ORIENTAÇÕES PARA FISCALIZAÇÃO DO COMÉRCIO DE VACINAS CONTRA A FEBRE AFTOSA E PARA CONTROLE E AVALIAÇÃO DAS ETAPAS DE VACINAÇÃO

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Ministry of Agriculture, Livestock and Food Supply
Secretariat of Animal and Plant Health

GUIDELINES FOR INSPECTING THE SALE OF FOOT AND MOUTH DISEASE VACCINE AND FOR THE CONTROL AND EVALUATION OF VACCINATION STAGES

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FOREWORD

In 2005, the Ministry of Agriculture, Livestock and Food Supply (MAPA) published its “Guidelines for Inspecting Foot and Mouth Disease Vaccine Commerce and for Controlling and Evaluating the Vaccination Stages” in order to establish minimum control points for such processes, and thus help perform activities before, during, and after each stage of Foot and Mouth Disease Vaccination.

In 2016 a working group was set up to review and update these guidelines: the group’s activities were conducted through meetings, conference calls, consultation of legislation, and by analyzing and compiling suggestions that the state-level veterinary services had received.

The present study aims, in a practical and updated form, to present the most important aspects of the FMD vaccine and the vaccination process, in alignment with activities and strategies laid down by Brazil’s National Program to Eradicate and Prevent Foot and Mouth Disease (PNEFA).

The material presented herein does not aim to be an exhaustive treatment of the topic, but rather to help in the execution of the official veterinary service’s activities, as well as those of private-sector veterinarians, vaccine retailers, and the entire chain that is involved; thus, as time goes on, it aims to promote further discussions, contributions, revisions, and additions.

We hope that users of the material will apply it in their activities as a source of information, understanding, and in order to standardize procedures, thus promoting improvements in the animal health protection system.

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list of abbreviations

AGV – VINHEDO GENERAL WAREHOUSE
BPF – GMP - GOOD MANUFACTURING PRACTICES
BHK - BABY HAMSTER KIDNEY CELLS
CGAL – GENERAL COORDINATION FOR LABORATORY SUPPORT
CVP – SOUTHERN CONE STANDING VETERINARY COMMITTEE
CTGRB - TECHNICAL COMMISSION ON BIOLOGICAL AND BIOSAFETY RISK MANAGEMENT
DFIP – DEPARTMENT OF INSPECTION OF LIVESTOCK INPUTS
DIFA – FOOT AND MOUTH AND OTHER VESICULAR DISEASES DIVISION **DSA -** ANIMAL HEALTH DEPARTMENT
ELISA - ENZYME LINKED IMMUNOSORBENT ASSAY
FA - FOOT AND MOUTH DISEASE
INMETRO - BRAZIL'S NATIONAL INSTITUTE FOR METROLOGY, QUALITY AND TECHNOLOGY
MAPA – MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY
NB-4 – BIOSECURITY LEVEL 4
OIE – WORLD ANIMAL HEALTH ORGANIZATION
NSP – NON-STRUCTURAL PROTEINS
PPG - PROTECTION AGAINST PODAL GENERALIZATION
PANAFTOSA - PAN-AMERICAN FMD CENTER
PE - STRATEGIC PLAN
PNEFA - BRAZIL'S NATIONAL PROGRAM FOR THE ERADICATION AND PREVENTION OF FOOT AND MOUTH DISEASE
RT - TECHNICALLY RESPONSIBLE INDIVIDUAL
SEI - MAPA ELECTRONIC INFORMATION SYSTEM
SDA - SECRETARIAT OF ANIMAL AND PLANT HEALTH
SFA - FEDERAL AGRICULTURE SUPERINTENDENT'S OFFICE
SINDAN - NATIONAL UNION OF THE ANIMAL HEALTH PRODUCTS INDUSTRY
SIPEAGRO - INTEGRATED SYSTEM FOR AGRICULTURAL AND LIVESTOCK PRODUCTS AND ESTABLISHMENTS
SVS – STATE VETERINARY SERVICE
OVS – OFFICIAL (FEDERAL AND STATE-LEVEL) VETERINARY SERVICE
UC – CENTRAL UNIT
UF - STATE (BRAZIL COMPRISES 27 STATES)
UVL (LVU) – LOCAL VETERINARY UNIT
VFA - FOOT AND MOUTH DISEASE VIRUS

1. introduction

Brazil's National Program to Eradicate and Prevent Foot and Mouth Disease (PNEFA) is entirely supported by the sharing of responsibilities between the public and private sectors. Regarding vaccination, the owners of animals are responsible for purchasing and applying FMD vaccine, while it is the responsibility of the Official Veterinary Service (SVO in Portuguese) to oversee the quality of the vaccine made, and to inspect, control and instruct the activities of selling and using the product. Execution and control of vaccination campaigns, in the sphere of each of the states of Brazil (UFs as they are called in Portuguese, standing for Federative Units) are the responsibility of the State Veterinary Services (SVS) in accordance with standards and procedures defined by the Ministry of Agriculture, Livestock and Food Supply (MAPA).

Given the responsibilities of the Official Veterinary Service (OVS), and in order to enhance the standards laid down for the procedures to be executed, in the present document we have addressed the major activities involving inspection of the sale and distribution of FMD vaccines, as well as the control and evaluation of vaccination campaigns.

Given the specificities and particularities of the country's several regions, it is impossible to lay down single sets of procedures that could apply to all the states of Brazil. This document therefore represents general guidelines to be employed by the several states after suitable regional adjustments have been made.

Before presenting specific topics, a brief history and some generic information on the FMD vaccine used in Brazil, and the vaccination strategies in force, are given.

2. evolution of the vaccine

Most of South America has been using FMD vaccination as one of the major strategies within the several national eradication and prevention programs. In Brazil, official vaccination campaigns began in 1960, and in the following decades spread to all the country's States. Significant advances were made in the struggle against foot and mouth disease after the employment of vaccination campaigns and other sanitary measures. In general terms, outbreaks of the disease in Brazil shrank from over 2,000 in the 1990s, to sporadic cases in the 2000s, and no cases have been reported since 2006. Thanks to these advances, Brazil is making strides towards a sanitary status as free of foot and mouth disease where vaccination is not practiced, through the execution of the strategic plan for 2017-2026 of PNEFA[1].

The preparation of the Strategic Plan arose from the need to reformulate the PNEFA, taking into consideration the national and regional scenario of foot and mouth disease, and the challenges and opportunities of the Brazilian production sector. Its main objective is to create and maintain sustainable conditions to guarantee Brazil's status as a country free of foot-and-mouth disease and expand the zones free of foot-and-mouth disease where vaccination is not practiced, protecting the national livestock assets and generating maximum benefit for the stakeholders in Brazilian society.

It therefore seeks to consolidate the sanitary status achieved, strengthen surveillance for vesicular diseases and the prevention of foot and mouth disease, and advance as an FMD-free zone where vaccination is not practiced, thus contributing to the health of the herds that make up Brazil's livestock wealth. The Plan is aligned with the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE) and the guidelines of the Hemispheric Program for Eradication of Foot-and-Mouth Disease (PHEFA) as efforts to eradicate the disease in South America.

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[1] **Available for access at http://www.agricultura.gov.br/assuntos/sanidade-animal-e-vegetal/saude-animal/programas-de-saude-animal/febre-aftosa/pnefa-2017-2026**

3. HISTORY OF VACCINE PRODUCTION IN BRAZIL

1930: The first vaccines that were truly effective against foot and mouth disease were produced. The antigen was obtained by inoculating the active virus into the tongues of live animals, subsequently removing the lingual epithelium to produce the vaccine.

1950: There was progress in the lingual tissue production technique, with production being introduced from virus inoculation into the epithelium harvested in slaughterhouses.

1960: Vaccines were produced from antigens produced in the kidneys of calves, which were deemed limited owing to the low density of cells that were obtained; in countries where foot and mouth disease outbreaks occurred, there was an increased risk of the virus or the antibodies being carried in the harvested kidneys. Other methods were used to produce the antigen, such as viral inoculation in rabbits, and in swine kidneys, although these were also abandoned owing to biosecurity problems.

1963: Vaccines produced in hamster kidney cells (BHK). These cells had a high yield, and could be reproduced in large-scale stainless steel tanks, enabling constant monitoring for quantity, sensitivity, and quality of the antigen being produced.

1980: Live attenuated vaccine use was banned, because although it induced good protection for vaccinated animals, it had several disadvantages: it was hard to obtain a reduction in the virulence of the several strains of the virus; the virus persisted in the organs and tissues of vaccinated animals; and there was a risk of provoking the disease in animals of species other than that for which the virus was attenuated (for example, a virus that had been modified for bovines could not be used in pigs, and vice versa).

1982 to 1985: Brazil, alongside other South American countries, took part in projects introduced by PANAFTOSA with the technical collaboration of the USDA's Plum Island animal disease center, in order to use a vaccine that would best comply with the objectives and strategies of eradication. The partnership culminated in the development of the oil-adjuvanted vaccine, and in the standardization of laboratory techniques to monitor the product more efficiently and with better quality.

Gradual introduction of the oil adjuvanted vaccine after PANAFTOSA transferred its technology to the private sector, inducing protection for six months, replacing the water-based vaccine that conferred immunity for three months at most. In addition to longer immunity because of the slow, steady release of the antigen into the bloodstream, the oil component protects the antigen from maternal antibodies, which in practical terms means it is possible to vaccinate calves at any age.

With new, more efficient methods for purifying and concentrating the antigen, the production process changed so as to obtain antigens with a greater immunogenic power, and the use of so-called first-order inactivants. Inactivants are a group of chemicals used because they are able to ensure a straight-line reduction of the infectious titer, indicating complete inactivation of the virus during the process, definitively replacing what was up until then a not very safe process of inactivation using formaldehyde.

1992: Brazilian herd vaccinated with oil-adjuvanted vaccine.

1994: Publication of the technical regulations for FMD virus handling, and the setting up of the biosecurity commission to evaluate laboratories handling the active virus.

1995: Replacement of direct proof of protection against podal generalization (PPG) to assess the potency of the vaccine (consisting of vaccination and inoculation of live virus into a group of vaccinated animals) by ELISA to assess the titer of antibodies at 28 days post-vaccination.

1998: FMD vaccine-producing laboratories in the South and South-east of Brazil begin compulsorily to comply with the biosecurity requirements laid down in Brazil's technical regulation, with level 4 (NB-4) OIE, which is characterized, among other things, by strict access controls for personnel, a permanent negative-pressure internal environment, a back-up electricity supply to ensure that there are no disruptions to the air system, high-efficiency double absolute filters to treat the air entering and leaving the laboratory, and the thermal or chemical treatment of liquid and solid wastes generated. This condition aims to ensure uninterrupted bio-containment of the virus in the handling environment.

2000: All vaccine-producing laboratories in Brazil adjusted their facilities to the NB-4 OIE requirements.

2003: Introduction of Good Manufacturing Practices (GMPs) to preserve the production process and the quality of the vaccines and drugs produced.

2008: Introduction of control of non-structural protein antibodies in all batches of FMD vaccine, in order to differentiate between the induction of these antibodies among vaccinated animals and the occurrence of viral circulation.

2012: The new regulation on biosecurity in handling FMD virus was updated and published (SDA Normative Instruction no. 5/2012), in which the principle of having back-up systems for air treatment, and separation of the production and quality assurance areas, was reinforced.

2017: Commencement of production and use of bivalent vaccines against strains O and A of the FMD virus.

2018: The new technical regulation for the production and quality assurance of FMD vaccine was updated and published in MAPA Normative Instruction no. 11/2018, which includes reduction of the dose from 5.0 to 2.0 mL. There was also a change in the tolerance testing criteria in order to assess the occurrence of unwanted reactions at the application site.

Starting with the November 2018 campaign, exclusive use of bivalent vaccines.

2019: Use of vaccines at a dose of 2.0mL.

4. GENERAL ASPECTS OF FOOT AND MOUTH DISEASE VACCINE

Control of production and types of vaccine employed

Control of the production and use of FMD vaccine is standardized through several legal acts that govern those activities. See below the most important legal acts in force:

- Decree-Law no. 467, enacted February 13, 1969: Addresses the inspection of veterinary products and establishments that manufacture them;

- Ministerial Ordinance (*Portaria*) no. 16, dated January 26, 1989: Bans research into, production, sale and use of FMD vaccine made from modified live virus, throughout Brazil;

- Ministerial Ordinance (*Portaria*) no. 768, dated December 13, 1993: Orders the Department of Animal Health, of the Secretariat of Animal and Plant Health, to use the principal means of communication in order to publish the laboratory test results each month by the tenth day of the month after qualitative testing of FMD vaccines has been performed;

- Normative Instruction SDA no. 229 published December 7, 1998: Authorizes the use of a Seal of Guarantee on FMD vaccine vials;

- Normative Instruction MAPA no. 13 published October 3, 2003: Approves the Regulation for Good Manufacturing Practices (GMP) of Veterinary Products;

- Decree no. 5,053, enacted 22 April, 2004 Approves the Regulation for the Inspection of Veterinary Products and of Establishments that manufacture or sell them.

- Normative Instruction SDA/MAPA no. 44 published October 2, 2007: Approves General Guidelines for the Eradication and Prevention of Foot and Mouth Disease contained in Appendix I, and Appendices II, III and IV of the present Normative Instruction, to be observed throughout Brazil, in order to introduce the National Program for the Eradication and Prevention of Foot-and-Mouth Disease (PNEFA), as laid down by the Unified Animal and Plant Health System;

- **Normative Instruction SDA no. 5 published March 28, 2012:** Establishes the technical regulation on biosecurity in handling the foot and mouth disease virus (FMDV).

- **SDA Ordinance (*Portaria*) no. 89 dated November 11, 2015:** Within the sphere of the Department for Inspection of Livestock Inputs (DFIP/SDA), sets up the Technical Commission for the Management of Biological Risks and Biosecurity (CTGRB) in establishments that manufacture, or perform quality control of, vaccines, antigens and hyperimmune sera for veterinary use.

- **MAPA Normative Instruction no. 11, dated January 18, 2018:** Approves the Technical Regulation for the Production, Quality Control, Sale and Use of FMD Vaccines, in accordance with the present Normative Instruction.

The legislation in force lays down criteria for assessing the efficacy and safety of FMD vaccine. During the several steps in the manufacture process for each batch, and after the filling step of the final product, samples will be taken for testing to prove inactivation of the virus and to control vaccine sterility, as well as to evaluate the integrity of the emulsion, using safe and effective methodologies recommended in international pharmacopoeias.

All testing on the product will be carried out by the vaccine manufacturer and repeated by MAPA, which has an FMD vaccine control laboratory in its Rio Grande do Sul facility (Lanagro-RS).

Currently, only the production and use of inactivated, bivalent vaccine formulated from viral strains A24 Cruzeiro and O1 Campos, using an oil adjuvant is permitted.

Brazil's FMD vaccine manufacturing plant capacity is able to meet the demand for the country's vaccination steps, and export vaccine to other South American countries, while maintaining a buffer stock for supply.

Vaccine producing laboratories are inspected and assessed by a MAPA technical team on an annual basis to verify compliance with biosecurity and with Good Manufacturing Practices. After going through all tests, the vaccine batch is approved and its sale is authorized. Otherwise, the entire batch is destroyed.

SDA Normative Instruction no. 229, dated 7 December, 1998, made it mandatory to use a holographic quality seal, aiming to ensure that the batch of vaccine for sale has undergone the quality controls laid down by MAPA.

Figure 1. Holographic seal placed on vials for batches approved in the safety and effectiveness testing.

If vials of vaccine are found in commerce without the holographic seal, they will be deemed irregular and seized for infringing article 3 of Normative Instruction no. 229 of 7 December, 1998.

The logistical operator Armazéns Gerais Vinhedo (AGV), located in the municipality of Vinhedo (São Paulo state), which is called the Vaccine Sealing Central (*Central de Selagem de Vacinas*) (Figures 2 and 3) is responsible for distribution of the vaccine from the industrial manufacturer to the veterinary product retailers, under control of the manufacturing companies. The structure is inspected by MAPA, and encompasses storage, distribution and transportation. MAPA is also responsible for the official approval of the batch, the placement of the quality seal and assurance of non-tampering (tamperproof holographic seal). The seal is applied under MAPA supervision. MAPA checks and records the numbers of the vials approved for sale. After control and registration of the quantities, the batches are approved for sale. The Sealing Central routinely provides MAPA and State Veterinary Services (SVSs) with information on the total amount and intended destination and purpose of the vaccines sold.

Figure 2. Sealing of vials of FMD vaccine. Source: AGV

The computerized system in the Sealing Central enables MAPA at any moment to obtain data on the stock, approval and sale of the product in all states and municipalities. Likewise, the SVSs have access to the data for their own specific states. The distribution logistics at the Sealing central Plant enhances MAPA's ability to oversee and inspect, preserves the concept of traceability, deters counterfeiting, avoids excessive handling of the product (reducing refrigeration failures and loss of quality) and facilitates control of the supply and distribution of the product between states and municipalities.

Foot and mouth disease vaccine must be preserved under refrigeration (at a temperature from 2ºC to 8ºC). Its expiration date is 24 months, and it must be sold in packages of 15 and 50 doses.

In order to comply with the new PNEFA strategy, the vaccine has undergone two important changes: removal of virus C from the composition, and reduction of the dose from 5 to 2 mL, available as of the May 2019 stage.

Figure 3. Storage of vaccines for distribution. Source: AGV

Vaccination strategy

Vaccination is mandatory only for bovines and buffaloes. FMD vaccination is mandatory—in other words, it is legally enforced, systematic and applied en masse—except in those states whose sanitary status no longer requires vaccination (they are free of foot and mouth disease where vaccination is not practiced).

Other FMD-susceptible species must not be vaccinated systematically. Only MAPA may determine when a sanitary situation: warrants the vaccination of other species, such as in cases where there is a need to contain the spread of the disease.

The States of Brazil are responsible for coordinating and executing the vaccination campaigns at state level; in order to do so they have the autonomy to issue legislation that supplements MAPA legislation. Concerning foot and mouth disease vaccination, the state-level standards principally establish the following: the vaccination calendar including deadlines for proving vaccination to the SVSs; the way in which the vaccine can be sold outside the vaccination stages; the way in which the sale of vaccination will be inspected and what documentation is necessary for control; and sanctions resulting from failure to comply with the standards in force. In specific situations such as weather problems, or when events are held, and after technical evaluation by the State Veterinary Serve, the vaccination stage may be brought forwards or pushed back, always with the backing of the responsible technical sector of MAPA, in accordance with a procedure described in the present document.

Twice-yearly vaccination of bovines and buffaloes under 24 months of age, including the vaccination of animals immediately after birth, is recommended because despite the fact that premature vaccination is unable to produce protective levels of circulating antibodies, its aim is to prepare the animals for a more intense and longer-lasting response when they are revaccinated. Above this age, animals with a history of at least four vaccinations may be vaccinated once annually, in accordance with the strategy adopted by MAPA.

In addition to the immunogenic characteristics of the vaccine, the definition of vaccination strategies takes into consideration the geographical features and farming practices prevailing in each region of Brazil. The months in which the vaccination stages take place vary in accordance with the State.

The current vaccination strategies in Brazil can be summed up in two distinct schemes:

1) vaccination stratified by age bracket, where immunization is mainly targeted at young animals (under 24 months of age), which are vaccinated twice-yearly; animals above 24 months of age being vaccinated once annually, or

2) annual vaccination, in 45- or 60-day stages, carried out in those regions of the country where the prevailing geographical conditions limit animal handling to a certain period of the year (the regions of the Pantanal wetlands in Mato Grosso, Ilha do Bananal (a northern island) and the Marajó Archipelago).

The FMD vaccination calendar currently in force in the several States can be consulted at www.agricultura.gov.br/febreaftosa. It is essential that this calendar be kept up to date in the local Veterinary Units. Any vaccination outside the official calendar may only be performed when authorized by the Official Veterinary Service (OVS). In each stage, the owner of the animals must prove that (s)he has bought the vaccine in an amount compatible with their herd, and declare that they have performed the vaccination by registering it in the Local Veterinary Units (LVUs). In those states where the SVS allows it, the declaration may be made within the established deadlines over the Internet. Those failing to comply will be subject to fines and to bans on the movement and sale of their animals. In such cases the recommendation is for the herd to be vaccinated under the supervision and enforcement of the SVS.

Bovines and buffaloes born between vaccination phases must be vaccinated before they can be allowed to be transported for any purpose. The withdrawal periods of 15 days for primo-vaccinated animals, and seven days for those animals with a history of two vaccinations, must be respected for transportation. Animals with a history of three vaccinations may be transported at any moment. These withdrawal periods are based on the serum antibody production curves. Transportation of animals during the vaccination stages must be preceded by vaccination, and the aforementioned withdrawal periods must be respected, except when they are going for immediate slaughter. This avoids the possibility of animals arriving at a destination farm that has already vaccinated its own animals, and thus going unvaccinated.

Vaccination may be performed strategically in at-risk areas, or on specific herds: for example, on small farms and in indigenous tribes-people's villages.

Vaccination may also be performed as an emergency, and employed in high-risk situations in order to reduce the number of susceptible animals that have not undergone systematic vaccination en masse, in order to contain the disease: for example, when an outbreak has occurred. These activities fit into the concepts explained below, in accordance with the execution of the SVS.

Thus, in order to standardize, the definitions of certain terms used by the SVS are given herein. For vaccination activities, and depending on the situation, these terms may run together and complement each other:

Compulsory (or mandatory) vaccination: performed in order to comply with the law. This may be systematic mass vaccination (e.g. foot and mouth disease) or more sporadic and targeting a given population (e.g. mandatory vaccination against rabies of herbivores in at-risk populations that are preyed upon by vampire bats.

Official vaccination (official syringe): vaccination performed by the OVS, which is responsible for applying the vaccine. This vaccination may take place because in certain prior stages or in certain at-risk areas, situations or farms, there has been a failure to vaccinate; as well as on other occasions defined by the OVS.

Assisted or witnessed vaccination: vaccination performed by the farmer under the direct supervision of the OVS throughout the vaccination process. This may occur in order to provide guidance, or assistance, to needy communities or as enforcement. In the latter situation, at the discretion of the OVS, and after official communication in writing with due prior warning, vaccination performed by the farmer or owner may only be officially recognized when assisted or witnessed by the official service. Both official vaccination and assisted or witnessed vaccination enable the OVS to guarantee that the vaccine has been totally applied to all of the animals on a given farm.

Enforced vaccination: this is vaccination enforced and inspected by the OVS in order to enhance the guarantee concerning the performance of the vaccination, and does not involve witnessing or oversight from-start-to-finish of the work of vaccination on a given farm. This inspection or enforcement may cover, for example, inspections carried out in a given period and region, involving a set of farms, visited for verification of the practice of vaccination. It may be performed for the purpose of guidance.

5. INSPECTION OF THE SALE OF FMD VACCINES

Retailers are an important space of contact and liaison with the community that is directly involved in animal health protection activities. These spaces therefore deserve special attention from the OVS.

It is important that shop-owners, when starting out in the business of selling agricultural products, receive guidance and explanations concerning their role within the agricultural-social context and become partners and communicators of information to farming populations.

Inspection of the trade in FMD vaccines plays an important role within the responsibilities of the OVS, as regards the activities of the PNEFA, since it aims to ensure that the community will consume genuine, quality products.

In accordance with legislation in force, all veterinary product retailers must, in order to operate, be registered and approved or licensed by MAPA.

Interested parties, in order to obtain an establishment license from MAPA, go to www.agricultura.gov.br, and at the 'SISTEMAS' link, locate SIPEAGRO (the Integrated System for Agricultural Products and Establishments) and key in the information requested.

Inspection of establishments selling FMD vaccines is the responsibility of MAPA. As a result of the delegation of jurisdictional competence by means of the Declaration of Commitment (*Declaração de Compromisso* - Appendix 1), this responsibility is shared with the SVSs.

Regarding FMD vaccination campaigns, the states are responsible for enacting legislation to supplement federal legislation, addressing at least:

a) the officialization of the vaccination calendar;

b) the banning of sales of vaccine outside the vaccination campaign stages; sale, if necessary, may only occur with the authorization of the OVS;

c) deadlines for the registration and proof of vaccination by owners or individuals responsible for the animals;

d) the documentation and procedures concerning control of sales and of stocks for veterinary products retailers; and

e) sanctions against offenders or defaulters.

Professionals responsible for inspection activities on FMD vaccine retailers must have all the legal documents governing the issue under their control and easily accessible.

Among the duties of the Federal Superintendents' Offices for Agriculture (SFA) the following stand out: to supervise the execution of the delegated activity; to pass on instructions and information to the SVS that are necessary for carrying out the delegated activity;

3) to analyze the documentation for registration and issuing of the license, or for the annual renewal of the license, and for granting registration owing to compliance with the demands - the latter registration being issued on the SIPEAGRO system;

4) to inspect retailers after granting of the license;

5) to determine fines based on the Notifications of Violation written up, when inspection is carried out by SFA, judgment of appeal defenses brought by offending companies in case files that begin inside the SFAs, when the inspections have been carried out by Federal Agricultural Inspectors/Auditors AFFAs.

The following responsibilities fall to the SVSs, in addition to on-site audit inspections:

1) to register establishments selling FMD vaccines;

2) to issue inspection reports or technical establishment inspection opinions for granting or renewing licenses;

3) to perform educational activities and provide explanations to veterinary product retailers;

4) periodically to inspect commercial establishments in the region under their jurisdictional competence;

5) to receive and check the vaccines, approving them for storage in the retailer's refrigerators;

6) to issue written warnings to commercial establishments that commit an offense and to seize vaccines that are irregular or unfit for use;

7) to render unusable the seized vaccines in those cases in which after ten working days have elapsed, there has been no appeal or defense presented by the offender;

8) in those cases where the offender has presented a defense, to render the seized vaccines unusable, although only after judgment and completion of appeals and legal deadlines. In such cases the retailer will be deemed to be the depositary;

9) to collect the administrative fine against offending companies when they have legal representation;

10) to provide SFA, in accordance with the frequencies agreed among the institutions, with a report on the enforcement activities that have been carried out, and resulting warnings and consequences, among other requested documentation and information.

General information is given on the inspection process, created on the basis of Decree no. 5,053, enacted 22 April, 2004, in Appendix 2.

General guidance for controlling the commerce of FMD vaccine

The retail establishments are responsible for the preservation and control of stock of the product. Inspection authorities must therefore make sure that the following conditions and procedures are complied with:

- Authorization for a retailer to begin to sell, or renew its license to sell, FMD vaccine will depend on the technical opinion provided by an OVS veterinarian certifying the necessary conditions for maintaining the cold chain and for sale of the product. Special attention must be given to alternatives used by the retailer to conserve the vaccine in the event of power cuts (ice produced by the retailer or another establishment in the municipality; electricity generator; thermograph; alarms, and so on);
- A commercial establishment licensed in MAPA to sell veterinary biological products must also be authorized by SVS to commence or to renew its license to sell FMD vaccine, with the guarantees of the aforementioned necessary conditions.
- The owner of, and technically responsible individual for, the retailer authorized to sell FMD vaccine must sign the Commitment document in accordance with the Template given in Appendix 3;
- Inspection of commercial establishments must be intensified during FMD vaccination phases, with a minimum frequency of two inspections per establishment per week.

For inspection of stock maintenance between vaccination stages, a monthly frequency must be followed, but always on different days and times of day so at to preserve the surprise factor. In addition to the aforementioned inspection activities, vaccine stocks must compulsorily be checked in the retailers involved whenever vaccine is received for the first time and/or at the end of the vaccination phases;

- All inspection activities must be recorded on dedicated forms, one copy to be kept in the establishment and another in the unit responsible for inspection;
- The commercial establishments must provide for each refrigerator a thermometer or other device for recording maximum and minimum temperatures, that has been duly approved by Brazil's National Metrology Institute (INMETRO); note that the act of resetting the thermometer to zero is the exclusive responsibility of the OVS;

- Only employees of the retail establishments who have been duly trained by the Technically Responsible Individual (RT), and who are registered in the SVS, having signed Statements of Responsibility and Commitment, may measure the temperature of refrigerators. The SVS is advised, during audits, to check the knowledge and procedural ability of the retailer employees in the measurement and recording of temperature. During the vaccination stages, the manual or electronic measurement and recording of temperatures of refrigerators used for storing vaccines must be performed in the morning and in the afternoon. During inspections, SVS professionals must check the temperature-reading records and carry out their own temperature measurements. Appendix 4 shows the template of a form for the manual recording of temperature readings, which must be attached to each refrigerator used, accurately identifying the refrigerator. For electronic temperature measurement, the retailer must ensure that the records can be evaluated, checked, verified and audited by the inspector;

- It is recommended that the retailer be advised of the importance of periodically calibrating their thermometers and installing more efficient equipment to control and record temperature, such as instruments allowing graphical representation of variations (thermographs) and digital thermometers with alarms.

When performing inspection, the SVS must take into consideration when reading the temperatures, the models of thermometers, and the maximum degree of error in showing the results (±), in accordance with the information given in the thermometer's manual.

It is essential that each inspection agent, registered employee and technically responsible individual be trained in correctly reading the thermometer.

The registered employee is responsible only for taking the reading and recording the temperatures shown; they may not reset thermometers to zero, or "join" the columns of the thermometer after readings. Improper handling of the thermometer will be deemed an infraction: it must be stressed that only OVS representatives may update the maximums and minimums (clearing the thermometers to zero). For digital thermometers, the sensor or bulb must not be placed near a door or fan; it must be centralized or placed in such a way as best to show the preservation temperature of the vaccines. In the event of a fault or breakage in the thermometer, the technically responsible individual will immediately notify the SVS and replace the instrument;

A refrigerator used in order to conserve biological products may only be used for that purpose. The following recommendations must followed when organizing the refrigerator:

- for commonplace refrigerators: FMD vaccine must not be stored in the door compartments, and under no circumstances must it be kept in the freezer, which must only contain ice in order to help maintain the temperature in the event of a fault or power outage;

- in refrigerators and chillers, there must be a space maintained between stacks or piles of products so as to enable the suitable circulation of air (e.g. store in slotted trays on shelves);
- where the refrigerator or chiller is placed must be level,

be protected from sunlight and at a distance from sources of heat.

The temperature of the refrigerators must be controlled on a daily basis by the retailers, which includes Saturdays and Sundays and public holidays (non-working days). It must be pointed out that the SVS has the right to enter the establishment on any day of the year in order to verify the condition of vaccine maintenance.

The SVS must pay special attention to retailers where the readings carried out showed temperature instability and in the event of power outages. In the latter event, on whatever day the outage occurs, and regardless of whether the retailer has their own electricity generator, the sale of biological products must be halted until the problem can be solved, and any opening of the refrigerators must be avoided. Sale may only be resumed after the SVS has checked the maximum temperature attained.

When the retail establishment receives FMD vaccine from the distributor or from another retail source, it must notify the SVS immediately, for the SVS to verify the seals of all the vials, their condition of conservation, origin, batch, expiration and quantity, and to authorize storage in the refrigerator. The SVS must be present even when outside the agency's working hours. When the vaccine is predicted to arrive outside normal working hours, the retailer must notify SVS so that the vaccine receiving step can be scheduled. No FMD vaccine may be removed from its transportation packaging and stored in the retailer without advance authorization from the SVS.

Only a duly trained OVS official may oversee the receiving of vaccines; however, in exceptional circumstances, under criteria standardized by the SVS, and in places where officials are not available to carry out this activity, the Technically Responsible Individual (RT) may receive the vaccine, provided it can be proven that (s)he has been duly trained for this task. Using the specific form defined by the SVS they can record the conditions in which the vaccine was received and the measurements needed for ensuring auditability by the SVS. However, even in exceptional circumstances at least one reception activity per step must be performed by an SVS official.

Specific forms must be used for sale and stock controls (controls per batch and laboratory). This auditable control must be carried out by establishments and inspected by the SVS; control may be kept in record books (ledgers with numbered pages) or in computerized systems, either of the retailer or of the SVS in those States where there is a specific official module that retailers can access on the SVS Internet page.

Vaccines may only be sold to farmers outside the vaccination stages when authorized by the SVS. Retail establishments and SVS units must keep copies of the authorizations issued on file.

FMD vaccine may only be sold when a tax invoice is issued at the same time; and the product must immediately be written down from the stock control. After the tax invoice has been issued, the corresponding vials of vaccine must be removed from the refrigeration device, placed in boxes for transportation, and dispensed immediately; neither the farmer nor anyone else may under any circumstances keep the vaccine on the premises of the retailer for later removal.

The vaccines must be transported in dedicated recipients able to maintain the ideal conservation temperature range of 2ºC to 8ºC; ordinary ice may be used (2/3 ice) or recyclable ice.

In order to facilitate stock control and checking, the vaccines must be stored tidily in the refrigerator, grouped by laboratory, batch and vial size. Retailers must make sure not to issue tax invoices that fail to match the laboratory and batch of the vaccine actually sold.

The recommendation is that any owner or individual responsible for animals, who wishes to purchase FMD vaccine outside the state in which the farm is located, must comply with one of the following procedures:

1. Prior to vaccination, the SVS of the State in which the farm is located must check and verify that the vaccine and the tax invoice that goes with it are inspected at a fixed inspection station, or a community veterinary care office, or some other venue defined by the SVS. At this moment the tax invoice must be stamped and signed by the inspector. Alternatively, the tax invoice for the purchase of the vaccine, and the proof of purchase, as issued by the OVS authorities of the State in which the veterinary product retailer is located, must be shown as part of the act of proving vaccination to the SVS of the State in which the farm is located.

2. Concerning the previous item, when necessary or in the event of some suspected irregularity, the SVSs must contact their counterparts in the States of origin of the FMD vaccine retailers, to verify the tax invoices and other documentation involved;

The SVSs must set up mechanisms whereby they can remain up to date with the amount of FMD vaccine in stock in the approved retailers.

6. CONTROL AND EVALUATION OF FMD VACCINATION STAGES

First of all, a distinction must be made between the terms “vaccination campaign” and “vaccination stage” used in the PNEFA. The former is a more wide-ranging term. It covers the set of activities and actions making up the entirety of the animal vaccination process, including: strategy, legal standards and technical procedures, the responsibilities of several agents from society at large, as well as the definition of periods in which the steps of vaccination will be staged. The term “vaccination stage” is employed to define the period in which vaccination per se is performed. In the present document, therefore, the procedures to control and evaluate every vaccination step will be established.

The set of evaluations of the vaccination stages must be employed in order to achieve an overall evaluation of the vaccination campaign. The term vaccination campaign must also not be mistaken for activities publicizing vaccination.

Vaccination campaigns not only allow a direct benefit resulting from the reduction of opportunities for the replication and maintenance of the viral agent in a given ecosystem, but also - indirectly - play a role as an important indicator for evaluation of the community’s involvement and participation, and the OVS’s capacity for mobilizing and persuading the community. Special attention must therefore be given to evaluating the results obtained from vaccination campaigns.

PNEFA adopts a regular mass vaccination campaign targeting bovines and buffaloes of all age groups, using strategies adapted to the geographical and socioeconomic circumstances prevailing in each region. In most States, for example, the FMD vaccination campaign is carried out each six months, with stages in specific months (for example, May and November), each involving the vaccination of all existing bovines and buffaloes or animals up to 24 months of age.

The management of the campaigns for vaccination against foot-and-mouth disease involves several procedures, including technical, administrative and operational (logistical) elements.

Given the existing complexity, the present document aims to establish minimum procedures to be carried out by the SVSs, seeking to generate standardized information and enabling the evaluation and oversight at different levels (municipal, state and federal) of control.

General procedures

Every year, **by the last working day of September**, the OVSs in the States must inform the Department of Animal Health (DSA) of the demand for FMD vaccine for the following year. The information must be sent by the SFA to the Foot and Mouth Division DIFA/DSA/MAPA, at pnefa@agricultura.gov.br . This information must be based upon the existing registry, and changes in the herd; an estimate of the sales of vaccine to other states must not be included. Per vaccination stage, it must include the expected number of doses in accordance with the presentations available on the market.

Once the states have sent in their data, DIFA/DSA/MAPA will send the information clustered by type of vial, by State, and by month, to the Department of Inspection of Livestock Inputs (DFIP), to the General Coordination Office for Laboratory Support (CGAL) and to Brazil's National Union of the Animal Health Products Industry (SINDAN), the latter being responsible for passing on the data to the vaccine manufacturers. If any of the levels involved is delayed in sending the information, this may lead to disruptions in vaccine availability the following year.

At the end of each stage, the Official Veterinary Service in the states (SFA and executing agencies) must perform technical evaluations (state- and municipality-level), taking into consideration the indicators used for each vaccination stage, and, if necessary, discuss the results obtained with the private sector, in order to define actions and activities which are a priority for the next stage. The calculation of indicators and the record of procedures are described in the Case File SEI 21000.032989/2018-28, documents 5351779 and 5351741, which may be consulted by the SFAs and forwarded to the SVSs.

The SVS must keep its registry of veterinary product retailers approved to sell FMD vaccine updated. It is important to remind the retail outlet owners of the need to annually renew their license to operate in MAPA.

Procedures leading up to vaccination stages

The veterinary Services must make sure the following procedures are scheduled and executed:

- Compiling the predictions (targets) for vaccination per municipality, including the total number of bovines and buffaloes and the total number of farms involved;
- Establishing targets per Local Veterinary Unit (LVU) for official vaccinations, assisted vaccinations, and vaccination inspection activities, in accordance with the definitions shown in the present document;
- Informing the selected farmers of the date when the activity described in the previous item will be performed;
- Checking the stock of FMD vaccine available in the municipalities;
- Scheduling inspection activities in the veterinary product retailers that are approved to sell FMD vaccine (each retailer will receive at least two inspections weekly from the OVS during the vaccination phases;
- Registering the employees trained by the technically responsible individuals (RTs) of the veterinary product retail establishments who are authorized to register the temperature of the refrigerators;
- Scheduling educational activities, preparing and distributing communication pieces to publicize the vaccination phase: digital media may also be used in the publicity, involving the private sector in such actions;
- Recording and compiling the number of community representatives involved or affected by the activities, because the data will be necessary for the PNEFA twice-yearly report.

Procedures during vaccination stages

The performance and oversight of the vaccination stages involve:

- Compliance with the targets established during the scheduling phase, above all the inspection activities and the performance of official, inspected, and assisted vaccinations, and the educational and publication actions. The SVSs must prepare specific forms for recording and proving the vaccination inspection and oversight activities, with suitable fields for: the identification and signature of the owner of, or individual responsible for, the animals; data which will allow consolidation by municipality; the number of farms involved; and the total number of susceptible animals on the aforementioned farms. The forms must be filed in the local SVS units, and may also be used in order to consolidate reports that will be sent to other levels of control in the animal health protection system;

- Inspect those veterinary product retailers authorized to sell FMD vaccine, in accordance with the frequency laid down in the present manual;

- Encourage the local community to help publicize and participate in the vaccination stage by means of representative agencies and entities, particularly the animal health councils when such exist;

- The LVU will notify the central unit (CU) using a specific form or the computer system, of the proportion of farms and numbers of animals already declared as vaccinated, in addition to data on purchase of vaccine (stocks and issue of tax invoices).

The CU will compile the information, analyze it, and intervene whenever necessary;

- Avoid extending the vaccination stage; however, if necessary, the request may be founded upon a **technical opinion of the executive agency** (reports, accounts, official documents proving the justification of the request, such as official acts of the declaration of an emergency or public calamity, rainfall figures, fires, floods, vaccine shortages, strikes and the like) **and of the SFA**, subsequently submitted by SEI case file to the Department of Animal Health, **at least 5 working days in advance of the termination of the original closing date of the vaccination** stage.

Extension will only be valid after analysis and approval by the DSA/MAPA technical area, which must be carried out by the last working day before the original closing date of the step.

Procedures after the completion of vaccination stages

The following procedures must be followed after the close of the dates for vaccination and registration in the SVS offices:

- Immediately after the completion of the stage, listing those owners who have not proved vaccination and record actions taken in regard to them;
- Consolidating and analyzing the data for the vaccination stage:

- Only those vaccinations performed during the officially established period of the vaccination stage should be taken into consideration to properly evaluate the efficiency of the work;
- Vaccinations that were performed outside the established period must be recorded on a separate form.

The SVS will have **30 days** after the completion of the vaccination stage to send its final FMD vaccination report to SFA using the template and format laid down by DSA (Appendix 5).

- SFA will have up to five (5) days to check, make corrections (if necessary) and send the report to DIFA/DSA/SDA/MAPA, at pnefa@agricultura.gov.br, as an electronic form (spreadsheet) in accordance with the template and instructions given in Appendix 5.

- The vaccine indices must be calculated in accordance with the numbers corresponding to the last day of the vaccination stage, and not the last day allowed for declaring vaccination.

- To inspect veterinary product vendors that are authorized to sell FMD vaccine, physically checking their stocks and assessing document-related controls.

- Assess compliance with the targets for vaccination inspection, performance of assisted, official and inspected vaccination (scheduled versus actually performed).

The recommendation is that fewer than 1% of the farms in the municipality receive some kind of inspection during the stages;

- Analyze the result of the vaccination stage: the recommendation is to assess the following indices or rates, calculated for the several levels of organization in the system (municipality, region, state):

- percentage of owners/farms with registered vaccination versus the existing total number of owners/farms having bovines or buffaloes;

- percentage of vaccinated bovines/buffaloes versus the existing total number of bovines/buffaloes (in the age group involved in the vaccination step);

- percentage of farms/owners undergoing assisted vaccination versus the existing total number of farms/owners, and versus the scheduled total number for assisted vaccination;

- percentage of farms/owners undergoing inspected vaccination versus the existing total number of farms/owners and versus the scheduled total number for inspected vaccination;

- percentage of farms/owners undergoing official vaccination versus the existing total number of farms/owners and versus the scheduled total number for official vaccination.

- For each of the aforementioned indices the rates of change over earlier steps must be assessed, and explanations and reasons found to justify the differences found;

- In accordance with state legislation, in order to correct failure to vaccinate (absence of vaccination or failure to declare vaccination, on different forms), record what procedures were followed (whether written warning, a fine, proof of search for defaulters, assisted or inspected vaccination).

It should be stressed that cases must be solved as quickly as possible, and should not exceed 60 days from the termination of the vaccination stage;

- The SVS must not allow defaulting or unresolved cases to carry over from one vaccination stage to the next. The SVS must present and discuss the results of the vaccination stage with representatives of the community at large, particularly with the municipal animal health councils when the communities have such councils, seeking support to solve cases of failure to vaccinate, if necessary, in accordance with SVS decision;
- The SVS must maintain a database covering at least the two most recent years, with a list of all defaulters in this period, for assessment of the efficiency of the service vis-a-vis those farmers;
- The contact point for PNEFA in the SVS should liaise with the contact point for PNEFA in the SFA to analyze the data and produce a state-level report for each stage, and communicate this internally to the regional and local units, as well as to the State-level animal health executors, providing recommendations and actions to be taken;
- This state-level analysis should follow the template given in the SEI Case File no. 21000.032989/2018-28.

The SFA in the State should send a copy of the state-level analysis by SEI to DIFA.

APPENDIX 1

RESPONSIBILITY STATEMENT FOR DELEGATING JURISDICTIONAL COMPETENCY FOR THE INSPECTION OF VETERINARY PRODUCT RETAILERS

STATEMENT OF COMMITMENT SIGNED BETWEEN THE FEDERAL GOVERNMENT THROUGH THE OFFICE OF THE FEDERAL SUPERINTENDENT FOR AGRICULTURE, LIVESTOCK AND FOOD SUPPLY IN THE STATE OF _____ AND THE GOVERNMENT OF THE STATE OF__, BY INTERMEDIATION OF_____, INTENDING TO DELEGATE COMPETENCY FOR INSPECTING ESTABLISHMENTS THAT SELL AND DISTRIBUTE VETERINARY PRODUCTS.

The Federal Government, through the agency of the Ministry of Agriculture, Livestock and Food Supply, CNPJ/MF Nº00.396.895/0001-25, located at Esplanada dos Ministérios Bloco "D", hereinafter simply indicated as MINISTRY, herein represented by its Federal Superintendent for Agriculture in the State of _____ - SFA/ , Mr/Ms_____,resident and domiciled at _____, bearer of identity no. _____, issued by SSP/__, registered in the CPF/MF as no. _____, under the terms of the delegation of competency granted by Ministerial Ordinance no._, published in the Official Gazette of the Federal Executive-DOU, dated __/__/__, and the Government of the State of ____, by means of_____, headquartered at _____, enrolled in CNPJ/MF as no. _____, hereinafter simply entitled (receiver of responsibility), herein represented by its Director and President _____ _____, a Brazilian citizen, bearer of identity card no. _____ SSP/_, enrolled in the CPF/MF as no. _____, resident and domiciled at _____, by virtue of the powers vested in him/her by the Act of Appointment no. _____ _____, Published in the Official Gazette of the State Government (DOE) no._____, on /_/_, hereby resolve to sign the present STATEMENT OF COMMITMENT, and to obey the dispositions, insofar as is applicable, contained in Decree-Law no. 467 dated 13.02.1969, Decree no. 5,053, enacted 22.04.2004, in compliance with the following Clauses and conditions:

CLAUSE 1 – OBJECTIVE

The present STATEMENT OF COMMITMENT aims to:

I. Transfer the duties that __ (receiver of responsibility)_____in the state of _____, undertakes to comply, through delegation of competence by the Secretariat of Animal and Plant Health of the Ministry of Agriculture, Livestock and Food Supply.

CLAUSE TWO – DUTIES

I - Of___the receiver of responsibility____of the State of _____

a) Within the territory of the State to execute the oversight and inspection of natural and legal entities of public and private law that sell and distribute veterinary products, exercising the activities provided for in the relevant legislation;

b) To seize, in the event of failure to comply with the relevant legislation, veterinary products;

c) To forward to the SFA of the State those lawsuits for violation so that cases may proceed to judgment.

d) To ban, for failure to comply with the relevant legislation, those public or private establishments that sell and distribute veterinary products;

e) To promote the control of stocks and sales of vaccines in establishments selling and distributing veterinary products in compliance with the provisions of relevant legislation.

f) To prepare a report on activities it has executed and present it periodically to the Ministry of Agriculture, Livestock and Food Supply;

g) To open case files of the registration of establishments that sell and distribute veterinary products, in compliance with the relevant legislation, sending them to the SFA in the state, for the purposes of registration in the Integrated Registration System for Products and Establishments.

h) To apply the penalties determined by MAPA after conclusion of the judgment.

II - The Ministry of Agriculture, Livestock and Food Supply:

a) To provide guidance, oversight and inspection of the activities assumed;

b) To register establishments selling and distributing veterinary products in accordance with relevant legislation, and notify the State-level Agriculture and Animal Health Service.

c) To train technical personnel in order to enhance performance of those decentralized activities that are the subject of the present Undertaking;

d) To ascribe to the Federal Superintendent's Office of Agriculture in the State of ____– SFA/ ,

the functions of supervising the execution of the actions resulting from the present Statement of Commitment, namely strategic consulting and performance of technical audits.

e) To hear cases and hand down penalties in the first instance.

CLAUSE THREE – TERM OF VALIDITY

The term of validity of the present Statement of Commitment shall commence as of the date of its publication in the Official Gazette, for a period of

__ months which may be extended for equal successive periods if the Parties are interested.

CLAUSE FOUR – PUBLICATION

The Ministry will publish a summary of this Statement of Commitment in the Official Gazette of the Federal Executive by the 5th (fifth) working day of the month following its signing, so that publication may take place within 20 (twenty) days of such signing.

CLAUSE FIVE – COURTS OF COMPETENT JURISDICTION

To address any issues arising from the present Statement of Commitment that cannot be solved by administrative mediation, the parties choose the venue of the Federal Justice System in the city of Brasilia, Federal District, by virtue of Article 109 of the Federal Constitution.

....., ... of .. 201_

Federal Agriculture Superintendent's Office SFA/____

State Authority Institution

Witnesses:

_____

Signature
Name: Identity:
CPF (taxpayer's ID):

_____

Signature
Name: Identity:
CPF (taxpayer's ID):

APPENDIX 2

GENERAL INFORMATION ON THE INSPECTION OF VETERINARY PRODUCT STORES

According to the provisions in Article 25 of Decree 5,053, *products for veterinary use are all chemical, biological, biotechnological products or manufactured preparations that may be administered individually or collectively, directly or mixed with feed to prevent, diagnose, cure or treat animal diseases. This includes additives, supplements, promotants, animal production enhancers, antiseptic products, disinfectants for the environment or for livestock equipment and facilities, pesticides and all types of products that, used in animals or in their habitats, will protect, restore or modify their organic or physiological functions, and those products for animal hygiene and grooming.* Of these products under consideration, those that need to be conserved under refrigeration deserve special attention from the Official Veterinary Service, as is the case with most biologicals (e.g. vaccines, sera, antigens, allergens). The following are considered pharmaceutical products: antimicrobials (antibiotics, sulfas, quinolones and disinfectants), antiparasitics (anthelmintics, coccidiostats, ectoparasiticides, insecticides, etc.), hormones, vitamins, anesthetics, antiinflammatories and hygiene and beauty products.

In order to carry out the inspection activities, the legislation in force defines the following prerogatives for inspection personnel (Article 80, Decree 5,052):

a) free access to places where processing, trade, transportation occur, or any place where there may be veterinary products;

b) authorization to take samples, if necessary, for quality control;

c) to make routine inspection visits;

d) to verify the provenance and conditions of products displayed for sale;

e) to partially or totally block the establishments, and draft the appropriate blocking document;

f) Render products unusable when the appeals have come to an end, of when the appealing time has expired;

SUCH RENDERING UNUSABLE WILL ONLY TAKE PLACE WHEN JUDGMENT OF THE DEFENDANT'S APPEAL IS COMPLETED IN THE HIGHER INSTANCE.

g) to write a Notification of Violation or of Seizure of the product to initiate the administrative proceedings established in the relevant legislation

If irregularities are found, the inspection procedures and the respective enforcement of penalties must comply with the provisions in Articles 89, 92 (Paragraphs 1 and 2), 104 and 105

It is to be remembered that:

• Officials in the course of their duties must show their professional ID when requested to identify themselves,

• If anyone refuses to collaborate or hinders the action of the inspection personnel, or prevents their access to the areas where there are veterinary products or the processing, fractionating or sale or such is performed, the officials may request "assistance of the police to ensure the inspection process, regardless of the sanctions laid down" in the legislation in force (Article 81 of Decree 5,053).

• A product may only be sold or displayed for sale (Article 65, Decree no. 5,053) if/when it:

I - Is registered;

II - Is intact, not tampered with, broken or corroded and kept in the original packaging from manufacturing;

III - Is kept at a suitable temperature for conservation; IV - It is within its use-by date;

V - Is labeled with an approved text, without crossings-out or changes, and undamaged;

VI - Its physical-chemical characteristics are maintained;

VII - Has the number of package inserts (IFUs) corresponding to the number of units of the product; in the case of FMD vaccine, inserts do not accompany the bottles, given that they are label-inserts, and

VIII - Meets, when so specified on the label, the requirement for veterinary prescription for use.

It is important for all inspection activities to be properly recorded, otherwise they cannot be evaluated or audited, and the entire service will lose its value. Therefore, **the veterinary services in the states must prepare specific forms to record the inspection activities at the retailers of veterinary products.**

Several actions may be taken during the inspection work such as blocking of the establishment, seizure and rendering products unusable, warning, etc. The professionals must have the registration documents for the inspection actions such as: Written Warning of Violation; Amendment Statement; Seizure Document; Release Document; Condemnation Statement; Statement of Rendering Unusable; Banning Document; Fine Notification; Sample-Taking Statement; Depositary Form; Expert Opinion and Notification Notice, and a copy of Decree no. 5,053 in its entirety.

Articles 71 through 78 of said Decree explain the use of those documents. It must be highlighted that it is critical for the documents to be completed correctly, given that errors in completing the documents may result in the annulment of the case file, and lead to a damaged image and loss of prestige for the official veterinary service.

APPENDIX 3

COMMITMENT DECLARATION

COMMITMENT DECLARATION TEMPLATE

We hereby DECLARE that we are aware of the legislation governing the commerce in veterinary products, particularly regarding the vaccination against foot-and-mouth disease, and we are aware of the duties and penalties therein. I further declare that I commit to:

a) Notifying the local unit of the Official Veterinary Service when receiving FMD vaccine, so that upon unloading, the preservation conditions of the vaccine may be inspected;

b) Delivering the vaccine to consumers within the standards demanded by the legislation and in accordance with the period in the official calendar laid down for the State, only in thermal boxes and packed in enough ice (2/3 of the box) so that optimal conditions of preservation may be ensured all the way through to its destination;

c) Issuing all the documentation defined by the Official Veterinary Service to control the sale of FMD vaccine;

d) Facilitating inspection by the Official Veterinary Service;

e) Keeping the entry and exit of the vaccination against foot-and-mouth disease on the forms established by the official service; and

f) Notifying the Local Official Veterinary Service unit if there has been a failure in the refrigerator or thermometer that may result in any damage to preservation or checking of the preservation temperature of biological products.

In witness of the truth,

I sign this document,

_____

Name and signature of the individual responsible for the company

_____

Name and signature of the individual responsible for the sale

APPENDIX 4

TEMPERATURE DEMONSTRATION;

Local Veterinary Unit:	Regional unit:	
Name of Establishment:	Registration in MAPA	
Municipality where located:	Identification of the refrigerator:	Month & Year:

DATE	TIME	TEMPERATURE			Name and Initial of the individual responsible for the reading	Observation
		MAX	MIN	CURRENT		

N.B.

1. **The temperature must be recorded in the morning and in the afternoon during FMD vaccination stages.**
2. **Reset the thermometer to zero: TO BE PERFORMED BY THE OFFICIALS OF THE OFFICIAL VETERINARY SERVICE.**
3. **Use one Demonstration label per refrigerator.**

APPENDIX 5

FORM FOR COMPLETION OF THE FMD VACCINATION STAGE

States must send their standardized forms for the completion of vaccination stages to SFA within 30 of completion of the vaccination stage[2].

If the SVS does not possess the standardized form, it must ask SFA for the template. Data sent in on the wrong form of template will not be consolidated or analyzed by DIFA.

The standard file has eight tabs entitled as follows:

1. Instructions,
2. Initial information,
3. Result of Vaccination,
4. Age range of the cattle,
5. Age range of the buffaloes,
6. Tests with foot-and-mouth disease vaccine,
7. Other species and
8. Requests, Remarks and Justifications.

Should you have questions about how to complete this file, after having read the instructions, please send an e-mail to pnefa@agricultura.gov.br .

[2] **Up to 30 days after the official period of the vaccination stage are considered; not up to 30 days after the end of the period of declaration of vaccination.**

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