CHAPTER 4.18.

VACCINATION

Article 4.18.1.

Introduction and objectives

Vaccination is intended to prevent and control the occurrence of a disease and reduce the transmission of the pathogenic agent. Ideally, vaccines should induce immunity that 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 Services* for the use 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 *listed disease*-specific chapters of the *Terrestrial Code*. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The *vaccination* strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation.

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 3.2. and 3.4.;
3) the recommendations on *vaccination* in the *listed disease*-specific chapters of the *Terrestrial Code*;
4) in vaccine-producing countries, the relevant general and specific recommendations for veterinary vaccine production and quality control in the *Terrestrial Manual*.

Article 4.18.2.

Definitions

For the purposes of this chapter the following definitions apply:

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

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

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.

Vaccination programme means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal *population* for the purposes of disease prevention or control.

Article 4.18.3.

Vaccination programmes

The objectives and strategy of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of *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.

Veterinary Authorities should liaise, as relevant, with public health authorities when developing and implementing *vaccination* programmes against zoonoses.

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 free countries or *zones*, the objective of systematic *vaccination* is to prevent the introduction of a disease from an infected neighbouring country or *zone*, or to limit the impact in the case of the introduction of that disease.
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 revaccination is 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 of a pathogenic agent or emergence of a disease in a free country or *zone*.

Vaccination programmes should 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 optimisation of resources.

Article 4.18.4.

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;
2) the probability that the disease cannot be rapidly contained by means other than *vaccination*;
3) the *incidence* and *prevalence* of the disease, if present;
4) the likelihood of introduction of a pathogenic agent or emergence of a disease;
5) the zoonotic potential of the disease;
6) the density of the exposed susceptible animal *population*;
7) the level of population immunity;
8) the risk of exposure of specific *subpopulations* of susceptible animals;
9) the suitability of a *vaccination* programme as an alternative to or an adjunct to other disease control measures such as a *stamping-out policy*;
10) the existence of an *animal identification system* to differentiate vaccinated from unvaccinated *subpopulations*;
11) the availability of a safe and effective vaccine;
12) the availability of human, financial, and material resources;
13) the cost-benefit analysis of the *vaccination* programme, including its impact on trade and public health.

Article 4.18.5.

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) **Barrier vaccination** means *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of *infection* into or from a neighbouring country or *zone*.
2) **Blanket vaccination** means *vaccination* of all susceptible animals in an area or an entire country or *zone*.

3) **Ring vaccination** means *vaccination* of all susceptible animals in a delineated area surrounding the location where an *outbreak* has occurred.

4) **Targeted vaccination** means *vaccination* of a *subpopulation* of susceptible animals.

Article 4.18.6.

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 several factors including:

1. Availability and cost
   a) Availability of the vaccine including relevant regulatory approvals and 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;
      – thermotolerance;
      – duration of the effective immunity;
      – number of doses required to achieve effective immunity;
      – ability to be monitored for vaccine-induced immunity;
      – ability for vaccinated animals to be differentiated from infected animals, at the individual or group level;
      – suitability of vaccine formulation for species, age or physiological status of animals in the target population;
      – safety for the users, the consumers and the environment.

   c) Side effects
      – Adverse reactions;
      – unintentional transmission of live vaccine strains;
      – reversion of attenuated strains to virulence.

When a single vaccine only is available, the same factors listed above should be considered in deciding whether or not to launch a *vaccination* programme.

Article 4.18.7.

Other critical elements of a vaccination programme

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

1. Legal basis

   There should be a legal basis for the *vaccination* programme, including for possible compulsory compliance and for possible compensation of animal owners for adverse reactions in their animals.

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 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 *infection* and the resources available. The target population may include *wildlife*.

   Factors to consider in determining the target population may include species, age, health status, 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

   It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary to achieve a sufficient population immunity to fulfil 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 in identifying subsets of the target population that have not been adequately immunised.

4. Stakeholder involvement

   Veterinary Services should demonstrate good governance of the *vaccination* programme by clearly identifying the involvement of different stakeholders including other governmental organisations, animal owners, 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 any *vaccination* campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

   The objective of a *vaccination* campaign should be to achieve the *vaccination* coverage necessary to attain or maintain 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 *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of *vaccination* campaigns should be determined taking into consideration the following factors:

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

8. Auditing of vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in any *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 a *vaccination* campaign may 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;
c) number of animals vaccinated compared to census figures for the relevant animal *population*;
d) number of reports of breaches of the cold chain;
e) performance of vaccinator teams in complying with the standard operating procedures;
f) timing and duration of the campaign;
g) 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 4.18.8.

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 subjected to the relevant regulatory approval 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 relevant regulatory approval should be obtained.

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

2. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables.

3. Implementation of the vaccination programme

Standard operating procedures should be established 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;

f) determine the disposition of partially used or unused containers of vaccine, such as ampoules, vials and bottles;

g) implement *biosecurity* to ensure *vaccination* teams do not transmit the pathogenic agent between *establishments*;

h) identify vaccinated animals;

i) ensure the safety and welfare of animals;

j) ensure the safety of *vaccination* teams;

k) record activities of *vaccination* teams;

l) document *vaccination*.

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

4. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary Services*. 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.

5. Public awareness and communication

The *Veterinary Services* should develop a communication strategy in accordance with Chapter 3.5., which should be directed at all stakeholders and the 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.

6. Animal identification

Animal identification allows for the differentiation of vaccinated from unvaccinated domestic 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 implemented in accordance with Chapters 4.2. and 4.3.

7. Record keeping and vaccination certificates

Vaccination programmes under the *Veterinary Service*'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.

8. 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, *biosecurity*, *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 4.18.9.

Evaluation and monitoring of a vaccination programme

A *vaccination* programme should provide for outcome-based evaluation and monitoring to assess its achievements. 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, age, 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 side effects;
4) reduction of *incidence*, *prevalence* or impact of the disease.

If the objectives and targets of the *vaccination* programme are not achieved, the reasons for this should be identified and addressed.

Article 4.18.10.

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 of the pathogenic agent or emergence of the disease;
3) reduction of the *incidence*, *prevalence* or impact of the disease to a level where alternative measures such as a *stamping-out policy* may be 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 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 4.18.11.

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 policy*. 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. *Listed disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management and trade of vaccinated animals and their products.

Free countries or *zones* applying systematic or emergency *vaccination* in response to an increased *risk* of introduction of a disease should inform trading partners and the OIE of their *vaccination* programme, as appropriate. Unless

otherwise specified in the relevant *listed disease*-specific chapter, in the absence of *cases*, demonstrated by adequate *surveillance*, *vaccination* of animals does not affect the status of the country or *zone* and should not disrupt trade.

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