USA Comments

Terrestrial Animal Health Standards Commission Report - February 2017

DRAFT CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

In general, Vaccination is intended to prevent and control and prevent the occurrence of a disease and reduce the transmission of the pathogenic agent. For the purpose of disease control Ideally, vaccines should induce immunity that, ideally, prevents infection. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

Vaccination may contribute to improvement of animal and human health, animal welfare, agricultural sustainability and to reduction of the use of antimicrobial agents in animals.

The objective of this chapter is to provide guidance to Veterinary Authorities for the successful implementation of vaccination in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the disease-specific chapters of the Terrestrial Code.

The vaccination strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation. The recommendations in this chapter are intended for all diseases for which a vaccine exists.

In addition to other disease control measures, vaccination may be a component of a disease control programme. The prerequisites to enable a Member Country to successfully implement vaccination include compliance with:

1) the recommendations on surveillance in Chapter 1.4.;
2) the relevant provisions in Chapters 3.1. and 3.4.;
3) the recommendations on vaccination in the disease-specific chapters of the Terrestrial Code;
4) the relevant general and specific recommendations for principles of veterinary vaccine production in Chapter 1.1.8 of the Terrestrial Manual.

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Standards for vaccines are described in the Terrestrial Manual.

Article 4.X.2.

Definitions

For the purpose of this chapter:

Vaccination programme: means a plan to apply vaccination to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of disease control.

Emergency vaccination: means a vaccination programme applied in immediate response to an outbreak or increased risk of introduction or emergence of a disease.

Systematic vaccination: means an ongoing routine vaccination programme.
Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

**Article 4.X.3.**

**Vaccination programmes**

The objectives and strategy of a vaccination programme should be defined by the Veterinary Authority before the implementation of the vaccination, taking into account the epidemiology of the disease, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the Veterinary Authority should liaise with the Veterinary Authorities of neighbouring countries. When appropriate, a regional approach to harmonise vaccination programmes is recommended.

Vaccination programmes may include systematic vaccination and emergency vaccination.

1) Systematic vaccination in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In disease-free countries or zones, the objective of systematic vaccination is to prevent the introduction of a pathogenic agent from an infected adjacent country or zone, or to limit the impact in the case of an the introduction of that pathogenic agent disease.

**Rationale:** Vaccination by itself does not prevent the introduction of a pathogenic agent; therefore, we recommend deleting the proposed new text as it is not technically correct.

2) Emergency vaccination provides an adjunct to the application of other essential biosecurity and disease control measures and may be applied to control outbreaks. Emergency vaccination may be used in response to:

   a) an outbreak in a disease-free country or zone;

   b) an outbreak in a country or zone that applies systematic vaccination, but when vaccines are applied to boost existing immunity;

   c) an outbreak in a country or zone that applies systematic vaccination, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the outbreak;

   d) a change in the risk of introduction or emergence of disease in a free country or zone.

Emergency vaccination programmes should consider other be integrated with other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing optimisation of resources.

**Article 4.X.4.**

**Launching a vaccination programme**

When deciding whether to initiate a vaccination programme the Veterinary Authority should consider, among others, the following:

1) the epidemiology of the disease;

1bis) the probability that the disease cannot be rapidly contained by means other than vaccination;

2) the increased incidence of an existing disease;

3) the increased likelihood of introduction or emergence of a disease;

3bis) the zoonotic potential of the disease.
4) the density of the exposed susceptible animals population;
5) the insufficient level of population immunity;
6) the risk of exposure of specific subpopulations of susceptible animals;
7) the suitability of a vaccination programme as an alternative to or an adjunct to other disease control measures such as a stamping-out policy;
8) the availability of an appropriate vaccine and human, financial, and material resources;
9) the cost-benefit analysis considerations of the vaccination programme, including the impact on trade.

Article 4.X.5.

Vaccination strategies

Different vaccination strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

1) Blanket vaccination: vaccination of all susceptible animals in an area or an entire country or zone.
2) Ring vaccination: vaccination primarily of all susceptible animals in a delineated area surrounding the location establishments where an outbreak has occurred. To prevent outward spread of disease, vaccination should be applied from the outer limit boundary of the area inwards.
3) Barrier vaccination: vaccination in an area along the border of an infected country or zone to prevent the spread of disease into or from a neighbouring country or zone.
4) Targeted vaccination: vaccination of a subpopulation of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

Choice of vaccine

Depending on the disease, several vaccines may be available. To achieve the objectives of the vaccination programme, the choice of a vaccine is a critical element that depends on different factors including:

1. Availability and cost
   a) availability of the vaccine including marketing authorisation and in adequate quantities at the time required;
   b) capacity of the providers to supply the vaccine for the duration of the vaccination campaign and to respond to increased needs;
   c) flexibility in the number of doses per vial to match the structure of the target population;
   d) a comparison of the costs of vaccines that meet the technical specifications established in the vaccination programme.

2. Vaccine characteristics
   a) Physical characteristics
      – route and ease of administration;
      – volume of dose;
      – type of adjuvant and other components.
   b) Biological characteristics
– immunity against circulating strains;
– live, inactivated or biotechnology-derived vaccines;
– number of strains and pathogens included in the vaccine;
– potency of the vaccine;
– onset of immunity;
– shelf-life and expiry date;
– thermostability;
– duration of the effective immunity;
– number of doses required to achieve effective immunity;
– ability to be monitored for vaccine-induced antibodies;
– effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;
– suitability of vaccine formulation for species in the target population;
– safety for the users, the consumers and the environment.

c) Side effects
– adverse reactions;
– transmission of live vaccine strains
  – Reversion to virulence of attenuated strains

Rationale: Some vaccines have reverted to a virulent form.

– Risk of vaccine pressure selecting new resistant strains of the disease agent

Rationale: For example, long term vaccination for highly pathogenic avian influenza.

– Risk of vaccination masking future outbreaks

Rationale: For example, a vaccine that only reduces clinical signs will make disease detection more difficult and potentially result in an increase spread of the disease.

General note on the three additions we recommend explicitly stating:
While the United States recognizes that an exhaustive listing of side effects is not possible, there are some, such as those noted above (reversion to virulence, selection of resistant strains, and masking), are important to note, and therefore, should be explicitly stated in this section to ensure their consideration.

Article 4.X.7.

Other critical elements of a vaccination programme
In addition to the choice of vaccine, the vaccination programme should include the following other critical elements, and the vaccination programme should be communicated to all stakeholders.

1. **Legal basis**

   The legal basis for a vaccination campaign, including a legal obligation for the vaccination and compensation for farmers for possible side effects, should be in place.

2. **Target population**

   The vaccination programme should define the animal population to be vaccinated and the geographical area where the target population is located.

   The target population may include the entire susceptible population or an epidemiologically relevant subpopulation depending on the likelihood of exposure, the consequences of the disease, the role of the different subpopulations in the epidemiology of the disease and the resources available. The target population may include wildlife.

   Factors to consider in determining the target population may include species, age, maternal immunity, sex, production types, geographical distribution as well as the number of animals and herds. These factors should be reviewed and updated regularly.

3. **Vaccination coverage**

   In practical terms, it may be difficult to immunise the entire target population. The vaccination programme should define the minimum vaccination coverage necessary to achieve the minimum sufficient population immunity required to achieve the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the disease, density of susceptible animals, efficacy of the vaccine and geographical factors.

   Measuring population immunity during the monitoring of the vaccination programme may assist in identifying subsets of the target population that have not been adequately immunised.

4. **Stakeholder involvement**

   The vaccination programme should demonstrate good governance by the Veterinary Services and by clearly identifying the involvement of different stakeholders including other government agencies, governmental organisations, farmers, farmer organisations, private sector veterinarians, non-governmental organisations, veterinary paraprofessionals, local government authorities and vaccine suppliers. Stakeholder acceptance of vaccination is crucial for the success of the vaccination programme. Different stakeholders should preferably be involved in the planning and implementation of vaccination, the awareness campaigns, the monitoring of vaccination, the production and delivery of vaccines and the financing of the vaccination programme.

5. **Resources**

   Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the vaccination programme.

6. **Actions and timeline**

   The vaccination programme should describe the responsibilities, expected deliverables and timeline for each activity.

7. **Timing of vaccination campaigns**

   The vaccination programme should describe the periodicity of the vaccination campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

   The objective of the vaccination campaign is should be to achieve the necessary vaccination coverage necessary to attain or maintain and the minimum population immunity in the target population within a defined timeframe. The vaccination campaign should be implemented in such a manner as to ensure that the majority of the target population is immunised within as short a time as possible. The vaccination programme should include a detailed description of the implementation of the vaccination campaigns, including frequency and starting and ending dates of each campaign.
The frequency, timing and duration of the vaccination campaigns should be determined taking into consideration the following factors:

a) vaccine characteristics and manufacturer’s directions for use;
b) accessibility of the target population;
c) animal handling facilities;
d) animal body condition and physiological state;
e) geographical factors;
f) climate conditions;
g) vector activity;
h) awareness, acceptance and engagement of stakeholders;
i) types of production systems and animal movement patterns;
j) timing of agricultural, social or cultural activities;
k) availability of resources.

87. Auditing of the vaccination campaigns

The vaccination programme should include periodic auditing of all the participants in the vaccination campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of the vaccination campaign include:

a) proportion of the targeted population of animals and herds vaccinated within the defined timeframe;
b) number of vaccine doses used compared with number of animals vaccinated;
bb) number of animals vaccinated compared to census figures for the relevant animal population;
c) number of reports of breaches of the cold chain;
d) performance of vaccinator teams in respect of complying with the standard operating procedures;
e) timing and length of the campaign;
f) overall cost and cost per individual animal vaccinated.

To enable auditing of the vaccination programme, a recording system should be in place to measure the indicators above.

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a vaccination programme should have been be subjected to the registration marketing authorisation procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).
For systematic vaccination campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the vaccination campaign.

National disease contingency plans should provide for emergency vaccination. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If vaccination is to be used systematically, definitive marketing authorisation registration should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the Terrestrial Manual, facilitate the timely procurement of vaccines.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the vaccination campaigns should include the procurement of all necessary equipment and consumables as well as the establishment of standard operating procedures to:

a) implement the communication plan;
b) establish, maintain and monitor the fixed and mobile components of the cold chain;
c) store, transport and administer the vaccine;
d) clean and disinfect equipment and vehicles, including heat sterilisation of reusable equipment;
e) dispose of waste;

else determine the disposition of partially used or unused containers of vaccine;

extra implement biosecurity to ensure vaccination teams do not transmit the pathogenic agent between establishments;

f) identify vaccinated animals;
g) ensure safety and welfare of animals and vaccination teams;
h) record activities of vaccination teams;
i) document vaccinations.

The availability of appropriate animal handling facilities at the vaccination site is essential to ensure effective vaccination as well as safety and welfare of animals and vaccination teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the Veterinary Authority. The vaccination programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of vaccination teams should be sufficient to implement the vaccination campaign within the defined timeframe. The vaccination teams should be adequately equipped and have means of transport to reach the places where vaccination is carried out sites.

4. Public awareness and communication

The Veterinary Authority should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and public to ensure awareness and acceptability of the vaccination programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the vaccination, target population and other technical aspects that may be relevant for the public to know.

5. Animal identification
Animal identification allows for the differentiation of vaccinated from non-vaccinated animals and is required for the monitoring and certification of vaccination.

Identification can range from temporary to permanent identifiers and can be individual or group-based. Animal identification should be carried out in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the Veterinary Authority’s responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the Veterinary Services should consider issuing official certificates of the vaccination status of animals or groups of animals.

7. Additional animal health related activities

In addition to vaccination against a specific pathogenic agent, vaccination programmes may include other animal health-related activities such as vaccination against other pathogenic agents, treatments, surveillance, animal identification and communication.

Including additional animal health-related activities may enhance the acceptability of the vaccination programme. These activities should not negatively affect the primary objective of the vaccination programme.

Simultaneous vaccination against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Evaluation and monitoring of a vaccination programme

The vaccination programme should provide for outcome-based evaluation and monitoring to assess the achievements of the vaccination programme. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the vaccination programme.

Based on the objectives and targets of the vaccination programme, the following outcomes should be assessed:

1) vaccination coverage stratified by species, geographical location and type of production system;

2) population immunity measured by testing, stratified by species, geographical location and type of production system;

3) frequency and severity of adverse reactions, side effects, adverse reactions

**Rationale:** The United States recommends replacing the term “side effects” with “adverse reactions”. “Adverse event” is VICH and OIE accepted terminology. “Side effects” conceivably can be beneficial; “adverse events” never are.

4) reduction of incidence, or prevalence or impact of the disease.

5) reduction of clinical signs

**Rationale:** The United States recognizes that not all outcomes can be listed in this Article. However, an outcome, such as “a reduction in clinical signs” is important enough that it should be listed to ensure its consideration. As mentioned previously, systematic vaccination may be used to minimize the consequences (i.e., clinical signs) of the disease on the animal population, such as brucellosis vaccination of cattle to minimize abortions.
If the objectives and targets of the vaccination programme are not achieved, the reasons for this should be identified and addressed.

Article 4.X.10.

Exit strategy of a vaccination programme

The vaccination programme may provide for an exit strategy to cease vaccination. The cessation of vaccination may apply to the entire target population or to a subset of it, as defined by the risk of exposure and as determined by the Veterinary Authority.

Criteria to cease vaccination may include:

1) eradication of the disease in a country or zone has been achieved;
2) risk analysis demonstrates sufficient reduction of likelihood of introduction or emergence of the disease;
3) reduction of the incidence or prevalence of the disease to a level where alternative measures such as stamping-out may be sufficient more appropriate to achieve disease control;
4) inability of the programme to meet the desired objectives;
5) adverse public reaction to the vaccination programme;
6) a revised cost-benefit analysis leads to decision to cease the vaccination programme.

When the achievement of disease-free status requires the cessation of vaccination, the Veterinary Authority should prohibit vaccination and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of vaccination may require the revision of the contingency plan and enhanced biosecurity, sanitary measures and surveillance for early detection of disease.

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate several diseases in addition to or as alternative to stamping-out. However, depending on the disease and type of vaccine used, vaccination may mask underlying infections, affect disease surveillance and have implications for the movement of vaccinated animals and their products.

When appropriate, vaccination programmes should include provisions for the management of vaccinated animals such as ‘vaccination to live’ or ‘suppressive vaccination’ policies. Disease-specific chapters of the Terrestrial Code provide additional recommendations on the management of vaccinated animals.

Disease-free countries or zones applying systematic or emergency vaccination in response to an change in the increased risk of occurrence of a disease should inform trading partners and the OIE, as appropriate. In the absence of cases and unless otherwise specified in the relevant disease-specific chapters, vaccination of animals does not affect the disease status of the country or zone, and should not disrupt trade.

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