DRAFT CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

In general, vaccination is intended to control and prevent the occurrence of a disease and reduce the transmission of the pathogenic agent. For the purpose of disease control, 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 vaccination strategy applied depends on 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;
4) the principles of veterinary vaccine production in Chapter 1.1.8. of the Terrestrial Manual.

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

This chapter applies to vaccines available for diseases for which the competent authority has developed (or is developing) an official control program. Producers may choose to voluntarily utilize available vaccines for diseases for which there is no official control program.

Rationale: not all diseases are under an official control program, and, as such vaccine utilization would not be under the control of the competent authority.

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.

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**Article 4.X.3.**

**Vaccination programmes**

The objectives 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 zoonotic potential, if any, 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.

**Rationale**: For some diseases in infected countries, systematic vaccination programs are used to control the spread of disease from the wild animal population to domestic animals (such as rabies vaccination of pets) and its subsequent risk to humans.

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 or consequence of a disease with the objective of controlling its effects and, for some diseases, possible eradication. In disease-free countries or zones, the objective of systematic vaccination is to limit the impact in the case of an introduction of disease.

**Rationale**: For some diseases, 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.

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 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.

**Vaccination programmes** should consider other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing resources.

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**Article 4.X.4.**

**Launching a vaccination programme**

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

1) the probability that the disease cannot be rapidly contained;

2) an increased incidence of an existing disease;

3) zoonotic risk;
Rationale: For some diseases in infected countries, systematic vaccination programs are used to control the spread of disease from the wild animal population to domestic animals (such as rabies vaccination of pets) and its subsequent risk to humans.

- an increased likelihood of introduction or emergence of a disease;
- the density of susceptible animals;
- an insufficient level of population immunity;
- the risk of exposure of specific subpopulations of susceptible animals;
- the suitability of vaccination as an alternative to or an adjunct to other disease control measures such as a stamping-out policy;
- the availability of resources, including the impact on the availability of resources that may be needed for other activities such as stamping-out;

Rationale: vaccination may be used to control the spread of an outbreak minimizing the use of resources that may needed to later stamp-out the outbreak.

- cost-benefit considerations of vaccination, 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 establishments where an outbreak has occurred. To prevent outward spread of disease, vaccination should be applied from the outer 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.

Article 4.X.6.

Critical elements of a vaccination programme

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

1. 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 epidemiological 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.

2. 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 for the minimum 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 and geographical factors.

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

3. Stakeholder involvement

The vaccination programme should demonstrate good governance by the Veterinary Services and clearly identify the involvement of different stakeholders including other government agencies, 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.

4. 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.

5. Actions and timeline

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

6. 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 to achieve the necessary vaccination coverage and the minimum population immunity in the target population within a defined time frame. 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) awareness, acceptance and engagement of stakeholders;
h) types of production systems and animal movement patterns;
i) timing of agricultural, social or cultural activities;
j) availability of resources.
7. Auditing of the vaccination campaigns

The vaccination programme should include periodic auditing of 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 the vaccination campaign include:

a) proportion of the targeted population of animals and herds vaccinated within the defined timeframe;

**Rationale:** Adds clarity.

b) number of vaccine doses used compared with number of animals vaccinated;

c) number of reports of breaches of the cold chain;

d) performance of vaccinator teams in respect of 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.7.**

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 depends on different factors including:

1. **Availability and cost**
   
a) availability of the vaccine 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;
   
   – 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;
- **Slaughter withholding period:**

**Rationale:** Some countries have mandatory withholding periods and some products require a withholding period.

- safety for 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.

**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 be subjected to the registration procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical 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 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 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, including partially used or unused vaccine vials;

Rationale: proper disposition of partially used or unused vaccine vials may be important to the disease control efforts.
f) identify vaccinated animals;
g) ensure safety and welfare of animals and vaccination teams, including biosecurity measures;

Rationale: inadequate biosecurity measures of vaccination teams has been associated with spread of disease.
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 vaccination 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.

Article 4.X.9.

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 to enable the timely application of corrective measures and to enhance the sustainability of the vaccination programme. For details see Manual on Post-Vaccination Monitoring for FMD published jointly by FAO & OIE.

Rationale: The Manual is an excellent guide and should be referenced here.

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;
4) reduction of incidence or prevalence;
5) reduction of clinical signs.

Rationale: For some diseases, 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.

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 to achieve disease control;
4) inability of the programme to meet the desired objectives;
5) adverse public reaction to 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 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 a change in the risk of occurrence of a disease should inform trading partners and the OIE, as appropriate. 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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