

Vaccines and OIE listed diseases

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OIE activities

The activities of the World Organisation for Animal Health (OIE) in relation to the prevention and control of infectious animal diseases are primarily focused on the following areas:

- collection, analysis and dissemination of veterinary scientific information in a timely and transparent manner
- promotion of technical assistance and the strengthening of international cooperation for the enhancement of the control and eradication of animal diseases worldwide
- improvement of the legal framework and capacity building of official Veterinary Services, especially in developing countries
- promotion of safe trade in animals and animal products by eliminating the unjustified barriers that are sometimes put in place as a result of animal diseases, while minimising the entry of pathogens into importing countries.

These activities are principally carried out through the development and application of standards, recommendations and guidelines. The OIE is regarded by the Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO) as the only international organisation responsible for setting standards on animal diseases, including zoonoses.

OIE standards

The procedure adopted by the OIE to create or update a standard is complex, but fully transparent. The request to create or update a standard can come from an OIE Delegate, a Specialist Commission, the OIE International Committee or any other authority following the outbreak of a disease or any significant epidemiological event. On receipt of the request, the OIE Central Bureau forwards it to the relevant Specialist Commission. The Commission

reviews the request or problem and may seek expert opinion from other experts or Commissions or may decide to refer it to an *ad hoc* group of specialists for consideration and advice. The final advice or suggestion is reviewed by the Specialist Commission, which then proposes a draft text for an appropriate standard to be developed. This draft text is then circulated to all OIE Member Countries, which are given sixty days to comment on the proposal. The comments are considered by the Commission, which may decide to withdraw the text altogether or to make certain amendments to accommodate the comments received. The revised version is then submitted to the International Committee during the General Session in May for discussions and subsequent adoption. Once adopted, it becomes an OIE standard.

The OIE standards are contained in the *Terrestrial Animal Health Code* (the *Terrestrial Code*), the *Aquatic Animal Health Code* (the *Aquatic Code*), the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) and the *Manual of Diagnostic Tests for Aquatic Animals* (the *Aquatic Manual*) (1, 2, 3, 4).

Terrestrial Animal Health Code/ Aquatic Animal Health Code

One of the main purposes of the *Codes* is to reduce the risk of the spread of infectious animal diseases or agents through the international trade of animals and animal products while at the same time facilitating safe trade. Through its Early Warning Disease Information System, the OIE promptly contacts its Member Countries via emails, faxes or other means of communication to inform them (in the official languages of the OIE) of the occurrences of major animal diseases in the world. This allows countries at risk, i.e. neighbouring countries or those importing animals or animal products from the infected country to take appropriate measures to prevent the entry of pathogens into their territory.

The *Codes* contain some generic chapters dealing with general issues (e.g. obligations and ethics in international

trade, import risk analysis, principles of epidemiology-surveillance with respect to specific diseases) and other chapters are devoted to specific diseases. Each disease chapter spells out the requirements for a country or zone to be considered free from the disease and lists the commodities that can be safely traded irrespective of the disease status. It also describes the health measures to be followed by importing countries when importing live animals and specific animal products from countries or zones where the disease exists. Importing countries are strongly urged to follow the recommendations prescribed by the OIE. However, it is the sovereign right of an importing country to apply stricter controls or a higher level of protection. In such cases, and in accordance with WTO rules, the importing country has to carry out a science-based risk assessment to demonstrate clearly why it wants to apply a higher level of protection. The OIE standards provide Member Countries with the appropriate guidance to apply an import risk analysis. As is clearly indicated in the OIE standards, the mere presence of a disease in an exporting country does not provide full justification for a total ban on animals or animal products from that country. Instead, a decision on whether or not to accept imports from infected countries should be based on the results of an import risk analysis. This is how, under certain conditions, countries with bovine spongiform encephalopathy (BSE) and foot and mouth disease (FMD) can continue to export meat and meat products.

The OIE also has an in-house dispute settlement system to resolve technical or scientific conflicts that may arise among Member Countries. This mediation system is science-based and is quick, effective and less costly than the complex system in place at the WTO.

Manual of Diagnostic Tests and Vaccines

The OIE *Terrestrial Manual* is a companion volume of the *Terrestrial Code*. It also contains some generic chapters dealing with important issues such as:

- sampling methods
- quality management of veterinary laboratories
- principles of validation of diagnostic tests
- tests for sterility and freedom from contaminants
- human safety in veterinary vaccine manufacture
- biotechnology in the diagnosis of infectious diseases
- the role of official bodies in the international regulation of veterinary biologicals.

Other chapters are devoted to specific diseases. These chapters include the prescribed tests for international trade and alternative tests that can be used under a bilateral

agreement between importing and exporting countries. The aims of the *Terrestrial Manual* are to facilitate the international trade of animals and animal products and also to contribute to the improvement of animal health services and the control of animal diseases by internationally recognised measures. It spells out the requirements for the manufacture and quality control of animal vaccines, including vaccines for 48 of the OIE listed diseases. The guidance on the requirements for vaccine manufacture lays emphasis on:

- a) Seed management:
 - characteristics of the seed
 - method of choice
 - validation as a vaccine.
- b) Method of manufacture:
 - in-process control
 - batch control
 - sterility
 - safety
 - potency
 - duration of immunity
 - stability
 - preservatives
 - precautions (hazards).
- c) Tests on final products:
 - safety
 - potency
 - purity.

The *Terrestrial Manual* also describes the various diagnostic tests that are recognised not only to prove the presence of disease but also the tests that can be used to demonstrate freedom from infection or absence of virus circulation. In this respect, the diagnostic tests that have recently been developed for the diagnosis and control of certain diseases such as FMD, classical swine fever, Aujeszky's disease and avian influenza have received considerable attention from the OIE. The *Terrestrial Manual* recognises the application of marker vaccines and the accompanying diagnostic tests that serve to differentiate vaccinated from infected animals (DIVA tests). These tests have in a certain way revolutionised disease control in that in certain conditions they help avoid the mass killing of animals, which poses ethical, ecological and economic problems. They have also immensely contributed to international trade, because infected countries can use vaccination as an additional tool to control important animal diseases and continue with trade, provided of course that vaccinated animals are clearly identified and only healthy animals are vaccinated. These tests are also accepted by the OIE for the recovery of country disease status. In the case of FMD, non-structural

protein (NSP) tests are now validated as screening tests and can be used to demonstrate absence of virus circulation. As regards Aujeszky's disease, the absence of gE antibodies in vaccinated pigs is accepted by the OIE as evidence of absence of virus circulation. Similarly, the OIE Ad hoc Group of experts on avian influenza has proposed that vaccination be used as an additional tool in the control of the disease, provided that DIVA tests are applied to demonstrate the absence of circulating virus. This should also enable trade of poultry and poultry products to continue from countries or zones which have experienced the disease.

will not compete with the existing vaccine banks but will complement them by including vaccines against diseases which are of particular relevance to developing countries. It is also the intention of the OIE, together with its world network of Reference Laboratories and international experts, to pursue research on DIVA tests to enable these tests to cover as many animal diseases as possible.

To date there are no vaccines recommended in the *Manual of Diagnostic Tests for Aquatic Animals*.

Future developments

The OIE continues to work towards creating vaccine and antigen banks which will be useful to Member Countries on a national, regional and international basis. These banks



References

1. World Organisation for Animal Health (OIE) (2004). – Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 5th Ed. OIE, Paris.
2. World Organisation for Animal Health (OIE) (2006). – Aquatic Animal Health Code, 9th Ed. OIE, Paris.
3. World Organisation for Animal Health (OIE) (2006). – Manual of Diagnostic Tests for Aquatic Animals, 5th Ed. OIE, Paris.
4. World Organisation for Animal Health (OIE) (2006). – Terrestrial Animal Health Code, 15th Ed. OIE, Paris.



