian influenza includes guidance on the surveillance of the disease. Although passive and active surveillance should always be part of the early warning and detection system these guidelines specifically aim to either regain an NAI-free status after an outbreak or maintain an NAI-free status. It should be emphasised, however, that the OIE does not officially recognise Member Countries or Territories as being free from avian influenza, but that countries may issue a self-declaration of freedom based on the surveillance guidelines. It is not scientifically possible to prove the absence of infection, so sufficient confidence that NAI virus is absent should be gained through a combination of surveillance approaches such as clinical, serological and virological detection. When countries declare themselves free from NAI this is by definition restricted to poultry.

In the EU, compulsory co-financed avian influenza surveillance programmes in poultry have been in place since 2003. Financial support is also granted to wild bird surveillance carried out in Member States on a voluntary basis. With the westward spread of HPAIV H5N1 from Asia during 2005, surveillance in wild birds in the EU was enhanced and existing guidelines were revised and have since been updated to focus on the surveillance of dead migratory and other wild birds (7). Member States have to annually submit their surveillance programmes for formal approval by the European Commission.

Furthermore, Member States have to define ‘high risk areas’ for HPAIV H5N1 introduction on their territory, taking into account: poultry husbandry systems (e.g. free-range), areas with a high density of poultry holdings, and proximity to staging and mixing points for wild migratory waterfowl – particularly those proceeding from areas in which HPAI H5N1 is present in poultry or wild birds. At farm level, additional biosecurity measures that aim to prevent contact between poultry and wild birds have to be implemented. Early detection systems require prompt reporting of increased morbidity/mortality and changes in production in poultry flocks (3).

The occurrence of HPAI H5N1 of the Asian lineage in the EU and its spread by wild migratory birds, in addition to its spread via trade of infected poultry and poultry products, necessitated the adoption of supplementary control measures. These include reporting increased abnormal morbidity and mortality in wild birds to the national veterinary authorities and notification of laboratory confirmed cases to the European Commission and Member States (2) via ADNS.

Upon detection of HPAI H5N1 in wild birds control and monitoring areas must be established in which restrictions on the movement of live poultry and their products must be applied until a possible virus introduction into poultry holdings has been excluded (5).

**Quality of Veterinary Services**

The OIE Tool for the Evaluation of the Performance of Veterinary Services

The OIE promotes eradication of the disease at the animal source and, therefore, states that once HPAI H5N1 is introduced into a country appropriate measures must be taken in poultry. Eradication at the animal source is essential for reducing virus load in the environment, minimising economic losses for farmers and diminishing
the risk of a possible pandemic. The Veterinary Services are in the frontline of early detection and rapid response. Many developing countries have either weak Veterinary Services or lack them altogether; therefore not all countries are able to react immediately when there is an HPAIV introduction and it is extremely important that infected or at-risk countries that are unable to mobilise the necessary resources receive direct and immediate technical assistance to help eradication efforts. Capacity building in countries with weak Veterinary Services is crucial. Moreover, improvement of Veterinary Services and infrastructure is not only relevant for the current avian influenza crisis but for the response to future emerging and re-emerging diseases as well. The OIE has developed the PVS Tool to evaluate the competence of Veterinary Services and to define programmes to bring them in line with OIE quality standards (23, 26). It must be clear that upgrading Veterinary Services cannot be done overnight, but it is an important medium- to long-term goal. The use of the PVS tool allows countries to define gaps in their Veterinary Services and areas in need of strengthening. Based on the outcome, projects can be developed to be submitted to donors.

European Union animal health and food safety standards

In the EU, the Food and Veterinary Office (FVO) is a part of the services of the Directorate General for Health and Consumers of the European Commission. It is responsible for inspections on compliance with EU legislation in Member States and third countries from where imports of live animals and animal products are authorised. Missions are carried out regularly, and on an ad hoc basis if serious disease outbreaks occur. In their reports the FVO identifies risks, draws conclusions and gives recommendations for improvements to animal health and food safety standards. If important infringements of EU law posing a risk to animal and/or public health are detected, the European Commission may take legal action, including implementing safeguard measures against the Member State or third country concerned.

International standards on vaccine production and vaccination against avian influenza

The OIE guidelines on the principles of veterinary vaccine production can be found in chapter 2.3.4 of the Terrestrial Manual. Vaccines should always be produced under quality schemes that assure the safety and efficacy of the product. In many instances the use of low quality vaccines may worsen instead of improve a disease situation. For avian influenza in particular, the use of vaccines that do not induce sufficient immunity may lead to asymptomatic virus shedding. Besides complicating disease control, asymptomatic shedding also leads to a zoonotic risk, since people will handle these apparently healthy animals. The chapter describes the requirements for the facilities and materials (master seed, master cell stocks) that should be used for vaccine production. Secondly, it defines the necessary quality assurance schemes, covering efficacy, safety and stability tests, and batch controls. It should be emphasised that each step in the production process must be well documented and records should be kept of all phases of this process. Besides the guidelines for diagnostic tests the avian influenza chapter of the Terrestrial Manual also contains specific guidelines for production of vaccines against avian influenza. For this disease conventional as well as recombinant vaccines are on the market and under development. Presently, there are still no ideal vaccines for mass vaccination campaigns. The currently available vaccines do not induce sterile immunity, which means that animals may still get infected after vaccination, although virus shedding and transmission will be reduced. Another important disadvantage of the current vaccines is that in the absence of a spray or oral vaccine, each animal must be handled individually to be vaccinated. The use of live attenuated vaccines against any subtype is not recommended because of the possibility of recombination and the development of highly pathogenic strains. Vaccines should be handled, stored and used according to the manufacturer’s recommendations. An intact cold chain is crucial for maintaining the immunological features of the vaccines. However, many developing countries do not have the capacity to implement the cold chain. Vaccines might stay at elevated temperatures for longer times at airports, distribution places and veterinary practices, or in cars. This can seriously compromise vaccine quality.

In line with the Terrestrial Manual, in the EU only inactivated vaccines have been authorised for use either by the individual National Competent Authorities of Member States (10) or via a centralised procedure managed by the European Medicines Agency (EMEA) (www.emea.europa.eu), in which case the authorisation is valid throughout the EU (19). This authorisation procedure has recently been streamlined and currently four inactivated, adjuvanted avian influenza vaccines containing either H5N2, H5N3, H5N6 or H7N1 subtypes have obtained marketing authorisation for administration by injection. Most countries have their own vaccine-licensing authorities and depending on the vaccine being used (local production or not) and on national legislation it might be possible to change the vaccine strain fairly easily. However, the existing regulatory framework in the EU and the United States of America does not allow for the rapid change of strain in an existing product. This is considered to be one of the factors having influenced international manufacturers of veterinary vaccines not to seek authorisation for their vaccines against diseases with a highly variable antigenic nature, such as avian influenza,
within these regions. At present, a separate authorisation is required for each vaccine strain or combination of strains. To ensure the availability of good and efficacious vaccines, manufacturers should be able to rapidly introduce new strains into the vaccines when the epidemiological situation demands. The EU has therefore introduced into its latest legislative proposals the concept of a ‘multi-strain’ dossier, which allows for the inclusion of several vaccine strains within the authorisation from which the most relevant strain(s) can be selected according to the epidemiological situation.

**Implementation of vaccination programmes**

The OIE has received many questions from countries asking for guidance on making decisions about whether or not to vaccinate against avian influenza and on how to implement a well designed vaccination programme. Some general principles can be given, although it is not possible to give detailed guidelines on vaccination programmes, since each programme is very much dependent on the local situation. Factors such as the level of infection, circulating strains, the structure of Veterinary Services, and the characteristics of the poultry sector have an important influence on a vaccination programme.

Vaccination against avian influenza can be a very valuable tool in the control of the disease but it should always be kept in mind that it is a logistically demanding and costly exercise. It is recommended, therefore, that a careful assessment is made of the advantages and disadvantages of implementing a vaccination programme and of the country/region’s capacity and capability to implement it. The Terrestrial Code states that vaccination does not need to interfere with trade or disease-free status as long as it can be shown that there is no virus infection or circulation. However, in practice it is often seen that trade barriers are installed after avian influenza vaccination.

The first aim of vaccination is to induce protective immunity in a flock and thus increase resistance to infection, decrease viral shedding by infected birds, and decrease virus transmission. To be effective, vaccination should always be combined with other control measures such as movement restrictions and an increase in biosecurity. Prolonged vaccination programmes are generally not sustainable, so all programmes should include an exit strategy based on epidemiological data. The OIE has an information document available for Member Countries and Territories with a thorough description of the factors to take into account when assessing the need for vaccination. When a decision to vaccinate has been taken the choice of an adequate vaccine is crucial. The circulating virus type should be known and the haemagglutinin of the vaccine should be as close as possible to the field virus since this is considered the most immunogenic part of the virus. To be effective, vaccines have to be of high quality and produced in accordance with OIE standards, and care should be taken that an intact cold chain is implemented. An appropriate vaccination strategy must be chosen: emergency vaccination in an outbreak situation; preventive vaccination when the country or zone is at high risk of introduction of the virus; routine vaccination in an endemic situation. These three strategies can all be used either in a mass programme, where all susceptible animals will be vaccinated, or in a targeted manner, whereby only certain specified groups of animals will be vaccinated. The choice of strategy depends on, amongst other things, logistical factors, the availability of high quality vaccine and the financial means. Ideally, all vaccination programmes, but particularly preventive vaccination programmes, should employ a strategy in which vaccinated animals can be distinguished from infected animals (DIVA strategies), including animals that become infected after vaccination. Since vaccinated birds may still become infected – particularly if exposed to high viral loads in the environment – and subsequently may shed virus, each programme should include monitoring for the circulation of field virus. This virus circulation monitoring is important for three reasons: firstly, when the final goal is virus eradication it should be known whether field virus is still circulating; secondly, since the virus mutates rapidly it is necessary to continuously monitor whether the vaccine strains used still protect against the circulating virus strains; thirdly, avian influenza is a zoonotic disease and clinically unapparent infections may pose a risk for human health. When the monitoring data show that it is possible to further control the virus with classical methods vaccination ceases.

EU legislation anticipates that emergency vaccination will be a ‘short-term’ measure in response to outbreaks of avian influenza occurring either in the Member State itself or a neighbouring Member State or third country. It also provides for preventive vaccination, as a ‘long-term’ measure, when the authorities of a Member State decide that on the basis of a risk assessment poultry in holdings of certain husbandry systems or located in certain areas of their territory are at an increased risk for avian influenza virus introduction.

Certain provisions for intra-Community movements of vaccinated birds are laid down and vaccination plans submitted by Member States must be formally approved by the European Commission. Vaccination has to be carried out following a DIVA strategy, which implies strict accompanying active surveillance of vaccinated and, as appropriate, unvaccinated poultry flocks. Furthermore, vaccine efficacy testing has to be carried out.

Following the major epidemic of HPAI of the H7N1 subtype during 1999/2000, Italy carried out vaccination in response to incursions of LPAI viruses of the H7 subtype in
the intensive poultry production area in the north of the country (see article by Capua et al. elsewhere in this issue [1]). Vaccination continued until April 2008.

In the light of HPAIV H5N1 occurrences in the EU, some Member States have introduced preventive vaccination. France implemented such a vaccination plan between February and July 2006 in a defined area at specific risk for avian influenza introduction in holdings keeping ducks and geese that could not be effectively confined and therefore could not be sufficiently protected against contact with wild birds. The Netherlands are giving keepers of hobby poultry and free-ranging laying hens the opportunity to have their birds vaccinated, but participation is very low (see Capua et al. [1]). In Germany, as part of a research-orientated field study with subsequent challenge trials in the laboratory, vaccination has been permitted on three poultry holdings (laying hens, fattening ducks and breeding geese) (see article by Rudolph et al. elsewhere in this issue [20]). In response to the occurrence of LPAI of the H5 and H7 subtype in some areas, chiefly on game bird farms, Portugal introduced emergency vaccination in January 2008 for a duration of six months to protect high-value breeding stocks of mallard ducks on one holding. Subsequently, preventive vaccination in the absence of infection in the country is continued on that holding. In 2006 vaccination plans for zoo birds were formally approved for 17 Member States.

The European Food Safety Authority has issued scientific opinions on vaccination against avian influenza of poultry and other captive birds (15) and of zoo birds (16).

**Diagnosis of avian influenza**

In view of the trade consequences related to infections of poultry and the methods used to control them, the use of internationally recognised methods of disease diagnosis is essential. The OIE has a network of Reference Laboratories which are centres of excellence in their fields and which develop the procedures for harmonised diagnosis and control of the disease. The OIE Reference Laboratories for avian influenza in Europe are located in the United Kingdom (UK), Germany and Italy. The Terrestrial Manual and the Terrestrial Code are continuously updated with the latest scientific information.

In 1992, when harmonised EU control measures against avian influenza were established, the Veterinary Laboratories Agency, Weybridge, UK was appointed as Community Reference Laboratory (CRL) for avian influenza (11). The functions and duties of the CRL include:

- coordination of diagnostic methods in order to standardise tests and reagents
- organisation of periodical comparative tests with the national reference laboratories (NRL) appointed in Member States
- assistance to Member States in the diagnosis of outbreaks by carrying out confirmatory diagnosis and further virus characterisation such as phylogenetic analysis
- training of laboratory experts of Member States and third countries
- organisation, in collaboration with the European Commission, of annual meetings with NRLs to discuss the latest scientific knowledge on the disease, diagnostic techniques and results of comparative tests.

Diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of an outbreak of avian influenza are laid down in the EU manual on avian influenza (6).

**Discussion on OIE standards and European Union legislation**

The OIE international standards assure the sanitary safety of international trade, thus protecting veterinary and human health. For poor countries with weak Veterinary Services and laboratory infrastructure it is very difficult to implement OIE standards and the key actions needed for animal disease control. Efficient Veterinary Services, including laboratories, are considered a global public good. Many definitions can be found for ‘public good’, but they all agree that a public good is for collective use and is non-excludable, non-discriminative and available for everyone. Some definitions even claim that a public good is positive for all people and all generations. For these reasons capacity building for Veterinary Services in developing and transition countries is one of the key priorities of the OIE. Strong Veterinary Services and the implementation of OIE standards will lead to fairer trade, which is particularly beneficial for poor countries. Implementation of avian influenza standards and of control and eradication programmes also depends very much on strong Veterinary Services.

The occurrence of avian influenza in the EU is considered to be a regular rather than a rare event. HPAI H5N1 has affected wild birds and poultry holdings in several EU Member States over the last 3 years. EU legislation and its implementation by Member States have so far successfully limited the impact of the disease on animal and human health. Fine-tuning appropriate biosecurity measures in poultry holdings and surveillance strategies for avian influenza in poultry and wild birds is still posing an ongoing challenge for the prevention and early detection of
avian influenza infection, HPAI H5N1 in particular. This is true for the EU as well as globally.

Another challenge for the implementation of OIE standards leading to control and eradication (e.g. disease notification standards) is the lack of compensation for infected animals that are culled in many countries. There is consensus that compensation of financial losses to farmers is necessary to encourage disease reporting.

In the current HPAI H5N1 crisis vaccination is being used as a tool to control the disease, mainly in Asian countries. The use of high quality vaccines is essential in each vaccination programme. For logistical and financial reasons it is difficult for many countries to maintain a good monitoring programme after implementation of vaccination. It can be argued, however, that vaccination can still be of value in certain situations where implementation of such a programme is difficult, since it will decrease the virus load in the environment and, consequently, decrease the risk of human infections. Nevertheless, experience with vaccination programmes, especially in Asian countries, has shown that it is essential to monitor the efficacy of the vaccine strain to ensure high-level protection after vaccination since any antigenic drift of field virus naturally influences the efficiency of a vaccination programme. It is therefore crucial that new avian influenza virus vaccine strains can be rapidly introduced into the vaccines in response to changes in the epidemiological situation.

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Réglementations et normes internationales relatives à l’influenza aviaire, y compris les normes de l’Organisation mondiale de la santé animale sur les vaccins

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Résumé
L’Organisation mondiale de la santé animale (OIE) a mis au point des normes internationales applicables à l’influenza aviaire, qui concernent la notification des foyers, les échanges internationaux, le diagnostic, la surveillance et la production et l’utilisation de vaccins. Ces normes, fondées sur les connaissances scientifiques et sur l’analyse du risque, visent à sécuriser les échanges de volailles et de produits aviaires sans imposer de barrières commerciales injustifiées. Les 27 États membres de l’Union européenne disposent d’une législation harmonisée qui s’inspire des normes de l’OIE. La détection précoce, le diagnostic rapide, la notification et la qualité des Services vétérinaires sont des conditions essentielles pour organiser une riposte rapide en cas de foyer d’influenza aviaire et pour contrecarrer tout risque de propagation virale due aux échanges commerciaux. Dans certaines situations, la vaccination peut également être un outil de lutte important. La réussite de la vaccination dépend des vaccins utilisés, qui doivent être de grande qualité, et du suivi postvaccinal réalisé. Il est primordial de se conformer aux normes internationales afin de protéger la santé animale et humaine dans la crise actuelle d’influenza aviaire hautement pathogène due au virus du sous-type H5N1.

Mots-clés
Reglas y normas internacionales relativas a la influenza aviar, en particular normas sobre vacunas de la Organización Mundial de Sanidad Animal

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Resumen
En relación con la influenza aviar, la Organización Mundial de Sanidad Animal (OIE) ha establecido normas internacionales sobre notificación, comercio, diagnóstico, vigilancia y fabricación y uso de vacunas. Estas normas, basadas en datos científicos y en un análisis de riesgos, tienen por objeto garantizar un comercio seguro y sin barreras injustificadas de aves de corral y sus productos derivados. La Unión Europea, con sus 27 Estados Miembros, tiene en vigor una legislación armonizada acorde con las normas de la OIE. La rapidez de la detección y el diagnóstico, la notificación y la calidad de los Servicios Veterinarios son elementos determinantes para reaccionar con prontitud a un brote de influenza aviar y atajar de raíz el riesgo de propagación del virus a través del comercio. Dependiendo de la situación, la vacunación puede constituir también un instrumento muy importante para luchar contra la enfermedad. El uso de vacunas de gran calidad y el seguimiento posterior son fundamentales para el éxito de una campaña de vacunación. En el momento de la crisis mundial de la influenza aviar altamente patógena causada por el subtipo H5N1, la observancia de las normas internacionales reviste máxima importancia para proteger la salud de los animales y las personas.

Palabras clave

References


