**MONTENEGRO’S STRATEGY FOR**

**TRANSPOSITION AND IMPLEMENTATION OF THE EU ACQUIS RELEVANT**

**FOR CHAPTER 12 – FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY INCLUDING A GENERAL ACTION PLAN AND A SPECIFIC ACTION PLAN FOR CONTROL AND ERADICATION OF CLASSICAL SWINE FEVER**

July 2015

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# LIST OF ACRONYMS

|  |  |
| --- | --- |
| EU | European Union |
| EC | European Commission |
| BIPs | Border Inspection Post |
| OG MN | Official Gazette of Montenegro |
| GMOs | Genetically Modified Organisms |
| IPA | Instrument for Pre-accession Assistance |
| MIDAS | Montenegro Institutional Development and Agriculture Strengthening |
| FVO | Food and Veterinary Office |
| TRACES | TRAde Control and Expert System |
| ADNS | Animal Disease Notification System |
| HACCP | Hazard analysis and critical control points |
| NGO | Non Governmental Organizations |
| BTSF | Better Training for Safer Food |
| TAIEX | Technical Assistance and Information Exchange instrument of the European Commission |
| DVL | Diagnostic Veterinary Laboratory |
| ISO | International Organization for Standardization |
| CETI | Centre for Ecotoxicological Research |
| IPH | Institute of Public Health |
| EPPO | European and Mediterranean Plant Protection Organization |
| IPARD | Instrument for Pre-Accession Assistance for Rural Development |

# 

# INTRODUCTION

The present document has been prepared in the framework of the preparation for EU accession and in line with opening benchmark 2 for Chapter 12 of the negotiations of Accession to fulfil this benchmark.

*BENCHMARK 2:*

*Montenegro presents to the Commission a comprehensive national strategy, including an action plan, which will serve as a basis for transposition, implementation and enforcement of the EU acquis for food safety, veterinary and phytosanitary policy, including plans for the development of the relevant administrative capacities and an estimation of the financial resources required. Particular attention should be given to a detailed action plan as regards the control and eradication of Classical Swine Fever for domestic pigs and wild boars after vaccination is discontinued.*

This document has been prepared by the relevant services: the Veterinary administration, the Phytosanitary administration, and the Working Group on Chapter 12. It is coordinated by the Ministry of Agriculture and Rural Development. It will be presented by the Minister of Agriculture and Rural Development and approved by the Government on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

In line with the Programme for accession to the EU, transposition is planned in the period between 2014 until the end of 2018, while finalisation of the measures necessary for implementation is planned for the period from 2019 until the end of 2020.

This document is structured in accordance with the benchmark and its first part concerns harmonisation of Montenegrin legislation with the EU Acquis in this area, the second part covers implementation, the third part reinforcement of administrative capacity and the fourth an estimation of the financial resources needed. The first annex is dedicated to a general action plan which provides the state of affairs with the dates for transposition and implementation. The second annex details the action plan as regards the control and eradication of Classical Swine Fever for domestic pigs and wild boars after vaccination is discontinued.

The general action plan will be updated regularly at least once a year to take account of the new EU acquis and new national legislation and progress achieved in the adoption of measures for implementation.

# I TRANSPOSITION

The Parliament of Montenegro adopts laws (primary/framework legislation) in accordance with the Constitution of Montenegro and the legal system, based on proposal of the Government of Montenegro, members of Parliament or 6,000 voters via members of Parliament.

Secondary Legislation is adopted by the Government of Montenegro and Ministries.

The Government of Montenegro is in charge of adoption of decrees and decisions, conclusions, plans and other general and specific legal acts, at proposal of the competent Ministries.

Ministries are in charge of adoption of rulebooks, orders and instructions for implementation of laws and other pieces of legislation for performing the activities under their authority.

Publishing in the Official Gazette of Montenegro – a piece of legislation usually enters into force on the 8th day from the day of its publishing in the Official Gazette.

In general, each act of secondary legislation is based on framework legislation.

The new framework legislation contains provisions enabling the Ministry to adopt the necessary secondary legislation. The adoption and preparation of secondary legislation is not a condition for the entry into the force of framework legislation.

In addition to the formal transposition of the EU acquis, its implementation requests adoption by the administration (competent services) of numerous measures of enforcement. It is also the case for the EU acquis which will have direct effect on the day of accession. This aspect is taken into consideration in the general Action Plan (see Annex) under the column implementation. The activities of the Administration are based on the Law of State Administration.

After accession to the European Union, Montenegro will apply directly the rules on imports from third countries (lists of: approved states, states with approved residue control plan, approved teams for semen collection, approved centres for collecting of bovine semen, approved centres for keeping of bovine semen, approved centres for collecting of pig semen, approved centres for collecting of equine semen, competent authorities, food and animal byproducts establishments and certificate form). Montenegro has to ensure that inspectors in BIPs are authorised to directly apply such conditions (without national legislation transposing EU acquis).

Safeguard measures will be adopted by the Ministry of Agriculture and Rural Development in the forms of orders and published according to urgency procedures. As regards the current safeguard measures in place in the Union for the intra-community trade and for imports from the third countries Montenegro will adopt progressively these measures. In any case, six months before the accession, Montenegro committed to adopt the measures which will be in force at that time.

In this context the safeguard measures adopted at the level of the Union are not mentioned individually in the General Action Plan.

## A. FRAMEWORK LEGISLATION

At the present time the situation as follows

FOOD SAFETY:

* Law on Food Safety (OG MN 14/2007);

VETERINARY POLICY:

* Veterinary Law (OG MN 30/2012);
* Law on Animal Welfare (OG MN 14/2008);
* Law on Animal Identification and Registration (OG MN 48/2007);
* Law on Livestock Breeding (OG MN 72/2010);

PHYTOSANITARY POLICY:

* Law on Plant Health Protection (OG MN 28/2006 and 28/2011);
* Law on Plant Protection Products (OG MN 51/2008 and 18/2014);
* Law on Seed Material of Agricultural Plants (OG MN 28/2006 and 61/2011);
* Law on Planting Material (OG MN 28/2006 and 61/2011);
* Law on Reproductive Material of Forest Trees (OG MN 37/2007);
* Law on Protection of Plant Varieties (OG MN 48/2007 and 48/2008);

GMOs:

* Law on Genetically Modified Organisms (OG MN 22/08);

New Law on food safety is planned; the draft is prepared and currently in Government procedure. Its adoption by Parliament is expected by the end of 2015.

As regards amendments to the Framework Legislation the current situation is following:

|  |  |  |
| --- | --- | --- |
| (1) | Veterinary Law | In Parliament |
|  |  |  |
| (2) | Law on Animal Welfare | In Parliament |
|  |  |  |
| (3) | Law of Registration and Identification of Animals | In Parliament |
| (4) | Law of Livestock production | In Parliament |
| (5) | Law on Plant Health Protection | In Parliament |
|  |  |  |
| (6) | Law on Seeds Material | In Parliament |
| (7) | Law on Planting Material | In Parliament |
| (8) | Law on Forest Reproductive Material | In Government procedure |
|  |  |  |

All amendments are expected to be adopted before the end of 2015.

Montenegro deems that with the adoption of amendments to existing laws and the new Law on Food Safety the necessary legal basis for transposition of all EU acquis will be in place.

It is expected that before the end of 2015, the necessary framework legislation will be in force. In this context references can be made to Benchmark 1.

***BENCHMARK 1:***

***Montenegro adopts the new framework legislation complying with the Acquis, and makes provisions for a clear assignment of responsibilities, in particular for control bodies.***

## B. SECONDARY LEGISLATION

The Ministry of Agriculture and Rural Development will be in charge of preparation and adoption of secondary legislation relevant for Chapter 12 of EU acquis. It must be noted that for the sector of genetically modified organisms the competencies are shared with the Ministry of Health and the Ministry of Sustainable Development and Tourism. Until the adoption of the new Food Safety Law the competencies is shared between Ministry of Agriculture and Rural Development and Ministry of Health.

Adoptions of measures of executions belong to different services. See II Implementation.

# II IMPLEMENTATION

Montenegro will ensure gradual implementation of the EU Acquis. The date of its implementation prior to Montenegro’s accession to the EU is specified for each piece of legislation. However, application of certain provisions can only begin on the day of Montenegro’s accession to the EU, which is specified in each separate piece of legislation (See Annex General Action Plan).

## A. FOOD SAFETY

This Strategy document is based on the draft of new Food Safety Law, currently in discussion in Government. The main change is designation of the competent authority and the reorganisation of the services in charge of enforcement. The new law will give competence to the Ministry of Agriculture and Rural Development and provide for establishing of the new administration: Administration for Food Safety, Veterinary and Phytosanitary Affairs.

Establishing this new Administration will put in place a more efficient system with clearly defined competencies and responsibilities, simplification of the chain of command, better coordination and communication and facilitation of the training of employees.

This reorganization will contribute to better implementation of EU acquis.

## B. VETERINARY POLICY

The Ministry of Agriculture and Rural Development is in charge of adoption of secondary legislation. The new administration: Administration for Food Safety, Veterinary and Phytosanitary Affairs will be in charge of enforcement.

### 1. CONTROL SYSTEM IN INTERNAL MARKET

In the context of implementation, one of the main tasks is setting up the registers in compliance with the Council Directive 90/425/EEC and Council Directive 89/662/EEC. Implementation of this task is underway and it is planned to be finished by the end of 2018. Safeguard measures will be adopted by the Ministry of Agriculture and Rural Development in the forms of orders and published by urgent procedures.

### 2. CONTROL SYSTEMS FOR IMPORTS

As regards implementation, the main task is setting up of an efficient system of border inspection posts (BIPs).

Montenegro preselected seven posts to be proposed as permanent Border Inspection Posts (BIPs) for veterinary checks:

1) Dobrakovo – Serbia: road border crossing;

2) Bijelo Polje – Serbia: rail border crossing;

3) Ilino brdo - Bosnia and Herzegovina: road border crossing;

4) Kula – Kosovo: road border crossing;

5) Božaj – Albania: road border crossing;

6) Bar – sea port;

7) Podgorica – airport;

Montenegro submitted requests for IPA financing for 2 BIPs: airport and road crossing with Bosnia and Herzegovina.

Currently, BIP Port of Bar is being constructed under the World Bank MIDAS, which will provide the facilities and equipment for the needs of the border inspection.

Construction or reconstruction of BIPs is planned in accordance with the requirements as laid down by the EU legislation.

The plans for construction or reconstruction of selected BIPs will be presented to FVO for approval.

Furthermore, full informatisation and networking of all BIPs in Montenegro is planned by 2018, in order to achieve more efficient implementation of controls as well as to establish internet connection in BIPs, which will make easier the procedures of border veterinary inspectors and other inspectors and harmonize them with the EU procedures.

The control of non-commercial movement of pets will be carried out by the administration authority in charge of customs affairs.

Training of border inspectors is ongoing.

Safeguard measures will be adopted by the Ministry of Agriculture and Rural Development in the forms of orders and published by urgent procedures.

### 3. TRACES INFORMATIC SYSTEM

Preparatory work is ongoing. Veterinary and phytosanitary inspectors attended the trainings. After completion of the preparatory work, Montenegro will ask the European Commission to use the TRACES system in the period prior to accession to the EU.

### 4. IDENTIFICATION AND REGISTRATION OF ANIMALS AND REGISTRATION OF THEIR MOVEMENTS

**a. Bovine animals**

Identification of bovine animals and registration of their movements has been implemented since 2007. Montenegro deems that the system is fully compliant and the database operational. The process of identification and registration of bovine animals was implemented with IPA financial assistance.

**b. Porcine animals**

The campaigns of registration of holdings and identification and registration of pigs have started in 2015. The process of identification and registration of pigs is implemented with support from IPA financial assistance. Montenegro deems that the system will be compliant at the end of 2015.

**c. Ovine/Caprine animals**

Identification of ovine/caprine animals and registration of its movement has been implemented since 2011. Montenegro deems that the system is fully compliant. The process of identification and registration of ovine/caprine animals was implemented with IPA financial assistance.

**d. Equine animals**

The introduction of a compliant system is planned for 2018.

### 5. CONTROL MEASURES FOR ANIMAL DISEASES

#### A. Foot and Mouth Disease

Contingency Plan is in preparation and will be adopted by the end of 2015 and submitted to the European Commission. This activity received IPA financial assistance.

#### B. Classical Swine Fever

Specific Action Plan has been requested (see V Action Plan for Control and Eradication of Classical Swine Fever in domestic pigs and wild boars in Montenegro, after discontinuation of vaccination).

#### C. African Swine Fever

The implementation of the rules is planned for the second half of 2017.

#### D. African Horse Sickness

The implementation of the rules is planned for the second half of 2017.

#### E. Avian Influenza

Contingency Plan is in preparation and will be submitted to the European Commission by the end of 2016.

#### F. Newcastle Disease

Contingency Plan is in preparation and will be submitted to the European Commission by the end of 2016.

#### G. Fish and Mollusc diseases

The rules are partially implemented and full implementation is planned at the day of accession.

#### H. Bluetongue disease

The rules are partially implemented and full implementation is planned at the day of accession.

#### I. Transmissible Spongiform Encephalopathies

The rules are partially implemented and full implementation is planned at the day of accession.

#### J. Zoonoses

The rules are partially implemented and full implementation is planned at the day of accession.

This activity received IPA financial assistance.

#### K. Other Diseases

The implementation of the rules is planned for the second half of 2017.

#### L. Notification of diseases

Montenegro has joined ADNS System on voluntary basis.

### 6. NON COMMERCIAL MOVEMENT OF PET ANIMALS

System compliant with EU acquis is planned for the end of 2016. A “Passport” fully compliant with EU “Passport” will be issued.

### 7. PROHIBITION OF SUBSTANCES AND CONTROL OF RESIDUES

#### A. Prohibition of substances

Rules on prohibition of substances have been implemented since 2013. Montenegro deems that the regime is compliant with EU acquis.

#### B. Residues Controls

Montenegro implements a plan partially compliant with EU. Full compliance is planned for 2020.

### 8. ANIMAL WELFARE

#### A. Farm animals

Rules are partially implemented (general, laying hens, chickens kept for meat production, calves, pigs). Full implementation is planned for the end of 2017. Problems occur in implementing rules, in particular for laying hens.

#### B. Animals during transport

Full implementation is planned for the end of 2018.

#### C. Animals for slaughtering

Full implementation is planned for the end of 2015.

### 9. ZOOTECHNICS

#### A. Bovine, porcine, ovine/caprine animals

Full implementation is planned for the end of 2018. The keeping of herd books is the responsibility of the Livestock Selection Service (service of the Ministry of Agriculture and Rural Development).

#### B. Equidae, equidae intended for competition and other purebred animals

Montenegro has intention to adopt rules compliant with EU acquis. However, the number of animals concerned is very limited.

## C. PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS

### 1. Hygiene rules, Specific rules for animal products; Control rules; Specific control rules for animal products; Rules for by-products

In Montenegro 172 establishments need to be approved in line with the EU legislation (meat, meat products, milk, milk products, fish, eggs, egg products, aquaculture products and by-products), while the number of establishments subject to the obligation of registration according EU legislation is significantly lower (58).

For establishments already registered, the assessment of their compliance with the general EU hygiene rules had been made and finished in December 2014 (Regulation (EC) No.852/2004). Twelve establishments are compliant and 46 are non compliant. The main problem is fulfilment of HACCP rules. Montenegro expects that corrective measures will be sufficient to reach full EU compliance.

For approved establishments, process of individual assessment of compliance has been achieved.

Based on assessments and future individual upgrade plans, the national programme for upgrade of food establishments will be developed. In this context reference has to be made to Benchmark 3.

Montenegro presents to the Commission a classification of all food establishments and all establishments handling animal by-products based on the acquis which will serve as a basis for a future National Program for the upgrading of food and animal by-products establishments.

### 2. Funding of checks

Montenegro has in place a system of fees. Its full compliance with EU acquis is under assessment which is planned by the end of 2017.

### 3. Specific rules for feed hygiene

At the present time Montenegro has no feed establishments.

## D. FOOD SAFETY RULES

### 1. Labelling presentation and advertising of foodstuffs including nutrition and health claims and nutritional labelling

Fully compliant system will be in place by the end of 2017.

### 2. Additives authorised and purity criteria

Fully compliant system will be in place by the end of 2016.

### 3. Food enzymes

Fully compliant system will be in place by the end of 2017.

### 4. Extraction solvents

Fully compliant system will be in place by the end of 2017.

### 5. Flavourings

Fully compliant system will be in place by the end of 2016.

### 6. Food contact materials

Fully compliant system will be in place by the end of 2016.

### 7. Food supplements

Fully compliant system will be in place by the end of 2016.

### 8. Food for particular nutritional uses

Fully compliant system will be in place by the end of 2017.

### 9. Quick frozen foodstuffs

Fully compliant system will be in place by the end of 2018.

### 10. Contaminants

Fully compliant system will be in place by the end of 2016.

### 11. Novel foods

Fully compliant system will be in place by the end of 2018.

### 12. Ionising radiation

Fully compliant system will be in place by the end of 2018.

### 13. Mineral waters

Compliant system has been partly in place since March 2015. Fully compliant system will be in place by the end of 2017.

## E. SPECIFIC RULES FOR FEED

### 1. Placing on the market and use of feed

Fully compliant system will be in place by the end of 2016.

### 2. Feed Additives

Fully compliant system will be in place by the end of 2017.

### 3. Undesirable substances

Fully compliant system will be in place by the end of 2017.

### 4. Medicated Feed

Fully compliant system will be in place by the end of 2017.

## F. PHYTOSANITARY

### 1. Plant Health – Harmful Organisms

#### a. General control measures

Partially implemented. Fully compliant system will be in place by the end of 2018.

#### b. Specific control measures

Fully compliant system will be in place by the end of 2017.

#### c. Protected zones

Fully compliant system will be in place by the end of 2016.

#### d. Registration of operators - Plant passports

The Phytosanitary Administration has established the phytosanitary register of producers, processors, importers and distributors of certain plants, plant products and other objects under supervision.

The total of 487 entities entitled to using the MNE number has been entered in the register by July 1, 2015.

Thus, the first step has been completed – preconditions for setting up the system of plant passports in Montenegro have been met, implementing the obligation as laid down by Article 6 of the Directive 2000/29 and 92/90 and 93/50.

The plan is to begin the setting up of the system of plant passports with support from the IPA Project, implementation of which has started in 2015.

The strategy for setting up the plant passport system:

* in 2015, setting up the system of plant passports for citrus fruits/seed potato (pilot project);
* in 2016, setting up the system of plant passports for planting material of grape wine;
* in 2017, setting up the system of plant passports for planting material of and fruit species;
* in 2018, setting up the system of plant passports for planting material of ornamental plants, forest reproduction material and planting material of vegetables and flowers, etc.

#### e. Import from third countries and Inspections and notification of interception and derogation

After accession to the European Union, Montenegro will directly apply the rules on imports from third countries. Montenegro has to ensure that inspectors at phytosanitary border points are authorised to directly apply such conditions (without national legislation transposing EU acquis).

The control of goods subject to phytosanitary checks will be done at the same points as veterinary border inspection posts, and additionally at the Main Post Office of Podgorica:

1) Dobrakovo – Serbia: road border crossing;

2) Bijelo Polje – Serbia: rail border crossing;

3) Ilino brdo - Bosnia and Herzegovina: road border crossing;

4) Kula – Kosovo: road border crossing;

5) Božaj – Albania: road border crossing;

6) Bar – sea port;

7) Podgorica – airport;

8) Podgorica – post office.

### 2. Plant Health – Plant Protection Products

#### a. Placing on the market

Partially implemented and full implementation will be achieved on the day of accession.

#### b. Pesticide residues

Fully compliant system is in place since March 2015.

### 3. Quality of Seeds and Propagating Material

EU Rules will be progressively implemented. The end of this exercise is planned for the end of 2018.

### 4. Plant Variety Rights

Fully compliant system will be in place on the day of accession.

## G. GENETICALLY MODIFIED ORGANISMS

### 1. Release into the environment

Partial implementation is possible. Fully compliant system will be in place on the day of accession.

### 2. Genetically modified food and feed

Partial implementation is possible. Fully compliant system will be in place on the day of accession.

# III. DEVELOPMENT OF THE ADMINISTRATIVE CAPACITIES

## A. ORGANISATION

Reorganisation of the existing system is planned. The Project has been submitted to the Government. Its full finalisation is linked to the adoption of the new Food Safety Law. The existing administrations (Veterinary and Phytosanitary Administrations) under the Ministry of Agriculture and Rural Development, as well as the Sector for Food Safety of the Ministry of Health will merge into a single administration: the Administration for Food Safety, Veterinary and Phytosanitary Affairs.

This new Administration will be a part of the Ministry of Agriculture and Rural Development.

Benefits from the new organisation are:

* responsibility located in a single place;
* simplified and faster administrative procedures;
* reduction in number of public bodies;
* cost-effective use of human, material and financial resources;
* increased efficiency in the administrations ’work’;
* a single contact point for EC is set up;
* setting up an independent unit for conducting internal audit;
* available administrative services of public bodies in a single place for business entities, natural persons, NGOs, media and citizens in general.

The issue of organisation of official controls (inspection) is under the discussion.

Montenegro will inform the European Commission on all changes in organisation.

## 

## B. TRAINING

1. Training of public employees is governed by the Law on Public Employees and Servants, published in the Official Gazette of Montenegro 39/2011 and 50/2011, as well as by the laws governing specific areas. Training is considered a part of obligations of public employees and servants, while heads of public bodies are obliged to provide training for employees. The costs of training in public bodies are covered from the budget of Montenegro.

Human Resources Management Authority is the competent authority for organisation and delivery of training for public employees and it adopts the plan of training for public employees for the following calendar year, with the training curricula specified, as well as deadlines for their delivery.

There are also programs for further development of skills intended for employees that have been covering a particular post for a longer period of time and these include negotiation skills, negotiations in the EU, presentation skills, etc.

As a part of the activities undertaken under the association process, other public bodies also organise and deliver training for public employees, such as the Ministry of Foreign Affairs and European Integrations on topics of EU integrations, the Ministry of Finance organizes special programmes and workshops on EU funds management.

Foreign languages courses and computer skills courses are organised as well.

2. In view of accession of Montenegro to European Union, specific trainings are foreseen.

With the assistance of TAIEX specific training plans are adopted each year. All the aspects of EU acquis are covered. Particular attention is given to the functioning of EU systems (BIPs, TRACES, etc).

Practical training courses are organised under the programme Better Training for Safer Food (BTSF).

In addition, trainings are included in IPA Projects.

World Bank MIDAS project also includes target trainings through seminars, workshops, roundtables, etc.

## C. HUMAN RESOURCES

### 1. Current situation

Veterinary Administration (Ministry of Agriculture and Rural Development):

* Food Safety Sector – 3 veterinarians and 1 technician;
* Veterinary Sector – 4 veterinarians, 2 livestock agronomist and 2 technicians;

Phytosanitary Administration (Ministry of Agriculture and Rural Development):

* Food Safety Sector and Plant Protection Products – 2 agronomists;
* Phytosanitary Sector – 5 agronomists;

Food Safety Department (Ministry of Health):

* 2 officials;

Livestock breeding Department (Ministry of Agriculture and Rural Development):

* 3 officials;

Veterinary Inspectorate (Administration for Inspection Affairs):

* 19 officials;

Sanitary Inspectorate (Administration for Inspection Affairs):

* 33 officials;

Phytosanitary Inspectorate (Administration for Inspection Affairs:

* 16 officials;

Agricultural Inspectorate (Administration for Inspection Affairs):

* 10 officials;

Livestock Selection Services (Ministry of Agriculture and Rural Development):

* 23 officials.

### 2. Reinforcement

According to the plans, creation of 15 new posts in the Veterinary Administration is planned. For Phytosanitary Administration, creation of 10 new posts it is planned. The job descriptions of these new posts will be flagged on transposition and implementation of EU acquis.

## D. LABORATORY

Montenegro is undertaking activities necessary for accreditation of laboratories in line with the European legislation. The accreditation of methods will be done, at the latest, on the day of Montenegro’s accession to the EU; otherwise, Montenegro will undertake measures necessary to have such analyses performed in accredited laboratories of the EU.

As regards of National Reference Laboratories, Montenegro at present time has not yet designated National Reference Laboratories. Montenegro will undertake this task and plan to finish the assesment by the end of 2016. In the case where no National Laboratories offer sufficient capacities, Montenegro commits to negotiate contract with References Laboratories located in member states.

### 1. ANIMAL HEALTH

Public Institution Diagnostic Veterinary Laboratory (DVL) has officially begun its activities on 1 March 2005, on the basis of the Decision on establishing of the Public Institution Diagnostic Veterinary Laboratory (Official Gazette of the Republic of Montenegro 68/04) adopted by the Government of the Republic of Montenegro in October 2004. The Laboratory performs its activities in its own business premises in Podgorica, under the supervision of the Ministry of Agriculture and Rural Development.

Diagnostic Veterinary Laboratory is accredited laboratory (ISO 17025:2011)

The Veterinary Laboratory has accredited methods for: Bluetongue, Brucellosis, Enzootic Bovine Leucosis, Classical Swine fever and Rabies.

### 2. FOOD LABORATORIES

Analyses of food samples are done by the Public Health Institute, the Centre for Ecotoxicological Researches, Veterinary Diagnostic Laboratory (DVL).

**a.Institute of Public Health** – IPH is accredited laboratory (ISO 17025:2011) and has accredited 40 methods, most of which are microbiological analyses.

**b. Veterinary Diagnostic Laboratory** (DVL) is accredited laboratory (ISO 17025:2011)

The Veterinary Laboratory has accredited methods for: Salmonella, Listeria, Enterobacteria, Escherichia Coli, Staphylococcus, Streptococcus and Trichinella.

### 3. RESIDUES AND CONTAMINANTS

Analyses of residues for the Programme of Residue Monitoring in line with the annual authorisation is done by the Centre for Eco-toxicological Researches of Montenegro – CETI. The programme is approved by EU for most commodities with the exception of equine, milk, rabbit and wild game. In addition, CETI is competent for the analysis of contaminants and residues of pesticides. It currently has 30 accredited methods.

### 4. FEED LABORATORY

Laboratory analyses of safety of feed are performed by the Diagnostic Veterinary Laboratory (DVL) and the Centre for Eco-toxicological Researches of Montenegro - CETI. Both laboratories are accredited, as well as a number of methods. Montenegro deems that the laboratories possess the facilities, equipment and staff necessary.

### 5. PHYTOSANITARY LABORATORY

#### PLANT HEALTH

Phytosanitary laboratory is authorised by the Phytosanitary Administration in accordance with the Law on Plant Health Protection for carrying out activities of plant health protection: laboratory examinations of harmful organisms, professional and technical affairs and other activities of public interest in plant health protection. The authorisation defines the activities of public interest and requirements for delegation of public activities performance to the Phytosanitary laboratory. The Phytosanitary Laboratory is authorised for examination of biological efficiency of pesticides, too. The Phytosanitary Laboratory was the beneficiary of IPA financial assistance.

Methods used for diagnostic examinations of harmful organisms for plant and plant products are: methods prescribed by the EU regulations for certain harmful organisms, EPPO methods or the laboratory’s own methods.

### 6. SEED LABORATORY

Laboratory for Seeds is authorised by the Phytosanitary Administration in accordance with the Law on Agricultural Plants Seeds Material for performing activities concerning seeds material: laboratory examinations and seed material quality, technical and professional affairs (certification) and other activities of public interest in this field. The authorisation defines the activities of public interest and conditions for delegating performance of public activities to the Seeds Laboratory. The Laboratory for Seeds is authorised by the Phytosanitary Administration performs certification of agricultural plants seeds material.

The Laboratory for Seeds was the beneficiary of the IPA financial assistance.

The Laboratory for Seeds was the beneficiary of the “SEEDNET” project.

Methods prescribed by national legislation, EU or the laboratory’s own methods are used in examination of agricultural seeds quality.

### 7. GMOs

Montenegro does not have a laboratory for GMOs.

Montenegro will undertake the measures necessary in order to have such analyses performed in accredited laboratories of the EU.

# IV. FINANCIAL RESOURCES

When Montenegro becomes an EU Member State, Montenegro will have the same conditions for co-financing by the EU in the area of food safety, veterinary and phytosanitary issues (Regulation (EU) No. 652/2014 and Regulations (EC) No.1040/2002 and No. 998/2002).

During the pre-accession period, Montenegro can us the EU assistance (IPA) for the food safety, veterinary and phytosanitary area.

Implementation of measures for the preparation of accession imply costs.

Upgrading of agri-food establishments requests investments. A part of these costs will be covered by IPARD and a part by the owner of the establishment. This topic is relevant for Chapter 11.

As regards the area of food safety, veterinary and phytosanitary issues, the main source of expenses for Montenegro will be:

- Building and equipment for Border Inspection Posts and Phytosanitary Border Points;

- Upgrading and development of laboratories (see III LABORATORIES);

- Measures for control and eradication of animal diseases;

- The system of safe disposal of animal by-products.

Human Resources issues will be addressed in more detail separately.

## a. Building and equipment for Border Inspection Posts and Phytosanitary Border Points

The list of pre-selected BIPs and Phytosanitary Border Points has been finalised (see F.1. e. and B.2.).

Montenegro estimated the cost of construction and equipment of compliant BIPs and Phytosanitary Border Points to EUR 7,000,000.

## b. Upgrading and development of laboratories

To cover tasks requested by the EU acquis, laboratories need to be upgraded and new equipment supplied for the development of accredited methods. A part of this task will be assigned to laboratories in the EU, but Montenegro wants to ensure that a part of the control activities are performed in its own system of laboratories.

For veterinary Laboratory the estimated costs are cca EUR 500,000.

For the Phytosanitary Laboratory the estimated costs are EUR 200,000.

For the Institute for Public Health the estimated costs are cca EUR 350,000.

For the Center for Ecotoxicological Researches the estimated costs are cca EUR 300,000.

## c. Measures for control and eradication of animal diseases

Eradication and control of animal diseases is in the interest of both the EU and Montenegro.

Currently, the funds allocated for 2015 amount to EUR 1,200,000. Accession preparations require implementation of additional tasks, in particular as regards qualification of herds (officially free status), regions, the entire country. The additional estimated costs are cca EUR 3,000,000 per year.

## d. Measures for control and eradication of harmful organisms

Eradication and control of harmful organisms is in the interest of both the EU and Montenegro.

Currently, the funds allocated for 2015 amount to EUR 120,000. Accession preparations require implementation of additional tasks, in particular as regards qualification of their status. The additional estimated costs are cca EUR 200,000 per year.

Preparation of national legislation compliant with the EU acquis is an important task. Reinforcement of services is already planned. This issue will be subject to new internal discussion.

# ANNEX I

# I. GENERAL ACTION PLAN

EXPLANATORY NOTE

The first column is for ease of references numbers for each text.

The second column refers to EU Legislation relevant for Chapter 12. Each text is mentioned with its title and EU number. It is based on the list of EU legislation in force on 1st of August 2014.

The third column referes to Montenegrin legislation. Each text already adopted is mentioned with its title and references to the Official Gazzette of Montenegro, and appears in bold characters. The text planned to be adopted, appears in italic characters with provisional title.

The fourth column refers to date of transposition and/or estimated date of transposition. The date appears in bold characters when the text has already been published. The estimated date of publication appears in italics characters when the text has not yet been published.

The fifth column refers to date of implementation and/or estimated date of implementation.

| **No** | **EU legislation / Reference to the**  **EU text** | | **MN legislation published in the Official Gazette of Montenegro or plan to be adopted** | | | **Date of transposition or**  **estimated date of transposition** | **Date of implementation or**  **the estimated date of implementation** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| TITLE 1 – GENERAL | | | | | | | |
| **Chapter 1 Food Law** | | | | | | | |
|  | [**Regulation (EC) No 178/2002**](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety | | * **Law on Food Safety**   **(OG MN 14/2007)**   * *New Law on Food Safety (replace the previous Law)* | | | * **21.12.2007** * *2015* | * **29.12.2007** * **1.01.2010** * **1.01.2011** * *2015* * *Fully implemented at the day of accession* |
|  | [**Commission Regulation (EC) No 2230/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R2230)of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority’s mission | | * *Rules on criteria for competent organization for Risk Analysis* | | | * *2015* | * *2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2004/478/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0478)of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management | | * *General contingency plan for emergency management in the field of food safety / food for animals* | | | * *2015* | * *2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 16/2011**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0016)of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed | | * *Regulations for establishing a system of rapid alert and notification* | | | * *2016* | * *2016* * *Fully implemented at the day of accession* |
| **Chapter 2 Committees** | | | | | | | |
|  | [**Regulation (EC) No 178/2002**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – Articles 58, 59 and 62. | |  | | |  | * *Fully implemented at the day of accession* |
| **Standing Committee on Zootechnics** | | | | | | | |
|  | **Council** [**Decision 1977/505/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31977D0505:EN:NOT) of 25 July 1977 setting up a Standing Committee on Zootechnics | |  | | |  | * *Fully implemented at the day of accession* |
| **Advisory Group** | | | | | | | |
|  | **Commission** [**Decision 2004/613/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0613:EN:NOT) of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health | |  | | |  | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2011/242/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0242:EN:NOT) of 14 April 2011 on the members of the advisory group on the food chain and animal and plant health established by Decision 2004/613/EC | |  | | |  | * *Fully implemented at the day of accession* |
| TITLE 2 VETERINARY | | | | | | | |
| **Chapter 1**  **Control system in the internal market** | | | | | | | |
| **I. Live animals, semen, ova and embryos** | | | | | | | |
|  | **Council** [**Directive 90/425/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31990L0425)of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market | | * *Rulebook concerning veterinary and zootechnical checks applicable in trade in certain live animals and products with a view to the completion of the internal market* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 93/444/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31993D0444)of 2 July 1993 on detailed rules governing intra-Community trade in certain live animalsand products intended for exportation to third countries | | * *Rulebook about detailed rules governing intra-Community trade in certain live animals and products intended for exportation to third countries* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 94/338/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994D0338)of 25 May 1994 laying down detailed rules for the application of Council Directive 90/425/EEC as regards the taking of samples for the purpose of veterinary inspections at the place of destination | | * *Rulebook concerning detailed rules for taking of samples for the purpose of veterinary inspections at the place of destination* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994D0339"94/339/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994D0339)of 25 May 1994 laying down detailed rules for the application of Article 9.1 of Council Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market | | * *Rulebook concerning veterinary and zoo technical checks applicable in intra-Community trade in certain live animals and products* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 599/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0599)of 30 March 2004 concerning the adoption of a harmonized model certificate and inspection report linked to intra-Community trade in animals and products of animal origin | | * *Rulebook about harmonized model certificate and inspection report* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
| **II. Animal Products** | | | | | | | |
|  | **Council** [**Directive 89/662/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31989L0662)of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market | | * *Rulebook concerning veterinary checks* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
| **III. Certification** | | | | | | | |
|  | **Council** [**Directive 96/93/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31996L0093)of 17 December 1996 on the certification of animals and animal products | | * **Veterinary Law**   **(OG MN 30/2012)**   * **Rulebook about certificates for animals and products of animal origin (OG MN 8/15)** | | | * **06.2012** * **03.2015** | * **06.2012** * **03.2015** |
|  | **Council** [**Directive 2002/99/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002L0099)of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption | | * *Rulebook on animal health conditions applicable to the production, processing and marketing of products of animal origin intended* *for human consumption* | | | * *IV.2015* | * *IV.2015* |
| **IV. Mutual Assistance** | | | | | | | |
|  | **Council** [**Directive 89/60HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31989L0608"8HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31989L0608"/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31989L0608)of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zoo technical matters | | * *Rulebooks about assistance between the administrative authorities and cooperation between the latter and to ensure the correct application of legislation on veterinary and zoo technical matters* | | | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
| **V. Computer Systems TRACES** | | | | | | | |
|  | **Commission** [**Decision 91/637/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31991D0637)of 3 December 1991 establishing the model for the message to be transmitted by means of the computerized network Animo | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 92/176/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31992D0176)of 2 March 1992 concerning maps to be provided for use for the Animo network | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31993D0070"93/70/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31993D0070)of 21 December 1992 on codification for the message 'Animo' | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2003/24/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003D0024)of 30 December 2002 concerning the development of an integrated computerized veterinary system | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2003/623/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003D0623)of 19 August 2003 concerning the development of an integrated computerized veterinary system known as Traces | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2004/292/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0292)of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2004/675/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0675)of 29 September 2004 establishing logistical support for the Traces system | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2009/821/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009D0821)of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces | |  | | |  | * *National measures of execution adopted by the date of accession* |
| **Chapter 2**  **Control system for imports** | | | | | | | |
| **I. Live animals** | | | | | | | |
|  | **Council** [**Directive 91/496/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31991L0496)of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC | | * *Rulebook the organization of veterinary checks on certain live animals* | | | * *2015 partly* * *II.2018* | * *2015 partly* * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 97/794/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997D0794)of 12 November 1997 laying down certain detailed rules for the application of Council Directive 91/496/EEC as regards veterinary checks on live animals to be imported from third countries | | * *Rulebook governing the detailed rules for veterinary checks on certain live animals* | | | * *II.2018* | * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 282/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0282)of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community | | * *Rulebook introducing a document for the declaration on and veterinary checks on certain animals* | | | * *2015 partly* * *II.2018* | * *2015 partly* * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2007/275/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32007D0275)of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC | | * *Rulebook on list of animals and products be subject to control at border inspection posts* | | | * *III.2015* | * *III.2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2010/57/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010D0075)of 3 February 2010 laying down health guarantees for the transit of equidae being transported through the territories listed in Annex I to Council Directive 97/78/EC | | * *Rulebook laying down health guarantee for the transit of certain equidae* | | | * *II.2018* | * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Regulation (EU) No 139/2013**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0139)of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof | | * *Rulebook laying down animal health condition for imports of certain birds on list and types of live animals and animal products subject to veterinary inspection* | | | * *III.2018* | * *III.2018* * *Fully implemented at the day of accession* |
| **II. Animal products** | | | | | | | |
|  | **Council** [**Directive 97/78/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997L0078)of 18 December 1997 laying down the principles governing the organization of veterinarychecks on products entering the Community from third countries. | | * *Rulebook the organization of veterinary checks on certain animal products* | | | * *2015 partly* * *II.2018* | * *2015 partly* * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 94/360/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994D0360)of 20 May 1994 on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries, under Council Directive 90/675/EEC | | * *Rulebook on the reduced frequency of physical checks of consignments of certain products* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2000/208/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000D0208)of 24 February 2000 establishing detailed rules for the application of Council Directive 97/78/EC concerning the transit of products of animal origin from one third country to another third country by road only across the European Community. | | * *Rulebook establishing detailed rules as regards the transit of certain products of animal origin* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2000/571/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000D0571)of 8 September 2000 laying down the methods of veterinary checks for products from third countries destined for introduction into free zones, free warehouses, customs warehouses or operators supplying cross border means of sea transport | | * *Rulebook on the method of veterinary checks on of certain products which are intended for storage in free zones, free warehouses, customs warehouses or operators registered for the direct supply of sea transport* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 136/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0136)of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries | | * *Rulebook on procedures for veterinary check at border inspection points for certain products* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2005/34/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005D0034)of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries | | * *Rulebook laying down harmonized standards for the testings of certain residues in certain products of animal origin* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2005/92/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005D0092)of 2 February 2005 as regards animal health conditions, certification and transitional provisions concerning the introduction and storage period for consignments of certain products of animal origin in free zones, free warehouses and premises of operators supplying cross border means of sea transport in the Community | | * *Rulebook on animal health conditions, certification and transitional provisions concerning the introduction and storage period for consignments of certain products of animal origin in free zones, free warehouses or registered entities for direct supply of sea transport* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2005/93/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005D0093)of 2 February 2005 as regards transitional provisions concerning the introduction and the storage period for consignments of certain products of animal origin in customs warehouses in the Community | | * *Rulebook on the transitional provisions relating to the introduction and storage period for consignments of certain products of animal origin in customs warehouses* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 206/2009**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009D0206)of 5 March 2009 on the introduction into the Community of personal consignments of products of animal origin and amending Regulation (EC) No 136/2004 | | * *Rulebook on the introduction of personal consignment of certain products of animal origin* | | | * *II.2017* | * *II.2017* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Decision 2011/215/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011D0215)of 4 April 2011 implementing Council Directive 97/78/EC as regards transshipment at the border inspection post of introduction of consignments of products intended for import into the Union or for third countries | | * *Rulebook for transshipment of certain products* | | | * *II.2018* | * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 28/2012**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R0028)of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009 | | * *Rulebook on establishing requirements for certification of imports and transit of certain composit products* | | | * *II.2018* | * *II.2018* * *Fully implemented at the day of accession* |
| **III. Border Inspection Posts** | | | | | | | |
|  | **Commission** [**Decision 93/352/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31993D0352)of 1 June 1993 laying down derogations from the conditions of approval for border inspection posts located in ports where fish is landed | | * *Rulebook conditions of approval for border inspection posts located in ports where fish is landed* | | | * *II.2018* | * *II.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2001/812/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001D0812)of 21 November 2001 laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries. | | * *Rulebook on technical requirements for the approval of border inspection posts responsible for veterinary checks* | | | * *II.2016* | * *II.2016* * *Fully implemented at the day of accession* |
| **IV. Computer Systems TRACES** | | | | | | | |
|  | **Council** [**Decision 92/438/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31992D0438)of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 92/563/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31992D0563)of 19 November 1992 on the database covering the Community's import requirements, envisaged by the Shift project | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 97/152/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997D0152)of 10 February 1997 concerning the information to be entered in the computerized file of consignments of animals or animal products from third countries which are re-dispatched | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 97/394/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997D0394)of 6 June 1997 establishing the minimum data required for the databases on animals and animal products brought into the Community | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2003/24/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003D0024)of 30 December 2002 concerning the development of an integrated computerized veterinary system | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2003/623/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003D0623)of 19 August 2003 concerning the development of an integrated computerized veterinary system known as Traces | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2004/292/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0292)of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2004/675/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0675)of 29 September 2004 establishing logistical support for the Traces system | |  | | |  | * *National measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision 2009/821/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009D0821)of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces | |  | | |  | * *National measures of execution adopted by the date of accession* |
| **VII. Miscellaneous** | | | | | | | |
|  | **Commission** [**Decision 78/685/EEC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31978D0685)of 26 July 1978 establishing a list of epizootic diseases in accordance with Directive 72/462/EEC | | * *Rulebook on a list of epizootic diseases* | | | * *IV.2018* | * *IV.2018* * *Fully implemented at the day of accession* |
| **Chapter 3**  **Identification and registration of animals and registration of their movements** | | | | | | | |
| **I. Bovine animals** | | | | | | | |
|  | [**Regulation HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000R1760"(EC) No 1760/2000**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000R1760)of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97. | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on the method of identification and registration of bovine animals and the keeping of registers and electronic databases**   **(OG MN 58/2007)** | | | * **9.08.2007** * **10.12.2010** * *IV 2015* | * **Partly implemented** * *2015* * *Fully implemented on the day of accession* |
|  | **Commission** [**Regulation (EC) No 494/98**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31998R0494)of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the systemfor the identification and registration of bovine animals | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on the method of identification and registration of bovine animals and the keeping of registers and electronic databases**   **(OG MN 58/2007)** | | | * **9.08.2007** * **10.12.2010** * *2015* | * **Already implemented** |
|  | **Commission** [**Regulation (EC) No 509/1999**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999R0509)of 8 March 1999 concerning an extension of the maximum period laid down for the application of ear-tags to bison (Bison bison spp.). | | * *Rulebook concerning the application of ear tag to bison’s* | | | * *If necessary* | * *If necessary* |
|  | **Commission** [**Regulation (EC) No 2680/1999**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31999R2680)of 17 December 1999 approving system of identification for bulls intended for cultural and sporting events | |  | | |  | * *Possible national measures of execution adopted by the date of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001D0672"2001/672/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001D0672)of 20 August 2001 laying down special rules applicable to movements of bovine animals when put out to summer grazing in mountain areas. | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on the method of identification and registration of bovine animals and the keeping of registers and electronic databases**   **(OG MN 58/2007)** | | | * **9.08.2007** * **10.12.2010** * *2015* | * **Already implemented** |
|  | **Commission** [**Regulation (EC) No 1082/2003**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003R1082)of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on control and the form of the annual report controls for the identification and registration of bovine animals**   **(OG MN 4/2015)** | | | * **9.08.2007** * **10.12.2010** * *2015* | * **Already implemented** |
|  | **Commission** [**Regulation (EC) No 911/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0911)of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on the method of identification and registration of bovine animals and the keeping of registers and electronic databases**   **(OG MN 58/2007)** | | | * **9.08.2007** * **10.12.2010** * *2015* | * **Already implemented** |
|  | **Commission** [**Regulation (EC) No 644/2005**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005R0644)of 27 April 2005 authorising a special identification system for bovine animals kept for cultural and historical purposes on approved premisesas provided for in Regulation (EC) No 1760/2000 of theEuropean Parliament and ofthe Council | | * *Rulebook on special identification system for bovine animals kept for cultural and historical purposes on approved premises* | | | * *II 2018* | * *II 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2006/28/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006D0028)of 18January 2006 on extension of the maximum period for applying eartags to certain bovine animals | | * *Rulebook for extension of maximum period for applying ear tags to certain bovine animals* | | | * *II 2018* | * *II 2018* * *Fully implemented at the day of accession* |
| **II. Porcine animals** | | | | | | |  |
|  | **Council** [**Directive 2008/71/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0071)of 15 July 2008 on the identification and registration of pigs | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on identification and registration of pigs (OG MN 48/2014)** | | | * **Full transposition in 2015** | * **Full implementation in 2015** |
|  | **Commission** [**Decision 2000/678/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000D0678)of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC. | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on identification and registration of pigs** | | | * **Full transposition in 2015** | * **Full implementation in 2015** |
| **III. Ovine and caprine animals** | | | | | | | |
|  | **Council** [**Regulation (EC) No 21/2004**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004R0021)of 17 December 2003 establishing a system for the identification and registration ofovine and caprineanimals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on identification and manner of keeping registers farms sheep and goats and electronic databases**   **(OG MN 33/2014)** | | | * **Full transposition in 2015** | * **Full implementation in 2015** |
|  | **Commission** [**Regulation (EC) No 1505/2006**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1505)of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * **Rulebook on control and the form of the annual report controls for the identification and registration of sheep****and goats**   **(OG MN 4/2015)** | | | * **Full transposition in 2015** | * **Full implementation in 2015** |
|  | **Commission** [**Decision 2006/968/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006D0698)of 15 December 2006 implementing Council Regulation (EC) No 21/2004 as regards guidelines and procedures for the electronic identification of ovine and caprine animals | | * **Law on Animal Identification and Registration as amended (OG MN 48/2007)** * *Guidelines and procedures for the electronic identification of ovine and caprine animals* | | | * *IV 2015* | * *IV 2015* |
| **IV. Equidae** | | | | | | | |
|  | **Council** [**Directive 90/427/EEC**](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1414062860200&uri=CELEX:01990L0427-20080903)of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae | | * *Rulebook on the zootechnical and genealogical conditions for marketing equidae* | | | * *I.2018* | * *I.2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 504/2008**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0504)of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae | | * *Rulebook as regards methods for identifications of equidae* | | | * *I.2018* | * *I.2018* * *Fully implemented at the day of accession* |
| **Chapter 4**  **Control measures for animal diseases** | | | | | | | |
| **I. Foot and Mouth Disease** | | | | | | | |
|  | **Council** [**Directive 2003/85/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0085:EN:NOT)of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC | | * *Rulebook on measures for the control of Foot and Mouth Disease* | | | * *III.2015* | * *III.2015* |
|  | **Commission** [**Decision 2007/18/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0018:EN:NOT)of 22 December 2006 approving contingency plans for the control of foot-and-mouth disease pursuant to Council Directive 2003/85/EC | | * *Contingency plans for the control of Foot and Mouth Disease* | | | * *III.2015* | * *If necessary* |
| **II. Classical Swine Fever** | | | | | | | |
|  | **Council** [**Directive 2001/89/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0089:EN:NOT)of 23 October 2001 on Community measures for the control of classical swine fever | | * **Rulebook on measures for the prevention, detection, control and eradication of classical swine fever**   **(OG MN 18/2014)** | | | * **11.4.2014** | * **19.4.2014** |
|  | **Commission** [**Decision 2002/106/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0106:EN:NOT)of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever | | * **Rulebook on measures for the prevention, detection, control and eradication of classical swine fever**   **(OG MN 18/2014)** | | | * **11.4.2014** | * **19.4.2014** |
|  | **Commission** [**Decision 2007/19/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0019:EN:NOT)of 22 December 2006 approving contingency plans for the control of classical swine fever pursuant to Council Directive 2001/89/EC | | * *Contingency plans for the control of classical swine fever* | | | * *2015* | * *2015* * *After the stop of vaccination, If necessary* |
| **III. African Swine Fever.** | | | | | | | |
|  | **Council** [**Directive 2002/60/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0060:EN:NOT)of 27 June 2002 laying down specific provisions for the control of African swine fever andamending Directive 92/119/EEC as regards Teschen disease and African swine fever | | * *Rulebook on measures for the control of African Swine Fever* | | | * *II.2017* | * *II.2017* |
|  | **Commission** [**Decision 2003/422/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0422:EN:NOT)of 26 May 2003 approving an African swine fever diagnostic manual | | * *Rulebook approving African Swine Fever diagnostic manual* | | | * *II.2017* | * *II.2017* |
| **IV. African horse sickness.** | | | | | | | |
|  | **Council** [**Directive 92/35/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0035:EN:NOT)of 29 April 1992 laying down control rules and measures to combat African horse sickness | | * *Rulebook on measures for control African horse sickness* | | | * *IV.2017* | * *IV.2017* |
|  | **Commission** [**Decision 2009/3/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0003:EN:NOT)of 18 December 2008 establishing Community reserves of vaccines against African horse sickness | |  | | |  | * *Possible national measures of execution adopted by the date of accession* |
| **V. Avian Influenza** | | | | | | | |
|  | **Council** [**Directive 2005/94/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005L0094:EN:NOT)of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC | | * *Rulebook on measures for the control of avian influenza* | | | * *III.2015* | * *Partially implemented*   *III.2015*   * *Fully implemented*   *I. 2017* |
|  | **Commission** [**Decision 2006/437/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0437:EN:NOT)of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC | | * *Rulebook approving diagnostic manual for avian influenza* | | | * *III.2015* | * *III.2015* |
|  | **Commission** [**Decision 2007/24/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0024:EN:NOT)of 22 December 2006 approving contingency plans for the control of avian influenza and Newcastle disease | | * *Contingency plans for the control of* *of avian influenza and Newcastle disease* | | | * *II.2016* | * *If necessary* |
|  | **Commission** [**Decision 2007/118/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0118:EN:NOT)of 16 February 2007 laying down detailed rules in relation to an alternative identification mark pursuant to Council Directive 2002/99/EC | | * *Rulebook laying down detailed rules in relation to an alternative identification mark pursuant* | | | * *II.2016* | * *If necessary* |
|  | **Commission** [**Decision 2007/598/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0598:EN:NOT)of 28 August 2007 concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres in the Member States | | * *Rulebook concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in certain entities* | | | * *II.2017* | * *If necessary* |
|  | **Commission** [**Regulation (EC) No 616/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0616:EN:NOT)of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments | | * *Rulebook on the approval poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments* | | | * *II.2016* | * *If necessary* |
|  | **Commission** [**Decision 2010/367/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0367:EN:NOT)of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds | | * *Surveillance programme for avian influenza in poultry and wild birds* | | | * *II.2016* | * *II.2016* * *Fully implemented*   *I. 2017* |
| **VI. Newcastle disease** | | | | | | | |
|  | **Council** [**Directive 92/66/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0066:EN:NOT)of 14 July 1992 introducing Community measures for the control of Newcastle disease | | * *Rulebook on the measures for the control of Newcastle disease* | | | * *III.2015* | * *III.2015* |
| **VII. Fish and Mollusc diseases** | | | | | | | |
|  | **Council** [**Directive 2006/88/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0088:EN:NOT)of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals | | * **Rulebook on** **on measures for the prevention, detection, control and eradication of exotic and non-exotic disease and aquatic animal health requirements for their marketing**   **(OG MN 34/2015)** | | | * **II.2015** * *II.2017* | * **Partially implemented** * **II. 2015** * *II. 2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2008/392/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0392:EN:NOT)of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means | | * *Rulebook on Information page on the Internet to information aquaculture operators and approved processing facilities were available electronically* | | | * *III.2018* | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2008/896/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0896:EN:NOT)of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC | | * *Guidelines for programs of health protection measures for aquaculture based on a risk assessment* | | | * *IV.2016* | * *IV.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2009/177/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0177:EN:NOT)of 31 October 2008 implementing Council Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of Member States, zones and compartments | |  | | |  | * *Fully implemented at the day of* *accession* |
| **VIII. Bluetongue disease** | | | | | | | |
|  | **Council** [**Directive 2000/75/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0075:EN:NOT)of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue | | * **Rulebook on measures for control and eradication of bluetongue**   **(OG MN 3/2015)** | | | * **Already adopted 2015** | * **Already implemented 2015** |
|  | **Commission** [**Regulation (EC) No 1266/2007**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007R1266:EN:NOT)of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue | | * **Rulebook on measures for the prevention, detection, control and eradication of bluetongue**   **(OG MN 3/2015)** | | | * **Already adopted 2015** | * **Partially implemented 2015** * *Fully implemented at the day of accession* |
| **IX. Transmissible Spongiform Encephalopathies** | | | | | | | |
|  | [**Regulation (EC) No 999/2001**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001R0999:EN:NOT)of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies | | | * *Rulebook on measures for the prevention, detection, control and eradication of TSE* | | * *III.2015* * *III. 2018* | * *Partially implemented* * *2015* * *2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2007/182/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0182:EN:NOT)of 19 March 2007 on a survey for chronic wasting disease in cervids | | | * *Rulebook on the Control of TSE in cervids* | | * *IV.2018* | * *IV.2018* |
|  | **Commission** [**Decision 2007/453/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0453:EN:NOT)of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk | | |  | |  | * *Possible national measures of execution adopted by the date of accession* |
| **X. Zoonoses** | | | | | | | |
|  | [**Regulation (EC) No 2160/2003**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R2160:EN:NOT)of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents | | | * *Regulations for the control of Salmonella and other specified zoonotic agents of foodborne* | | * *III.2015* | * *Partially implemented* * *2015* * *2016* * *Fully implemented at the day of accession* |
|  | [**Directive 2003/99/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0099:EN:NOT)of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC | | | * **Regulations on the monitoring of zoonoses and zoonotic agents**   **(OG MN 7/2015)** | | * **2015** | * **Partialy implemented 2015** * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2004/564/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0564:EN:NOT)of 20 July 2004 concerning Community reference laboratories for the epidemiology of zoonoses and for salmonella and national reference laboratories for salmonella | | |  | |  | * *National Reference Laboratory designated by National Measures of Execution by end of 2016* |
|  | **Commission** [**Regulation (EC) No 1177/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1177:EN:NOT)of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry | | | * *Rulebook on specific control methods in the framework of national programs for the control of salmonella in poultry* | | * *IV.2016* | * *IV.2016* |
|  | **Commission** [**Decision 2006/759/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0759:EN:NOT)of 8 November 2006 approving certain national programmes for the control of salmonella in breeding flocks of Gallus gallus | | |  | |  | * *Possible National Control Programme will be approved by National Measures of Execution* |
|  | **Commission** [**Decision 2007/843/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0843:EN:NOT)of 11 December 2007 concerning approval of Salmonella control programmes in breeding flocks of Gallus gallus in certain third countries in accordance with Regulation (EC) No 2160/2003 of the Eurpoean Parliament and of the Council and amending Decision 2006/696/EC, as regards certain public health requirements at import of poultry and hatching eggs | | |  | |  | * *Possible National Control Programme will be approved by National Measures of Execution* |
|  | **Commission** [**Decision 2007/848/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0848:EN:NOT)of 11 December 2007 approving certain national programmes for the control of salmonella in flocks of laying hens of Gallus gallus | | |  | |  | * *National Control Programme will be approved by National Measures of Execution by the end of 2016* |
|  | **Commission** [**Decision 2008/815/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0815:EN:NOT)of 20 October 2008 approving certain national programmes for the control of Salmonella in flocks of broilers of Gallus gallus | | |  | |  | * *National Control Programme will be approved by National Measures of Execution by the end of 2017* |
|  | **Commission** [**Decision 2009/771/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0771:EN:NOT)of 20 October 2009 approving certain national programmes for the control of salmonella in turkeys | | |  | |  | * *National Control Programme will be approved by National Measures of Execution by the end of 2017* |
|  | **Commission** [**Decision 2010/75/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0075:EN:NOT)of 5 February 2010 concerning a financial contribution from the Union towards a coordinated monitoring programme on the prevalence of Listeria monocytogenes in certain ready-to-eat foods to be carried out in the Member States | | |  | |  | * *National Programme of monitoring the prevalence of Listeria monocytogenes in food for immediate consumption by the end of 2015* |
|  | **Commission** [**Regulation (EU) No 200/2010**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0200:EN:NOT)of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus | | | * *Rulebook on procedures for reducing the prevalence of Salmonella serotypes in breeding flocks of Gallus gallus* | | * *II.2016* | * *Possible Implementation if necessary* |
|  | **Commission** [**Regulation (EU) No 517/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0517:EN:NOT)of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010 | | | * *Rulebook on procedures for reducing the prevalence of Salmonella serotypes in flocks of laying hens of Gallus gallus* | | * *IV.2015* | * *IV.2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 200/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0200:EN:NOT)of 8 March 2012 concerning a Union target for the reduction of Salmonella enteritidis and Salmonella typhimurium in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council | | | * *Rulebook on procedures for reducing prevalence of Salmonella enteritidis and Salmonella typhimurium with the chickens for broilers* | | * *IV.2016* | * *IV.2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 1190/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R1190:EN:NOT)of 12 December 2012 concerning a Union target for the reduction of Salmonella enteritidis and Salmonella typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council | | | * *Rulebook for the control of Salmonella enteritidis and Salmonella typhimurium in flocks of turkeys* | | * *II.2016* | * *IV.2017* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Decision 2013/652/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013D0652:EN:NOT)of 12 November 2013 on the monitoring and reporting of antimicrobialresistance in zoonotic and commensal bacteria | | | * *Rulebook on monitoring the resistance of zoonotic and commensal bacteria to antimicrobial agents* | | * *IV.2017* | * *IV.2017* * *Fully implemented at the day of accession* |
| **XI. Other Diseases** | | | | | | | |
|  | **Council** [**Directive 92/119/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0119:EN:NOT)of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease | | | * *Rulebook on measures for the control of certain animal diseases and specific measures relating to swine vesicular disease* | | * *II.2017* | * *IV.2017* |
|  | **Commission** [**Decision 2000/428/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000D0428:EN:NOT)of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease. | | | * *Rulebook on diagnostic procedures, methods and sampling and criteria for evaluating the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease* | | * *II.2017* | * *IV.2017* |
| **XII. Notification of diseases** | | | | | | | |
|  | **Council** [**Directive 82/894/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0894:EN:NOT)of 21 December 1982 on the notification of animal diseases within the Community | | | * *Rulebook on the notification of animal diseases* | | * *III.2017* | * **Partially implemented 2008** * *III.2017* |
| **Chapter 5**  **Trade in live animals semen, ova and embryos within the Union** | | | | | | | |
| **I. Bovine and Porcine animals** | | | | | | | |
|  | **Council** [**Directive 64/432/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31964L0432:EN:NOT)of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine | | * *Rulebook on health requirements for trade in bovine animals and swine* | | | * **2008 partly (brucellosis, leucosis and tuberculosis)** * *III.2015 (partly status, trade)* * *I. 2017 full transposition codified rules* | * **Partially implemented 2008 (brucellosis, leucosis and tuberculosis)** * *IV 2015 (partly status, trade)* * *At the day of accession* |
|  | **Commission** [**Decision 2002/598/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0598:EN:NOT)of 15 July 2002 approving vaccines against bovine brucellosis within the framework of Council Directive 64/432/EEC | | * *Rulebook approving a vaccine against brucellosis* | | | * *I. 2017* | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2003/886/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0886:EN:NOT)of 10 December 2003 laying down criteria for information to be provided in accordance with Council Directive 64/432/EEC | |  | | |  | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2004/226/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0226:EN:NOT)of 4 March 2004 approving tests for the detection of antibodies against bovine brucellosis within the framework of Council Directive 64/432/EEC | | * *Rulebook on approval tests for the detection of antibodies against bovine brucellosis* | | | * *I. 2017* | * *I. 2017* |
|  | **Commission** [**Decision 2004/315/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0315:EN:NOT)of 26 March 2004 recognising the system of surveillance networks for bovine holdings I mplemented in Member States or regions of Member States under Directive 64/432/EEC | |  | | |  | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2004/558/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0558:EN:NOT)of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States | | * *Rulebook on additional guarantees for the transport of cattle in relation to infectious bovine rhinotracheitis and conditions for determining the status of flocks* | | | * *I. 2017* | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2008/185/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0185:EN:NOT)of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky’s disease and criteria to provide information on this disease | | * *Rulebook on additional guarantees in trade of pigs in relation to Aujeszky's disease and criteria for the collection of information about disease* | | | * *I. 2017* | * *IV. 2018* |
|  | **Commission** [**Decision 2009/712/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0712:EN:NOT)of 18 September 2009 implementing Council Directive 2008/73/EC as regards Internet-based information pages containing lists of establishments and laboratories approved by Member States in accordance with Community veterinary and zootechnical legislation | | * *Rulebook on data approved establishments and laboratories*   *in accordance with the veterinary and zootechnical legislation to be published on the website* | | | * *I 2018* | * *Fully implemented at the day of accession* |
| **II. Ovine and caprine animals** | | | | | | | |
|  | **Council** [**Directive 91HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0068:EN:NOT"/HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0068:EN:NOT"68HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0068:EN:NOT"/HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0068:EN:NOT"EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0068:EN:NOT)of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals | | * *Rulebook on health requirements for trade in ovine and caprine animals* | | | * *2015 partly* * *II. 2018 (partly status, trade)* | * *2015* * *IV. 2018(partly status, trade)* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0052:EN:NOT"93/52/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0052:EN:NOT)of 21 December 1992 recording the compliance by certain Member States or regions with the requirements relating to brucellosis (B. melitensis) and according them the status of a Member State or region officially free of the disease | |  | | |  | * *Fully implemented at the day of accession* |
| **III. Equidae** | | | | | | | |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995D0329:EN:NOT"95/329/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995D0329:EN:NOT)of 25 July 1995 defining the categories of male equidae to which the requirement regarding viral arteritis laid down in Article 15 (b) (ii) of Council Directive 90/426/EEC | | * *Rulebook defining the categories of male equidae to which the requirement in terms of arteritis* | | | * *II.2017* | * *IV.2018* |
| **IV. Poultry and hatching eggs** | | | | | | | |
|  | **Council** [**Directive 2009/158/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0158:EN:NOT)of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs | | * *Rulebook on health requirements governing trade in and imports from third countries of poultry and hatching eggs* | | | * *IV.2015* * *Fully transposed II. 2018* | * *I. 2016* * *Fully implemented IV. 2018* |
|  | **Commission** [**Decision 93/152/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0152:EN:NOT)of 8 February 1993 laying down the criteria for vaccines to be used against Newcastle disease in the context of routine vaccination programmes | | * *Rulebook on establishing criteria for vaccines to be used against New Castle disease within routine vaccination program* | | | * *2015* * *II. 2018* | * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 94/327/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994D0327:EN:NOT)of 19 May 1994 fixing the criteria for annual testing of breeding poultry for Newcastle disease, in application of Article 12 (2) of Council Directive 90/539/EEC | | * *Guidelines for defining the criteria for annual testing of breeding poultry in New Castle Disease* | | | * *II. 2018* | * *If necessary* |
|  | **Commission** [**Decision 2006/605/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0605:EN:NOT)of 6 September 2006 on certain protection measures in relation to intra-Community trade in poultry intended for restocking of wild game supplies | |  | | |  | * *Fully implemented at the day of accession* |
| **V. Aquaculture animals** | | | | | | | |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001D0183:EN:NOT"2001/183/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001D0183:EN:NOT)of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC | | * **Rulebook on** **on measures for the prevention, detection, control and eradication of exotic and non-exotic disease and aquatic animal health requirements for their marketing**   **(OG MN 34/2015)**   * *Rulebook on sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases* | | | * **2015** | * *Partially implemented*   *II. 2016*   * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0878:EN:NOT"2002/878/E**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0878:EN:NOT)**C** of 6 November 2002 establishing the sampling plans and diagnostic methods for the detection and confirmation of the presence of the mollusc diseases Bonamiosis (Bonamia ostreae) and Marteiliosis (Marteilia refringens) | | * **Rulebook on** **on measures for the prevention, detection, control and eradication of exotic and non-exotic disease and aquatic animal health requirements for their marketing**   **(OG MN 34/2015)**   * *Rulebook on the development of sampling plans and diagnostic methods for the detection and confirmation of mollusc diseases Bonamiosis (Bonamia ostreae) and Marteiliosis (Martelia feringens)* | | | * **II.2015** | * *Partially implemented*   *II. 2016*   * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0466:EN:NOT"2003/466/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0466:EN:NOT)of 13 June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA) | | * *Rulebook on criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA)* | | | * *IV.2018* | * *If necessary* |
|  | **Commission** [**Regulation (EC) No 1251/2008**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R1251)of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species | | * *Rulebook on conditions and certification requirements for the placing on the market and the import of aquaculture animals and products thereof and laying down a list of vector species* | | | * *IV.2016* | * *Partially implemented*   *IV. 2016*   * *Fully implemented at the day of accession* |
| **VI. Embryos of bovine animals** | | | | | | | |
|  | **Council** [**Directive 89/556/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0556:EN:NOT)of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species | | * *Regulation on conditions for placing on the market and import of aquaculture animals, their products and the list of vector species* | | | * *III 2018* | * *IV 2018* |
| **VII. Semen of bovine animals** | | | | | | | |
|  | **Council** [**Directive 88/407/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0407:EN:NOT)of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species. | | * **Rulebook on conditions for veterinary organizations for collection and storage of semen for artificial insemination of cattle and circulation**   **(OG MN 41/2014)**   * *Rulebook on amendments to the Ordinance on health requirements for trade in and imports of semen of bovine animals* | | | * **3.10.2014 Partly** * *I.2018 Fully transposed* | * **12.10.2014** * *I.2018* |
| **VIII. Semen of porcine animals** | | | | | | | |
|  | **Council** [**Directive 90/429/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0429:EN:NOT)of 26 June 1990 laying down the animal health requirements applicable to intra- Community trade in and imports of semen of domestic animals of the porcine species. | | * *Rulebook on animal health conditions governing trade in and imports of semen of domestic pig species* | | | * *IV 2017* | * *IV 2017* |
| **IX. Other animals, semen, ova and embryos.** | | | | | | | |
|  | **Council** [**Directive 92/65/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0065:EN:NOT) **o**f 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC | | * *Rulebook on animal health requirements governing trade in and imports of animals, semen, ova and embryos not subject to the requirements of regulations in the Schedule to the Ordinance on veterinary and zootechnical checks in certain live animals and products of animal origin in domestic traffic* | | | * *IV 2018* | * *IV 2018* |
|  | **Council** [**Decision 2000/258/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000D0258:EN:NOT)of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies | |  | | |  | * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 1739/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R1739:EN:NOT)of 21 October 2005 laying down animal health requirements for the movement of circus animals between Member States | | * *Rulebook on animal health conditions governing the movement of animals used in circuses* | | | * *III 2017* | * *IV 2018* |
|  | **Commission** [**Decision 2010/436/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0436:EN:NOT)of 9 August 2010 implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2010/470/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0470:EN:NOT)of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Decision 2013/519/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32019D0503:EN:NOT)of 21 October 2013 laying down the list of territories and third countries authorised for imports of dogs, cats and ferrets and the model health certificate for such imports | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **Chapter 6**  **Non commercial movements of pet animals** | | | | | | | |
|  | [Regulation (EU) No 576/2013](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0576:EN:NOT) of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 | | * *Rulebook on on the non-commercial movement of pet animals* | | | * *II 2016* | * *II 2016* |
|  | Commission [Decision 2007/25/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0025:EN:NOT) of 22 December 2006 as regards certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Community | | * *Rulebook on protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners* | | | * *II 2016* | * *II 2016* |
|  | Commission Delegated [Regulation (EU) No 1152/2011](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1152:EN:NOT) of 14 July 2011 supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs | | * *Rulebook on preventative health measures for the control of Echinococcus multilocularis infection in dogs with monitoring* | | | * *I 2016* | * *II 2016* |
|  | Commission Implementing [Regulation (EU) No 577/2013](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0577:EN:NOT) of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council | | * *Rulebook on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations* | | | * *IV 2016* | * *IV 2016* |
| **Chapter 7**  **Prohibition of substances and control of residues** | | | | | | | |
| **I. Prohibition of substances** | | | | | | | |
|  | **Council** [**Directive 96/22/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0022:EN:NOT)of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC | | **Order on the prohibition on the use and treatment of animals bred by certain substances and veterinary medicine**  **(OG MN 39/2013)** | | | * **2013** * *IV 2018* | * **2013** * *IV 2018* |
|  | **Council** [**Decision 1999/879/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999D0879:EN:NOT)of 17 December 1999 concerning the placing on the market and administration of bovine somatotrophin BST) and repealing Decision 90/218/EEC | | **Order on the prohibition on the use and treatment of animals bred by certain substances and veterinary medicine**  **(OG MN 39/2013)** | | | * **2013** * *IV 2018* | * **2013** * *IV 2018* |
| **II. Residues controls** | | | | | | | |
|  | **Council** [**Directive 96/23/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0023:EN:NOT)of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC | | * **Rulebook on the monitoring of certain substances and residues thereof in live animals animal products and feed**   **(OG MN 46/2006)** | | | * **2006** * *IV 2016* | * **2006** * *IV 2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0747:EN:NOT"97/747/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0747:EN:NOT)of 27 October 1997 fixing the levels and frequencies of sampling provided for Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products | | * **Rulebook on the monitoring of certain substances and residues thereof in live animals animal products and feed**   **(OG 46/2006)**  *Rulebook on the levels and frequency of sampling for the monitoring of certain substances and residues thereof in certain animal products* | | | * **2006** * *IV 2016* | * **Partially implemented****2006** * *Partially implemented IV 2016* * *If necessary fully implemented at the day of accession* |
|  | **Commission** [**Decision 98/179/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998D0179:EN:NOT)of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products. | | * **Instructions for sampling by program monitoring residues in animals, animal products and animal feed (2007, 2008)** * *Rulebook on detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products.* | | | * **Decree of the Director of the Veterinary Administration** * *IV 2016* | * **2007** * *IV 2016* |
|  | **Commission** [**Decision 2002/657/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0657:EN:NOT)of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results | | **Rulebook on methods of control of residues in animals and animal products (OG 45/2014)** | | | * **2014** | * **2014** |
| **Chapter 8**  **Import requirements for live animals and animal products** | | | | | | | |
| **A. Live animals Semen Ova and Embryos** | | | | | | | |
| **I. Bovine, Porcine, and Ovine Animals** | | | | | | | |
|  | **Council** [**Directive 2004/68/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0068:EN:NOT)of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC | | * *Rulebook on health requirements for import and transit and certification of domestic ungulates* | | | * *IV 2017* | * *IV 2017* |
| **List of third countries and certification** | | | | | | | |
|  | **Commission** [**Decision 2007/240/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0240:EN:NOT)of 16 April 2007 laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community pursuant to Decisions 79/542/EEC, 92/260/EEC, 93/195/EEC, 93/196/EEC, 93/197/EEC, 95/328/EC, 96/333/EC, 96/539/EC, 96/540/EC, 2000/572/EC, 2000/585/EC, 2000/666/EC, 2002/613/EC, 2003/56/EC, 2003/779/EC, 2003/804/EC, 2003/858/EC, 2003/863/EC, 2003/881/EC, 2004/407/EC, 2004/438/EC, 2004/595/EC, 2004/639/EC and 2006/168/EC | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 206/2010**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32010R0206)of 12 March 2010 laying down lists of third countries, territories or parts thereof authorized for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Regulation (EU) No 750/2014**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0750)of 10 July 2014 on protection measures in relation to porcine epidemic diarrhoea as regards the animal health requirements for the introductioninto the Union of porcine animals | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **II. Equidae** | | | | | | | |
| ***Lists of third countries*** | | | | | | | |
|  | **Commission** [**Decision 2004/211/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0211)of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **Certification** | | | | | | | |
|  | **Commission** [**Decision 92/260/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0260:EN:NOT)of 10 April 1992 on animal health conditions and veterinary certification for temporary admission of registered horses | | * *Rulebook on health requirements for animal health and veterinary certificate for temporary admission of registered horses* | | | * *IV 2017* | * *IV 2018* |
|  | **Commission** [**Decision 93/195/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0195:EN:NOT)of 2 February 1993 on animal health conditions and veterinary certification for the re- entry of registered horses for racing, competition and cultural events after temporary export | | * *Rulebook on health conditions and veterinary certificate for re-entry of registered horses for racing, competition and cultural events after temporary export* | | | * *IV 2017* | * *IV 2018* |
|  | **Commission** [**Decision 93/196/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0196:EN:NOT)of 5 February 1993 on animal health conditions and veterinary certification for imports of equidae for slaughter | | * *Rulebook on health conditions and veterinary certificates for the importation of horses for slaughter* | | | * *II 2018* | * *IV 2018* |
|  | **Commission** [**Decision 93/197/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993D0197:EN:NOT)of 5 February 1993 on animal health conditions and veterinary certification for imports of registered equidae and equidae for breeding and production | | * *Rulebook on health conditions and veterinary certificates for the importation of horses for breeding and keeping* | | | * *II 2018* | * *IV 2018* |
| **III. Poultry, Hatching Eggs, Day-Old Chicks and specified Pathogen-Free Eggs** | | | | | | | |
| **Animal Health** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | **Commission** [**Regulation (EC) No 798/2008**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0798)of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **IV. Aquaculture Animals - Fish** | | | | | | | |
| **Quarantine** | | | | | | | |
|  | **Commission** [**Decision 2008/946/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0946:EN:NOT)of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals | | * *Rulebook on requirements for quarantine of aquaculture animals* | | | * *III. 2017* | * *III. 2017* |
| **V. Embryos of Bovine Animals** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | **Commission** [**Decision 2006/168/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0168:EN:NOT)of 4 January 2006 establishing the animal health and veterinary certification requirements for imports into the Community of bovine embryos and repealing Decision 2005/217/EC | | * *Rulebook on establishing the animal health and veterinary certification requirements for imports into the Community of bovine embryos* | | | * *III. 2018* | * *IV 2018* * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **VI. Semen of Bovine Animals** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | **Commission Implementing** [**Decision 2011/630/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0630:EN:NOT)of 20 September 2011 on imports into the Union of semen of domestic animals of the bovine species | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **VII. Ova and embryos of Porcine Animals** | | | | | | | |
| **List of third countries** | | | | | | | |
|  | **Commission** [**Decision 2008/636/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008D0636)of 22 July 2008 establishing the list of third countries from which Member States authorise imports of ova and embryos of the porcine species | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **VIII. Semen of Porcine Animals** | | | | | | | |
| List of third countries, certification and list of semen collection centres | | | | | | | |
|  | **Commission Implementing** [**Decision 2012/137/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0137:EN:NOT)of 1 March 2012 on imports into the Union of semen of domestic animals of the porcine species | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **IX. Equine semen, ova and embryos** | | | | | | | |
|  | Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae | | * *Rulebook on health conditions governing the movement and importation of equine* | | | * *II.2017* | * *IV.2018* * *Fully implemented at the day of accession* |
| **Certification** | | | | | | | |
|  | **Commission** [**Decision 2010/471/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0471:EN:NOT) of 26 August 2010 on imports into the Union of semen, ova and embryos of animals of the equine species as regards lists of semen collection and storage centres and embryo collection and production teams and certification requirements | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **X. Semen ova and embryos of the ovine and caprine species** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | **Commission** [**Decision 2010/472/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0472:EN:NOT)of 26August 2010 on imports of semen, ova and embryos of animals of the ovine and caprine species into the Union | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **XI. Other Animals, Semen, Ova and Embryos** | | | | | | | |
| **3. Rabbit Meat and other wild and farm game meat other than those mentioned above** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | Commission [Regulation (EC) No 119/2009](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0119:EN:NOT) of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **4. Meat products (including treated stomachs, bladders and intestines)** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | Commission [Decision 2007/777/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0777:EN:NOT) of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **5. Minced meat (excluding poultry minced meat) and meat preparation** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | Commission [Decision HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000D0572"2000/572/EC](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32000D0572) of 8 September 2000 laying down animal and public health conditions and veterinary certification for imports of minced meat and meat preparations from third countries and repealing Decision 97/29/EC. | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **6. Milk and milk products** | | | | | | | |
| **List of third countries and certification** | | | | | | | |
|  | **Commission** [**Regulation (EU) No 605/2010**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0605:EN:NOT) **of** 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption | | * *Rulebook on laying down animal and public health and veterinary certification conditions for the introduction of raw milk and dairy products intended for human consumption* | | | * *IV.2015* | * *I.2016* * *Fully implemented at the day of accession* |
| **7. Fishery products and aquaculture products (human consumption)** | | | | | | | |
| **Fishery products (including processed bivalve molluscs), fish and crustaceans of aquaculture origin** | | | | | | | |
| **List of third countries** | | | | | | | |
|  | **Commission** [**Decision 2006/766/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0766:EN:NOT) **of 6** November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted  (Annex II fishery products) | | * *Rulebook on establishing a list of countries and the territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted* | | | * *I.2016* | * *I.2016* * *Fully implemented at the day of accession* |
| **8. Eggs and egg products** | | | | | | | |
| **9. Other products for human consumption** | | | | | | | |
|  | **Council** [**Directive 92/118/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0118:EN:NOT)of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC | | * *Rulebook on establishing requirements for animal health and public health requirements governing trade in and imports of products which are not subject to the requirements laid down in specific rules* | | | * *I.2016* | * *I.2016* * *Fully implemented at the day of accession* |
| **List of third countries** | | | | | | | |
|  | **Commission** [**Decision 2003/812/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0812:EN:NOT) **o**f 17 November 2003 drawing up lists of third countries from which Member States are to authorize imports of certain products for human consumption subject to Council Directive 92/118/EEC | | * *Rulebook on establishing requirements for animal health and public health requirements governing trade in and imports of products which are not subject to the requirements laid down in specific rules* | | | * *I.2016* | * *I.2016* * *Fully implemented at the day of accession* |
| **Animal casings Certification** | | | | | | | |
|  | **Commission** [**Decision 2003/779/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0779:EN:NOT)of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries | | * *Rulebook on establishing requirements for animal health and veterinary certification for imports of animal casings* | | | * *I.2016* | * *II.2016* * *Fully implemented at the day of accession* |
| **D. Lists of establishments** | | | | | | | |
| **Part I Animal Products for Human Consumption** | | | | | | | |
|  | * **According to Article 12 of Regulation (EC) No 854/2004, subsequent lists of the establishments are drawn up, kept up-to-date and communicated to the Commission by the competent authorities of third countries.** * **The Commission shall arrange for up-to-date versions of all lists to be available to the public.** * **In addition Article 2 of Directive 2004/41/EC states that during a transitional period previous implementing rules continue to apply pending adoption of the necessary provisions** * **Last updated lists of establishments are available at the following web site:**   [**http://ec.europa.eu/food/food/biosafety/establishments/third\_country/index\_en.htm**](http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm)   * **The establishments are listed according to the following classification:** * **Fresh Meat** * **Fresh Poultry Meat** * **Farmed Game Meat and Rabbit Meat** * **Ratite Meat** * **Wild game Meat** * **Minced Meat and Meat Preparations** * **Meat Products** * **Milk and milk-products** * **Fish and fishery products** * **Live Bivalve Mollusc** * **Animal Casings Stomachs and Bladers** * **Gelatine** | | * **Veterinary Law**   **(OG MN 30/2012)**   * *2015* | | | * **IV 2012 Partly** * *2015 Partly* | * **IV 2012 Partly** * *2015 Partly* * *Fully implemented at the day of accession* |
| **Part III Semen Ova and Embryos** | | | | | | | |
| **1. List of Bovine embryos collection teams** | | | | | | | |
|  | **In accordance with article 8.2 of Directive 89/556/EEC see Sanco web site**  [**http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html**](http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html)  **for the list of embryo collection and production teams** | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **2. Semen of Bovine animals** | | | | | | | |
|  | **In accordance with article 9 of Directive 88/407/EEC see Sanco web site** [**http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html**](http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html)  **For the list of**  **- semen collection centres**  **- semen storage centres** | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **3. Semen of porcine animals** | | | | | | | |
|  | **In accordance with article 8.2 of Directive 90/429/EEC see Sanco web site:**  [**http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html**](http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html) | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **X. International Organisations** | | | | | | | |
|  | **Council** [**Decision 2003/822/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0822:EN:NOT)of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission | |  | | |  | * **MNE is member of Codex Alimentarius Commission** |
| **XI. European Convention** | | | | | | | |
| **Farm Animals** | | | | | | | |
|  | **Council** [**Decision 78/923/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31978D0923:EN:NOT)of 19 June 1978 concerning the conclusion of the European Convention for the protection of animals kept for farming purposes | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
|  | **Council** [**Decision 92/583/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0583:EN:NOT)of 14 December 1992 on the conclusion of the Protocol of amendment to the European Convention for the Protection of Animals kept for Farming Purposes | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
|  | **92/1231/EEC** [**Protocol of amendment to the European Convention for the protection of animals**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:21992A1231%2801%29:EN:NOT) **kept for Farming Purposes** | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
| **Transport** | | | | | | | |
|  | **Council** [**Decision 2004/544/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0544:EN:NOT)of 21 June 2004 on the signing of the European Convention for the protection of animals during international transport | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
|  | [**European Convention**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:22004A0713%2801%29:EN:NOT)for the Protection of Animals during International Transport (revised) | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
| **Slaughter** | | | | | | | |
|  | **Council** [**Decision 88/306/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998D0306:EN:NOT)of 16 May 1988 on the conclusion of the European Convention for the Protection of Animals for Slaughter | | * *Law on Ratification of the Convention* | | | * *I.2017* | * *I.2017* |
| **Chapter 10**  **Animal welfare** | | | | | | | |
| **I. Farm animals** | | | | | | | |
|  | **Council** [**Directive 98/58/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0058:EN:NOT)concerning the protection of animals kept for farming purposes | | * **Law on Animal Welfare Protection**   **(OG MN 14/2008)**   * **Rulebook on detailed conditions to be met by facilities and equipment for keeping and breeding of animals for the production of (OG MN 28/2011)** * *Rulebook on Amendments to the Rulebook on detailed conditions to be met by facilities and equipment for keeping and breeding of animals for the production* (2017) * *Rulebook on minimum standards for the protection of pigs* | | | * **29.2.2008. Partly** * **29.2.2010. Partly** * **10.6.2011. Partly** * **2015** | * **29.2.2008.** * **29.2.2010.** * **19.6.2011.** * **1. 7. 2012.** * **2015** |
|  | **Commission** [**Decision 2006/778/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0778:EN:NOT)of 14 November 2006 concerning minimum requirements for the collection of information during the inspections of production sites on which certain animals are kept for farming purposes | | * *Rulebook on the minimum requirements for the collection of information during the inspections of production sites where the bred animals for the production are held* | | | * *IV.2017* | * *IV.2017* |
| **Laying hens** | | | | | | | |
| *Basic texts* | | | | | | | |
|  | **Council** [**Directive 1999/74/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0074:EN:NOT)of 19 July 1999 laying down minimum standards for the protection of laying hens. | | * *Rulebook on minimum standards for the protection of laying hens.* | | | * *II.2016* | * *II 2017* |
|  | **Commission** [**Directive 2002HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0004:EN:NOT"/HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0004:EN:NOT"4HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0004:EN:NOT"/HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0004:EN:NOT"EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0004:EN:NOT)of 30 January 2002 on the registration of establishments keeping laying hens, covered by Council Directive 1999/74/EC | | * *Rulebook on the registration of establishments keeping laying hens* | | | * *III.2018* | * *III.2018* |
| **Chickens kept for meat production** | | | | | | | |
|  | **Council** [**Directive 2007/43/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007L0043:EN:NOT)of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production. | | * *Rulebook on minimum rules for the protection of chickens kept for meat production* | | | * *IV.2016* | * *IV.2016* |
| **Calves** | | | | | | | |
|  | **Council** [**Directive 2008/119/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0119:EN:NOT)of 18 December 2008 laying down minimum standards for the protection of calves | | * *Rulebook on minimum standards for the protection of calves* | | | * *III.2017* | * *III.2017* |
| **Pigs** | | | | | | | |
|  | **Council** [**Directive 2008/120/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0120:EN:NOT)of 18 December 2008 laying down minimum standards for the protection of pigs | | * *Rulebook on minimum standards for the protection of pigs* | | | * *II.2018* | * *II.2018* |
| **II. Animals during transport** | | | | | | | |
|  | **Council** [**Regulation (EC) No 1255/97**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R1255:EN:NOT)of 25 June 1997 concerning Community criteria for staging points and amending the route plan referred to in the Annex to Directive 91/628/EEC | | * *Rulebook on Protection of animals during transport* | | | * *IV.2015 partly* * *II.2018* | * *IV.2015 partly* * *Fully implemented at the day of accession* |
|  | **Council** [**Regulation (EC) No 1/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0001:EN:NOT)of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 | | * *Rulebook on Protection of animals during transport* | | | * *IV.2015 partly* * *II.2018* | * *IV.2015 partly* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Decision 2013/188/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013D188:EN:NOT)of 18 April 2013 on annual reports on non-discriminatory inspections carried out pursuant to Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 | | * *Rulebook on the minimum requirements for the collection of information during the inspections of production sites where they are held and bred animals for the production o* | | | * *IV.2015 partly* * *II.2018* | * *IV.2015 partly* * *Fully implemented at the day of accession* |
| **III. Animals at the time of slaughter or killing** | | | | | | | |
|  | **Council** [**Regulation (EC) No 1099/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1099:EN:NOT)of 24 September 2009 on the protection of animals at the time of killing | | * *Rulebook on Protection of animals during killing or slaughtering* | | | * *III.2015* | * *III.2015* |
| **CHAPTER 11**  **ZOOTECHNICS** | | | | | | | |
| **I. Bovine animals** | | | | | | | |
|  | **Council** [**Directive 2009/157/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0157:EN:NOT)of 30 November 2009 on pure-bred breeding animals of the bovine species | | * **The Law of Livestock production**   **(OG MN 72/2010)**   * *Rulebook on pure-bred breeding animals of the bovine species* | | | * **2010** * *2015* * *II 2016* | * **2010** * *2015* * *II 2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31984D0247:EN:NOT"84/247/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31984D0247:EN:NOT) of 27 ApriL 1984 laying down the criteria for the recognition of breeders organizations and associations which maintain or establish herd-books for pure-bred breeding animals of the bovine species | | * *Regulation on e criteria for the recognition of breeders organizations and associations which maintain or establish herd-books for pure-bred breeding animals of the bovine species* | | | * *IV.2015* | * *IV.2015* |
|  | **Commission Decision 84/419/EEC laying** down the criteria for entering cattle in herd-books | | * *Rulebook on* *criteria for entering cattle in herd-books* | | | * *II.2016* | * *II.2016* |
|  | **Council** [**Directive 87/328/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987L0328:EN:NOT)of 18 June 1987 on the acceptance for breeding purposes of pure-bred breeding animals of the bovine species | | * *Rulebook breeding purposes of pure-bred breeding animals of the bovine species* | | | * *II.2016* | * *II.2016* |
|  | **Council** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0463:EN:NOT"96/463/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0463:EN:NOT)of 23 July 1996 designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species | | * *Rulebook on designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision 2005/379/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0379:EN:NOT)of 17 May 2005 on pedigree certificates and particulars for pure-bred breeding animals of the bovine species, their semen, ova and embryos | | * *Rulebook on pedigree certificates and particulars for pure-bred breeding animals of the bovine species, their semen, ova and embryos* | | | * *II 2016* | * *II 2016* |
|  | **Commission** [**Decision 2006/427/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0427:EN:NOT)of 20 June 2006 laying down performance monitoring methods and methods for assessing cattle's genetic value for pure-bred breeding animals of the bovine specie | | * *Regulation on performance monitoring methods and methods for assessing cattle's genetic value for pure-bred breeding animals of the bovine specie* | | | * *II 2016* | * *II 2016* |
| **II. Porcine animals** | | | | | | | |
|  | **Council** [**Directive HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0661:EN:NOT"88/661/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0661:EN:NOT)of 19 December 1988 on the zoo technical standards applicable to breeding animals of the porcine species | | * *Rulebook on the zoo technical standards applicable to breeding animals of the porcine species* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0501:EN:NOT"89/501/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0501:EN:NOT)of 18 July 1989 laying down the criteria for approval and supervision of breeders' associations and breeding organizations which establish or maintain herd-books for pure- bred breeding pigs | | * *Rulebook on criteria for approval and supervision of breeders associations and breeding organizations which establish or maintain herd-books for pure- bred breeding pigs* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0502:EN:NOT"89/502/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0502:EN:NOT) of 18 July 1989 laying down the criteria governing entry in herd-books for pure-bred breeding pigs | | * *Rulebook on the criteria governing entry in herd-books for pure-bred breeding pigs* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0503:EN:NOT"89/503/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0503:EN:NOT)of 18 July 1989 laying down the certificate of pure-bred breeding pigs, their semen, ova and embryos | | * *Rulebook on the model of the certificate certificate of pure-bred breeding pigs, their semen, ova and embryos* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0504:EN:NOT"89/504/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0504:EN:NOT)of 18 July 1989 laying down the criteria for approval and supervision of breeders associations, breeding organizations and private undertakings which establish or maintain registers for hybrid breeding pigs | | * *Regulation on the criteria for approval and supervision of breeders'associations, breeding organizations and private undertakings which establish or maintain registers for hybrid breeding pigs* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0505:EN:NOT"89/505/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0505:EN:NOT)of 18 July 1989 laying down the criteria governing entry in registers for hybrid breeding pigs | | * *Rulebook on criteria governing entry in registers for hybrid breeding pigs* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0506:EN:NOT"89/506/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0506:EN:NOT)of 18 July 1989 laying down the certificate of hybrid breeding pigs, their semen, ova and embryos | | * *Rulebook on the model of the certificate of hybrid breeding pigs, their semen, ova and embryos* | | | * *III.2017* | * *III.2017* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0507:EN:NOT"89/507/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989D0507:EN:NOT)of 18 July 1989 laying down methods for monitoring performance and assessing the genetic value of pure-bred and hybrid breeding pigs | | *Rulebook on methods for monitoring performance and assessing the genetic value of pure-bred and hybrid breeding pigs* | | | * *III.2017* | * *III.2017* |
|  | **Council** [**Directive HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0118:EN:NOT"90/118/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0118:EN:NOT) of 5 March 1990 on the acceptance of pure-bred breeding pigs for breeding | | * *Rulebook on acceptance of pure-bred breeding pigs for breeding* | | | * *III.2017* | * *III.2017* |
|  | **Council** [**Directive HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0119:EN:NOT"90/119/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0119:EN:NOT)of 5 March 1990 of hybrid breeding pigs for breeding | | * *Rulebook hybrid breeding pigs for breeding* | | | * *III.2017* | * *III.2017* |
| **III. Ovine and Caprine animals** | | | | | | | |
|  | **Council** [**Directive 89/361/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0361:EN:NOT)of 30 May 1989 concerning pure-bred breeding sheep and goats | | * *Rulebook on pure-bred breeding sheep and goats* | | | * *II.2016* | * *II 2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0254:EN:NOT"90/254/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0254:EN:NOT)of 10 May 1990 laying down the criteria for approval of breeders' organizations and associations which establish or maintain flock-books for pure-bred breeding sheep and goats | | * *Rulebook on conditions that must be met by breeding organization herdbooks for quality breeding sheep and goat* | | | * *III.2016* | * *III.2016* |
|  | **Commission** [**DHYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0255:EN:NOT"ecision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0255:EN:NOT"90/255/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0255:EN:NOT)of 10 May 1990 laying down the criteria governing entry in flock-books for pure-bred breeding sheep and goats | | * *Rulebook the criteria governing entry in flock-books for pure-bred breeding sheep and goats* | | | * *III.2016* | * *III.2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0256:EN:NOT"90/256/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0256:EN:NOT)of 10 May 1990 laying down methods for monitoring performance and assessing the genetic value of pure-bred breeding sheep and goats | | * *Rulebook the methods for monitoring performance and assessing the genetic value of pure-bred breeding sheep and goats* | | | * *III.2016* | * *III.2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0257:EN:NOT"90/257/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0257:EN:NOT) of 10 May 1990 laying down the criteria for the acceptance for breeding purposes of pure-bred breeding sheep and goats and the use of their semen, ova or embryos | | * *Rulebook criteria for the acceptance for breeding purposes of pure-bred breeding sheep and goats and the use of their semen, ova or embryos* | | | * *III.2016* | * *III.2016* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0258:EN:NOT"90/258/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0258:EN:NOT)of 10 May 1990 laying down the zootechnical certificates for pure-bred breeding sheep and goats, their semen, ova and embryos | | * *Rulebook on the* *the zootechnical certificates for pure-bred breeding sheep and goats, their semen, ova and embryos* | | | * *III.2016* | * *III.2016* |
| **IV. Equidae** | | | | | | | |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0353:EN:NOT"92/353/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0353:EN:NOT)of 11 June 1992 laying down the criteria for the approval or recognition of organizations and associations which maintain or establish stud-books for registered equidae | | * *Rulebook on the* *criteria for the approval or recognition of organizations and associations which maintain or establish stud-books for registered equidae* | | | * *III.2018* | * *IV.2018* |
|  | **Commission** [**Decision 92/354/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0354:EN:NOT)of 11 June 1992 laying down certain rules to ensure coordination between organizations and associations which maintain or establish stud-books for registered equidae | | * *Rulebook certain rules certain rules to ensure coordination between organizations and associations which maintain or establish stud-books for registered equidae* | | | * *III.2018* | * *IV.2018* |
|  | **Commission** [**Decision 96/78/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0078:EN:NOT)of 10 January 1996 laying down the criteria for entry and registration of equidae in stud-books for breeding purposes | | * *Rulebook on criteria criteria for entry and registration of equidae in stud-books for breeding purposes* | | | * *III.2018* | * *IV.2018* |
|  | **Commission** [**Decision 96/79/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0079:EN:NOT)of 12 January 1996 laying down the zootechnical certificates of semen, ova and embryos from registered equidae | | * *Rulebook on the zootechnical certificates of semen, ova and embryos from registered equidae* | | | * *III.2018* | * *IV.2018* |
| **V. Equidae intended for competition** | | | | | | | |
|  | **Council** [**Directive 90/428/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0428:EN:NOT)of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein. | | * *Rulebook on trade in equidae intended for competitions and laying down the conditions for participation therein.* | | | * *III.2018* | * *IV.2018* |
|  | **Commission** [**Decision HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0216:EN:NOT"92/216/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0216:EN:NOT)of 26 March 1992 on the collection of data concerning competitions for equidae as referred to in Article 4 (2) of Council Directive 90/428/EEC | | * *Rulebook on the collection of data concerning competitions for equidae* | | | * *III.2018* | * *IV.2018* |
| **VI. Other pure-bred animals** | | | | | | | |
|  | **Council** [**Directive 91/174/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0174:EN:NOT)of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals and amending Directives 77/504/EEC and 90/425/EEC | | * *Rulebook on zootechnical and pedigree requirements for the marketing of pure-bred animals* | | | * *III.2018* | * *IV.2018* |
| **VII. Imports from third countries** | | | | | | | |
|  | **Council** [**Directive 94/28/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0028:EN:NOT)of 23 June 1994 laying down the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species | | * *Rulebook on the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos* | | | * *II.2016* | * *II2016* |
|  | **Commission** [**Decision 96/509/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0509:EN:NOT)of 18 July 1996 laying down pedigree and zootechnical requirements for the importation of semen of certain animals | | * *Rulebook on pedigree and zootechnical requirements for the importation of semen of certain animals* | | | * *III.2017* | * *III2017* |
|  | **Commission** [**Decision 96/510/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996D0510:EN:NOT)of 18 July 1996 laying down the pedigree and zootechnical certificates for the importation of breeding animals, their semen, ova and embryos | | * *Ordinance on the pedigree and zootechnical certificates for the importation of breeding animals, their semen, ova and embryos* | | | * *III.2017* | * *III2017* |
| **CHAPTER 12**  **VETERINARY EXPENDITURES**  *At the day of accession* | | | | | | | |
| TITLE 3 PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS | | | | | | | |
| **CHAPTER 1**  **HYGIENE RULES** | | | | | | | |
|  | [**Regulation (EC) No 852/2004**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0852:EN:NOT)of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs | | * **Law on Food Safety**   **(OG MN 14/2007)**   * ***Rulebook on food hygiene***   **("OG MN" 14/2009)** | | | * **29.12.2007.** * **1.01.2009** * *2015* * *2016* | * **Partly implemented** * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 2073/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2073:EN:NOT)of 15 November 2005 on microbiological criteria for foodstuffs | | * **Rukebook on microbiological criteria for foodstuffs**   **(OG MN 53/2012)** | | | * **24.10.2012** * *2016* | * **Partly** **2.11.2012** * *2016* |
|  | **Commission** [**Regulation (EC) No 2074/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2074:EN:NOT)of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 | | * *Instruction for laying down implementing measures for certain products and for the organisation of official controls* | | | * *IV.2016* | * *IV.2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 210/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0210:EN:NOT)of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council | | * *Rulebook on approval of establishments producing sprouts* | | | * *IV.2017* | * *IV.2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 579/2014**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0579)of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea | | * *Rulebook as regards the transport of liquid oils and fats by sea* | | | * *IV.2018* | * *IV.2018* * *Fully implemented at the day of accession* |
| **CHAPTER 2**  **SPECIFIC RULES FOR ANIMAL PRODUCTS** | | | | | | | |
|  | [**Regulation (EC) No 853/2004**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0853:EN:NOT)of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin | | * **Rulebook on laying down specific hygiene rules for food of animal origin**   **("OG MN" 14/2009)** | | | * **1.01.2009** * *2015* * *I 2016* | * **9.01.2009** Partly * *2015* * *2016* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Regulation (EU) No 931/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0931:EN:NOT)of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin | | * *Rulebook on requirements traceability for food of animal origin* | | | * *III. 2016* | * *IV. 2016* |
|  | **Commission** [**Regulation (EU) No 101/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0101:EN:NOT)of 4 February 2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases | | * *Rulebook on the use of lactic acid to reduce microbiological surface contamination on bovine carcases* | | | * *IV .2016* | * *I. 2017* |
|  | **Commission** [**Regulation (EU) No 1079/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R1079:EN:NOT)of 31 October 2013 laying down transitional measures for the application of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council | | * *Rulebook on the special requirements for hygiene, criteria for determining small amounts manufacturer to the local market of small quantities of meat from poultry and lagomorphs slaughtered on the farm* | | | * *2015* | * *2015* |
|  | **Commission Implementing** [**Regulation (EU) No 636/2014**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0636)of 13 June 2014 on a model certificate for the trade of unskinned large wild game | |  | | |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **CHAPTER 3**  **CONTROL RULES** | | | | | | | |
|  | Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law,  animal health and animal welfare rules | | * **Law on Food Safety**   **(OG MN 14/2007)**   * **Veterinary Law**   **(OG MN 30/2012)**   * *New Law on Food Safety* * *Rulebooks for official controls* | | | * **2007 partly** * **2012 partly** * *2015* * *2018* | * **06.2012** * *2015* * *2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2006/677/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0677:EN:NOT)of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules | | * *Gguidelines laying down criteria for the conduct of audits* *on official controls to verify compliance with feed and food law, animal health and animal welfare rules* | | | * *II 2016* | * *II 2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2007/363/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0363:EN:NOT)of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council | | * *Guidelines in preparing the single integrated multi-annual national control plan* | | | * *I. 2017* | * *I.2017* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Regulation (EC) No 152/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0152:EN:NOT)of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed | | * *Rulebook on the methods of sampling and analysis for the official control of feed* | | | * *IV 2016* | * *IV 2016* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Regulation (EC) No 669/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0669:EN:NOT)of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC | | * *Rulebook on level of official controls on imports of certain feed and food of non-animal origin* | | | * *I. 2016* | * *I. 2016* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Regulation (EC) No 401/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0401:EN:NOT)of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs | | * *Rulebook on laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs* | | | * *IV.2016* | * *IV.2016* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Decision 2008/654/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0654:EN:NOT)of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council | | * *Instructions on guidelines for preparing the annual report on the single integrated multiannual national control plan* | | | * *I. 2017* | * *IV. 2017* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Regulation (EU) No 619/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0619:EN:NOT)of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired | | * *Rulebook on laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material* | | | * *IV. 2016* | * *IV. 2016* * *Fully implemented on the day of the accession* |
|  | **Commission** [**Regulation (EU) No 211/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0211:EN:NOT)of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts | | * *Rulebook on certification requirements for imports of sprouts and seeds intended for the production of sprouts* | | | * *II. 2018* | * *2018* * *Possible national measures of execution* * *Fully implemented on the day of the accession* |
| **CHAPTER 4**  **SPECIFIC CONTROL RULES FOR ANIMAL PRODUCTS** | | | | | | | |
|  | [**Regulation (EC) No 854/2004**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0854:EN:NOT)of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption | | * **Law on Food Safety**   **(OG MN 14/2007)**   * *New Law on Food Safety*   (2015)   * *Rulebook on the specific requirements for official controls on products of animal origin* * *Rulebook on amendments to the Ordinance on the specific requirements for official controls on products of animal origin* | | | Partly   * **21.12.2007** * **21.12.2012.** * **I.2015** * *IV.2015* * *I.2017* | Partly   * **29.12.2007.** * **1.01.2010.** * **1.01.2011.** * **I.2015** * *IV.2015* * *I.2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 2075/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2075:EN:NOT)of 5 December 2005 laying down specific rules on official controls for Trichinella in meat | | * *Rulebook on official control of Trichinella in meat* | | | * *IV.2015* | * *IV.2015* |
|  | **Council** [**Decision 92/608/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992D0608:EN:NOT)of 14 November 1992 laying down methods for the analysis and testing of heat-treated milk for direct human consumption | | * *Rulebook on laying down methods for the analysis and testing of heat-treated milk for direct human consumption* | | | * *II.2016* | * *II.2016* |
|  | **Commission** [**Regulation (EU) No**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0037:EN:NOT) **37/2010** of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin | | * **Rulebook on maximum levels of residues of pharmacologically active substances of veterinary medicines in animal products**   **(OG MN 41/14)** | | | * **3.10.2014** | * **11.10.2014** |
| **CHAPTER 5**  **RULES FOR ANIMAL BY-PRODUCTS** | | | | | | | |
|  | [Regulation (EC) No 1069/2009](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1069:EN:NOT) of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 | | * *Rulebook on the byproducts of animal origin* | | | * *2015* | * *2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 142/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0142:EN:NOT)of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive | | * *Rulebook on rules for the application of the Rules of the byproducts of animal origin* | | | * *2015* | * *2015* |
| **CHAPTER 6**  **FUNDING OF CHECKS** | | | | | | | |
| **CHAPTER 7**  **SPECIFIC RULES FOR FEED HYGIENE** | | | | | | | |
|  | [**Regulation (EC) No 183/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0183:EN:NOT)of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene | | * *Rulebook on the hygiene requirements for feed* | | | * *I 2016* | * *I 2016* * *Fully implemented at the day of accession* |
|  | Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category coccidiostats and histomonostats | | * *Rulebook on the requirements for the approval of production and marketing of additives from category coccidiostats and histomonostat* | | | * *I 2016* | * *I 2016* * *Fully implemented at the day of accession* |
| TITLE 4 FOOD SAFETY RULES | | | | | | | |
| **Chapter 1**  **Labelling** | | | | | | | |
|  | [**Regulation (EC) No 1924/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1924:EN:NOT)of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods | | * *Rulebook on nutrition and health claims made on foods* | | | * *III 2017* | * *III 2017* * *Fully implemented at the day of accession* |
|  | [**Regulation (EU) No 1169/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1169:EN:NOT)of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 Text with EEA relevance | | * *Rulebook on labeling, labeling, advertising and presentation of food of plant origin after primary production, composite and other food* | | | * *III 2017* | * *III 2017* * *Fully implemented at the day of accession* |
|  | [**Directive 2011/91/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0091:EN:NOT)of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs | | * *Rulebook on labeling, labeling, advertising and presentation of food of plant origin after primary production, composite and other food* | | | * *III 2017* | * *III 2017* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 353/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0353:EN:NOT)of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council | | * *Rulebook on nutrition and health claims*   *A list of allowed:*   * *health claims made on foods, other than those relating to the reduction of disease risk and to children's development and health:* * *of nutrition claims* * *health claim made on foods and referring to the reduction of disease risk* | | | * *III 2017* | * *III 2017* * *Fully implemented at the day of accession* |
|  | Commission Implementing [Regulation (EU) No 828/2014](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0828) of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food | | * *Rulebook requirements for the provision of information to consumers on the absence or reduced presence of gluten in food* | | | * *III 2016* | * *III 2016* * *Fully implemented at the day of accession* |
| **CHAPTER 2**  **ADDITIVES AUTHORISED AND PURITY CRITERIA** | | | | | | | |
|  | [**Regulation (EC) No 1331/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1331:EN:NOT)of the European Parliament and of the Council of 16 December 2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings | | * *Rulebook on for food additives, food enzymes and food flavorings* | | | * *III 2016* | * *III 2016* * *Fully implemented at the day of accession* |
|  | [**Regulation (EC) No 1333/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1333:EN:NOT)of the European Parliament and of the Council of 16 December 2008 on food additives | | * *Rulebook on for food additives, food enzymes and food flavorings with list of allowed food additives* | | | * *III 2016* | * *III 2016* * *Fully implemented at the day of accession* |
|  | Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners | | * *Rulebook on for food additives, food enzymes and food flavorings with list of allowed food additives* | | | * *III 2016* | * *III 2016* |
|  | **Commission** [**Regulation (EU) No 231/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0231:EN:NOT)of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Text with EEA relevance | | * *Rulebook on for food additives, food enzymes and food flavorings with list of allowed food additives* | | | * *III 2016* | * *III 2016* |
| **CHAPTER 3**  **FOOD ENZYMES** | | | | | | | |
|  | [**Regulation (EC) No 1332/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1332:EN:NOT)of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 | | * *Rulebook on enzymes used in food production* | | | * *I 2017* | * *I 2017* |
| **CHAPTER 4**  **EXTRACTION SOLVENTS** | | | | | | | |
|  | [**Directive 2009/32/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0032:EN:NOT)of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients | | * *Rulebook on on extraction solvents used in the production of foodstuffs and food ingredients* | | | * *I 2017* | * *I 2017* |
| **CHAPTER 5**  **FLAVOURINGS** | | | | | | | |
|  | [**Regulation (EC) No 2232/96**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R2232:EN:NOT)of the European Parliament and of the Council of 28 October 1996 **Articles 1 and 2, Article 3(1) and (2), and Article 4(1) and (2) of Regulation (EC) No 2232/96 and the Annex thereto shall continue to apply** to flavoring substances under evaluation pending their inclusion as evaluated substances in Part A of the Union list or their removal from that list)**Repealed by 32012R0872** | | | | * *Rulebook on flavourings* | * *IV 2016* | * *IV 2016* |
|  | [**Regulation (EC) N° 2065/2003**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R2065:EN:NOT)of the European Parliament and of the Council of 10 November on smoke flavourings used or intended for use in or on foods. | | | | * *Rulebook on flavourings* | * *IV 2016* | * *IV 2016* |
|  | [**Regulation (EC) No 1334/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1334:EN:NOT)of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC | | | | * *Rulebook on flavourings* | * *IV 2016* | * *IV 2016* |
|  | **Commission Implementing** [**Regulation (EU) No 872/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0872:EN:NOT)of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC | | | | * *Rulebook on flavourings with List of allowed flavourings* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EU) No 873/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0873:EN:NOT)of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council | | | | * *Rulebook on flavourings with List of allowed flavourings* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EU) No 907/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0907:EN:NOT)of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations) | | | | * *Rulebook on flavourings with List of allowed flavourings* | * *IV 2016* | * *IV 2016* |
|  | **Commission Implementing** [**Regulation (EU) No 1321/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R1321:EN:NOT)of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings | | | | * *Rulebook on flavourings with List of allowed flavourings* | * *IV 2016* | * *IV 2016* |
| **CHAPTER 6**  **FOOD CONTACT MATERIALS** | | | | | | | |
|  | [**Regulation 1935/2004/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R1935:EN:NOT)of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food | | | | * *Rulebook on materials and articles intended to come into contact with food* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EC) No 2023/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R2023:EN:NOT)of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food | | | | * *Rulebook good manufacturing practice for materials and articles intended to come into contact with food* | * *IV 2016* | * *IV 2016* |
|  | **Council** [**Directive 82/711/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0711:EN:NOT)of 18 October 1982 laying down the basic rules necessary for testing migration of the  constituents of plastic materials and articles intended to come into contact with foodstuffs | | | | * *Rulebook on basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs* | * *IV 2016* | * *IV 2016* |
|  | **Council** [**Directive 85/572/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31985L0572:EN:NOT)of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs | | | | * *List of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EU) No 10/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0010:EN:NOT)of 14 January 2011 on plastic materials and articles intended to come into contact with food | | | | * *Rulebook on plastic materials and articles intended to come into contact with food* | * *IV 2016* | * *IV 2016* |
|  | **Council** [**Directive 84/500/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31984L0500:EN:NOT)of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs | | | | * *Rulebook on relating to ceramic articles intended to come into contact with foodstuffs* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Directive 2007/42/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007L0042:EN:NOT)of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs | | | | * *Rulebook relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs* | * *IV 2016* | * *IV 2016* |
|  | **Council** [**Directive 78/142/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31978L0142:EN:NOT)of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs | | | | * *Rulebook relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs* | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Directive 93/11/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0011:EN:NOT)of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers | | * *Rulebook concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers* | | | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EC) No 1895/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R1895:EN:NOT)of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food | | * *Rulebook restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food* | | | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EC) No 450/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0450:EN:NOT)of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food | | * *Rulebook on active and intelligent materials and articles intended to come into contact with food* | | | * *IV 2016* | * *IV 2016* |
|  | **Commission** [**Regulation (EU) No 284/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0284:EN:NOT)of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People’s Republic of China and Hong Kong Special Administrative Region, China | | * *Ordinance specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People’s Republic of China and Hong Kong Special Administrative Region, China* | | | * *2015* | * *2015* |
| **CHAPTER 7**  **FOOD SUPPLEMENTS** | | | | | | | |
|  | [**Directive 2002/46/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0046:EN:NOT)of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements | | * *Rulebook on food supplements* | | | * *II 2016* | * *II 2016* |
|  | [**Regulation (EC) No 1925/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1925:EN:NOT)of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods | | * *Rulebook on addition of vitamins and minerals and of certain other substances to foods* | | | * *II 2016* | * *II 2016* |
|  | **Commission Implementing** [**Regulation (EU) No 307/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0307:EN:NOT)of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods | | | | * *Rulebook on the addition of vitamins and minerals and of certain other substances to foods* | * *II 2016* | * *II 2016* |
|  | **Commission Implementing** [**Regulation (EU) No 489/2012**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R0489:EN:NOT)of 8 June 2012 establishing implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods | | | | * *Rulebook on the addition of vitamins and minerals and of certain other substances to foods* | * *II 2016* | * *II 2016* |
| **CHAPTER 8**  **FOOD FOR PARTICULAR NUTRITIONAL USES** | | | | | | | |
|  | [**Regulation (EU) No 609/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0609:EN:NOT)of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 | | | | * *Rulebook on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control* | * *II 2017* | * *II 2017* |
| **CHAPTER 9**  **QUICK FROZEN FOODSTUFFS** | | | | | | | |
|  | **Council** [**Directive 89/108/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0108:EN:NOT)of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption | | | | * *Rulebook on quick-frozen foodstuffs for human consumption* | * *II 2018* | * *II 2018* |
|  | **Commission** [**Directive 92/2/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0002:EN:NOT)of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption | | | | * *Rulebook on the sampling procedure and method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption* | * *II 2018* | * *II 2018* |
|  | **Commission** [**Regulation (EC) No 37/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0037:EN:NOT)of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption | | | | * *Rulebook on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption* | * *II 2018* | * *II 2018* |
| **CHAPTER 10**  **CONTAMINANTS** | | | | | | | |
|  | **Council** [**Regulation (EEC) No 315/93**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993R0315:EN:NOT)of 8 February 1993 laying down Community procedures for contaminants in food | | | | * **Rulebook on permitted amounts of heavy metals, mycotoxins and other substances in food**   **OG MN 81/2009**   * *Rulebook on procedures for contaminants in food* | * **2009 partly** * *2015* | * **2009 partly** * *2015* |
|  | **Commission** [**Recommendation 2003/598/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003H0598:EN:NOT)of 11 August on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages | | | | * *Instruction* on *the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages* | * *II 2016* | * *II 2016* |
|  | **Commission** [**Recommendation HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006H0794:EN:NOT"2006/794/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006H0794:EN:NOT)of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs | | | | * *Monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs* | * *II 2016* | * *II 2016* |
|  | **Commission** [**Regulation (EC) No 1881/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT)of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs | | | | * **Rulebook on permitted amounts of heavy metals, mycotoxins and other substances in food**   **OG MN 81/2009**  The monitoring program for nitrate in plant foods - leafy vegetables for 2010,2011, 2012, 2013, 2014. 2015  OG MN12/2010, 8/2011, 28/2012, 28/2013, 16/2014(Aneks Regulative komisije (EC) br. 1881/2006 Sekcija I Nitrati)   * *Rulebook on amendments to the rulebook on permitted amounts of heavy metals, mycotoxins and other substances in food* | * **8.12.2009.** * **5.3.2010.** * **1.2.2011.** * **1.6.2012.** * **14.6.2013.** * **28.3.2014.** * *2015* | * **16.12.2009.** * **13.3.2010.** * **9.2.2011.** * **9.6.2012.** * **22.6.2013.** * **7.4.2014.** * *2015* |
|  | **Commission** [**Regulation (EC) No 1882/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1882:EN:NOT)of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs | | | | * **Rulebook on detailed manner and procedure for taking samples for laboratory testing of lettuce or spinach nitrate**   **OG MN 6/2014** | * **4.2.2014.** | * **12.2.2014.** |
|  | **Commission** [**Regulation (EC) No 333/2007**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007R0333:EN:NOT)of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs | | | | * *Rulebook on the manner of methods of sampling and analysis of lead, cadmium, mercury, tin, 3 - MCPD and benzo (a) pyrene in foodstuffs* | * *I 2016* | * *I 2016* |
|  | **Commission** [**Regulation (EC) No 124/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0214:EN:NOT)of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed | | | | * *Rulebook on determining the maximum allowable amount of coccidiostats or histomonostats in food resulting from the unavoidable transporting these substances in non-target feed* | * *I 2018* | * *I 2018* |
|  | **Commission** [**Regulation (EU) No 589/2014**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0589)of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012 | | | | * *Rules on the sampling methods for the control of levels of dioxins, dioxin-like PCBs and PCB s which are not similar to dioxin in food* | * *II 2016* | * *II 2016* |
| **CHAPTER 11**  **NOVEL FOODS** | | | | | | | |
|  | [**Regulation (EC) No 258/97**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997R0258)of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients | | | | * *Rulebook on novel foods and novel food ingredients with List of authoriyed novel foods and novel food ingredients* | * *II 2018* | * *II 2018* |
| **CHAPTER 12**  **IONISING RADIATION** | | | | | | | |
|  | [**Directive 1999/2/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0002:EN:NOT)of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation | | | | * *Rulebook on foods and food ingredients treated with ionising radiation* | * *III 2018* | * *III 2018* |
|  | [**Directive 1999/3/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0003:EN:NOT)of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation | | | | * *List of foods and food ingredients treated with ionising radiation* | * *III 2018* | * *III 2018* |
|  | **Commission** [**Decision 2002/840/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0840:EN:NOT)of 23 October 2002 adopting the list of approved facilities in third countries for the irradiation of foods | | | | * *List of of approved facilities in third countries for the irradiation of foods* | * *III 2018* | * *III 2018* |
| **CHAPTER 13**  **MINERAL WATERS** | | | | | | | |
|  | [**Directive 2009/54/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0054:EN:NOT)of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters | | | | * **Rulebook on the exploitation and marketing of natural mineral waters**   **(OG MN 32/2015)** | * **2015** | * **2015** * *2017* |
|  | **Commission** [**Directive 2003/40/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0040:EN:NOT)of 16 May 2003 establishing the list, concentration limits and labeling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters | | | | * **Rulebook on the exploitation and marketing of natural mineral waters**   **(OG MN 32/2015)** | * **2015** | * **2015** * *2017* |
|  | **Commission** [**Regulation (EU) No 115/2010**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010R0115:EN:NOT)of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters | | | | * **Rulebook on the exploitation and marketing of natural mineral waters**   **(OG MN 32/2015)**   * *Rulebook the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters* | * *2015 partly* * *2016* | * ***2015*** |
| TITLE 5 SPECIFIC RULES FOR FEED | | | | | | | |
|  | [**Regulation (EC) No 767/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0767:EN:NOT)of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC | | | | * *Rulebook on on the placing on the market and use of feed* | * *III 2016* | * *III 2016* |
|  | **Commission** [**Directive 82/475/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0475:EN:NOT)of 23 June 1982 laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals | | | | * *Rulebook on on categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals* | * *III 2017* | * *III 2017* |
|  | **Commission** [**Directive 2008/38/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0038:EN:NOT)of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes | | | | * *Rulebook on on list of intended uses of animal feedingstuffs for particular nutritional purposes* | * *III 2017* | * *III 2017* |
|  | **Commission** [**Recommendation 2011/25/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011H0025:EN:NOT)of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products | | | | * *Guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products* | * *III 2017* | * *III 2017* |
|  | **Commission** [**Regulation (EU) No 68/2013**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013R0068:EN:NOT)of 16 January 2013 on the Catalogue of feed materials | | | | * *List of feed materials* | * *III 2017* | * *III 2017* |
| **Chapter 2**  **Feed Additives** | | | | | | | |
|  | [**Regulation (EC) No 1831/2003**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1831:EN:NOT)of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition | | | | * *List of additives for use in animal nutrition* | * *III 2017* | * *III 2017* |
|  | [**List of the authorised additives**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52004XC0225%2803%29:EN:NOT)in feedingstuffs published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in  and all Application Text(s) | | | | * *List of additives for use in animal nutrition* | * *III 2017* | * *III 2017* |
|  | **Commission** [**Regulation (EC) No 378/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0378:EN:NOT)of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives | | | |  |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
| **Chapter 3**  **Undesirable Substances** | | | | | | | |
|  | [**Directive 2002/32/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0032:EN:NOT)of the European Parliament and the Council of 7 May 2002 on undesirable substances in animal feed | | | | * **Rulebook on maximum permited quantities of undesidable substances in animal feed**   **(OGMN 15/15)** | * **2015** * *III.2017* | * **2015** * *III.2017* |
|  | **Commission** [**Recommendation HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006H0088:EN:NOT"2006/88/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006H0088:EN:NOT)of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs | | | | * *Rulebook on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs* | * *III 2017* | * *III 2017* |
|  | **COMMISSION RECOMMENDATION**  of 11 October 2004  on the monitoring of background levels of dioxins and dioxin-like PCBs in feedingstuffs | | | | * *Monitoring of background levels of dioxins and dioxin-like PCBs in feedingstuffs* | * *III 2017* | * *III 2017* |
| **CHAPTER 4**  **MEDICATED FEED** | | | | | | | |
|  | Council [Directive 90/167/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0167:EN:NOT) of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community | | | | * *Rulebook on the conditions governing the preparation, placing on the market and use of medicated feedingstuffs* | * *III 2017* | * *III 2017* |
| TITLE 6 PHYTOSANITARY | | | | | | | |
| **Chapter 1**  **Plant Health – Harmful Organisms** | | | | | | | |
|  | **Council** [**Directive 2000/29/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000L0029:EN:NOT)of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community | | | | * **Law on Plant Health Protection as amended**   **(OG MNbr. 28/2006)**   * **Rulebook on measures to prevent the introduction, spread and suppression of harmful organisms and and the lists of harmful organisms, plant products and regulated objects**   **(OGMN 39/2011)**   * **Rulebook on fees for phytosanitary inspection of plants, plant products and regulated object**   **(OG MN 15/2014)**   * *2015* | * **03.05.2006.** * **10.06.2011.** * **04.08.2011.** * **25.03.2014.** * *2015* | * **11.05.2006.** * **18.06.2011.** * **04.02.2012.** * **1. 01. 2013.** * **21.09.2014.** * *2015* * *Fully implemented at the day of accession* |
|  | **Commission Regulation (EC) No 1756/2004** of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC | | | | * *Rulebook of a specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V* | * *IV 2018* | * *IV 2018* * *Fully implemented at the day of accession* |
|  | **Commission** [**Directive 2004/103/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0103:EN:NOT) of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks | | | | * *Rulebook of a identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks* | * *IV 2015* | * *IV 2017* * *Fully implemented at the day of accession* |
| **II. Specific control measures** | | | | | | | |
|  | **Council** [**Directive 69/464/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31969L0464:EN:NOT) of 8 December 1969 on control of Potato Wart Disease | | | | * **Rulebook on phytosanitary measures for the detection, prevention of the spread and eradication of the *Synchytrium Endobioticum* (Schilb.) Perc., causes cancer of potato**   **(OG MN 15/2010)** | * **23.03. 2010** | * **29.03. 2010** |
|  | **Council** [**Directive 74/647/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31974L0647:EN:NOT) of 9 December 1974 on control of carnation leaf-rollers | | | | * **Rulebook on phytosanitary measures to prevent the introduction, spread and eradicate moth carnations (*Cacoecimorpha Pronubana* hb. and *Epichoristodes Acerbella* (walk.) diak.)**   **(OG MN 20/2012)** | * **12.04.2012.** | * **20.04.2014** |
|  | **Council** [**Directive 93/85HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0085:EN:NOT"/HYPERLINK "http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0085:EN:NOT"EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0085:EN:NOT) of 4 October 1993 on control of Potato Ring Rot | | | | * **Rulebook on phytosanitary measures for the to prevent the introduction, spread and eradicate of potato ring rot (Potato ring rot) caused by bacteria *Clavibacter michiganensis***   **(OG MN 66/2010)** | * **19.11.2010.** | * **27.11.2010.** |
|  | **Council** [**Directive 98/57/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0057:EN:NOT) of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi *et al*. | | | | * **Rulebook on phytosanitary measures for the to prevent the introduction, spread and eradicate brown rot in potato tubers and of bacterial wilting of potato and tomato (Potato brown rot) caused by bacteria *Ralstonia solanacearum* (Smith) Yabuuchi et al.**   **(OG MN 67/2010)** | * **24.11.2010** | * **02.12.2010** |
|  | **Council** [**Directive 2006/91/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0091:EN:NOT)of 7 November 2006 on control of San José Scale | | | | * **Rulebook on phytosanitary measures to prevent the introduction, spread and eradicate Quadraspidiotus perniciosus Comst. (San José Scale)**   **(OG MN 48/2014)** | * **13.11.2014.** | * **21.11.2014.** |
|  | **Council** [**Directive 2007/33/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007L0033:EN:NOT)of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC | | | | * **Rulebook on phytosanitary measures for to prevent the introduction, spread and eradicate of potato cyst nematodes**   **(OG MN 43/2010)** | * **29.07.2010.** * **19.4.2013.** | * **6.08.2010.** * **27.4.2013.** |
|  | **Commission Implementing** [**Decision 2015/789/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014D0497)of 18 May 2015 as regards measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread and suppression *Xylella fastidiosa***   **(OG MN 24/2015)**   * *2015* | * **11.05.2015.** * *2015* | * **19.05.2015.** * *2015* |
|  | **Commission** [**Decision 2002/757/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0757:EN:NOT) of 19 September 2002 on provisional emergency phytosanitary measures to prevent the introduction into and the spread within the Community of *Phytophthora ramorum* Werres, De Cock & Man in 't Veld sp. Nov | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread and suppression *Phytophthora ramorum* Werres, De Cock & Man in ‘t Veld sp. nov.**   **(OG MN 11/2012)** | * **22.02.2012.** | * **01.03.2012** * **01.01.2013.** |
|  | **Commission** [**Decision 2004/200/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0200:EN:NOT) of 27 February 2004 on measures to prevent the introduction into and the spread within the Community of Pepino mosaic virus | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread and suppression pepino mosaic virus)**   **(OG MN 54/2011)** | * **17.11.2011.** | * **25.11.2011** |
|  | **Commission** [**Decision 2007/365/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0365:EN:NOT) of 25 May 2007 on emergency measures to prevent the introduction into and the spread within the Community of *Rhynchophorus ferrugineus* (Olivier) | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread and suppression *Rhynchophorus ferrugineus* (Oliver)**   **(OG MN 54/2012)**   * **The action plan for the eradication and control red palm weevil - *Rhynchophorus ferrugineus* (Oliver) (novembar 2012 do novembar 2015)**   **(OG MN 60/2012)**   * **The action plan for the eradication and control red palm weevil - Rhynchophorus ferrugineus (Oliver) (novembar 2012. do novembra 2015.)**   **(OG MN 61/13)**   * **Order on conducting emergency phytosanitary measures to prevent the introduction and spread of the red palm weevil Rhynchophorus ferrugineus (Oliver)**   **(OG MN 9/2015)**   * **Order on conducting emergency phytosanitary measures to prevent the spread and prevention of the red palm weevil Rhynchophorus ferrugineus (Oliver)**   **(OG MN 18/2015)** | * **26.10.2012.** * **30.11.2012.** * **30.12.2013.** * **05.03.2015.** * **20.04.2015.** | * **03.08.2012.** * **08.12.2012.** * **07.01.2014.** * **13.03.2015.** * **28.04.2015.** |
|  | **Commission** [**Decision 2007/410/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0410:EN:NOT) of 12 June 2007 on measures to prevent the introduction into and the spread within the Community of Potato spindle tuber viroid | | | | * **Rulebook on phytosanitary measures for the eradication and suppression**   **potato spindle tuber viroid**  **(OG MN 56/2011)** | * **25.11.2011.** | * **03.12.2011.** * **01.01.2013.** |
|  | **Commission** [**Decision 2007/433/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0433:EN:NOT) of 18 June 2007 on provisional emergency measures to prevent the introduction into and the spread within the Community of *Gibberella circinata* Nirenberg | | | | * **Rulebook on phytosanitary measures for the eradication and suppression**   ***Gibberella circinata* Nirenberg & O´Donnell**  **(OG MN 21/2012)** | * **18.04.2012.** | * **18.04.2012.** * **01.01.2013.** |
|  | **Commission Implementing** [**Decision 2012/138/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0138:EN:NOT) of 1 March 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of *Anoplophora chinensis* (Forster) | | | | * **Rulebook on phytosanitary measures for the eradication and suppression**   ***Anoplophora chinensis* (Forster)**  **(OG MN 11/2012)** | * **22.02.2012.** * *2015* | * **01.03.2012.** * *2015* |
|  | **Commission Implementing Decision (EU) 2015/893** of 9 June 2015 as regards measures to prevent the introduction into and the spread within the Union of *Anoplophora glabripennis* (Motschulsky) | | | | * **The Program of phytosanitary measures for 2014, 2015 -** **Official survey *Anoplophora glabripennis* (Motschulsky)** * *Rulebook on phytosanitary measures for the eradication and suppression*   *Anoplophora glabripennis (Motschulsky)* | * **2014** * **2015** * *2017* | * **2014** * **2015** * *2017* |
|  | **Commission Implementing** [**Decision 2012/270/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0270:EN:NOT) of 16 May 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of *Epitrix cucumeris* (Harris), *Epitrix similaris* (Gentner), *Epitrix subcrinita* (Lec.) and *Epitrix tuberis* (Gentner) | | | | * **The Program of phytosanitary measures for 2014, 2015 - Official survey of Epitrix cucumeris (Harris), Epitrix similaris (Gentner), Epitrix subcrinita (Lec.) and Epitrix tuberis (Gentner)** * *Rulebook on phytosanitary measures for the eradication and suppression*   *Epitrix cucumeris (Harris), Epitrix similaris (Gentner), Epitrix subcrinita (Lec.) i Epitrix tuberis (Gentner)* | * **2014** * **2015** * *VI 2017* | * **2014** * **2015** * *VI 2017* |
|  | **Commission Implementing** [**Decision 2012/535/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0535:EN:NOT) of 26 September 2012 on emergency measures to prevent the spread within the Union of *Bursaphelenchus xylophilus* (Steiner et Buhrer) Nickle *et al*. (the pine wood nematode) | | | | * **Rulebook on phytosanitary measures for the eradication and suppression *Bursaphelenchus xylophilus* (Steiner et Buhrer) Nickle et al.**   **(OG MN 12/2014)** | * **07.03.2014** | * **15.03.2014** |
|  | **Commission Implementing** [**Decision 2012/697/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0697:EN:NOT) of 8 November 2012 as regards measures to prevent the introduction into and the spread within the Union of the genus Pomacea (Perry) | | | | * *Rulebook on phytosanitary measures for the eradication and suppression genus Pomacea (Perry)* | * *VI 2017* | * *VI 2017* |
|  | **Commission** [**Recommendation 2014/63/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014H0063) of 6 February 2014 on measures to control *Diabrotica virgifera virgifera* Le Conte in Union areas where its presence is confirmed | | | | * **Recommendation measures to control *Diabrotica virgifera virgifera* Le Conte in areas where its presence is confirmed**   **(OG MN 47/2014)** | * **07.11.2014** | * **16.11.2014** |
| **III. Protected zones** | | | | | | | |
| **Application texts** | | | | | | | |
|  | **Commission** [**Directive 92/70/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0070:EN:NOT) of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community | | | | * **Rulebook on measures to prevent the introduction, spread and suppression of harmful organisms and and the lists of harmful organisms, plant products and regulated objects**   **(OGMN 39/2011)**   * R*ulebook on detailed rules for surveys to be carried out for purposes of the recognition of protected zones* | * **04.08.2011.** * *IV 2016* | * **04.02.2012.** * *IV 2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Directive 93/51/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0051:EN:NOT) of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone | | | | * *Rulebook on rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone* | * *IV 2016* | * *IV 2016* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 690/2008**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0690:EN:NOT) of 4 July 2008 recognizing protected zones exposed to particular plant health risks in the Community | | | | * **Rulebook on measures to prevent the introduction, spread and suppression of harmful organisms and the lists of harmful organisms, plant products and regulated objects**   **(OGMN 39/2011)**   * *List of Protected Areas* | * **04.08.2011.** * *IV 2016* | * **04.02.2012.** * *IV 2016* * *Fully implemented at the day of accession* |
| **IV. Registration of operators - Plant passports** | | | | | | | |
|  | **Commission** [**Directive 92/90/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0090:EN:NOT) of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration | | | | * **Regulation on obligation for registration of producers, processors, importers, distributors and store plants, plant products and regulated objects**   **(OG MN 15/2013)**   * **Rulebook on the manner of keeping records of production, processing and trade in plants, plant products and regulated object**   **(OG MN 19/2013)** | * **22.03.2013.** * **19.04.2013.** | * **30.03.2013.** * **27.04.2013.** |
|  | **Commission** [**Directive 92/105/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0105:EN:NOT) of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement | | | | * *Rulebook on for plant passports to be used for the movement of certain plants, plant products or other objects* | * *IV 2015* | * *IV 2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Directive 93/50/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0050:EN:NOT) of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register | | | | * **Rulebook on conditions for registration of producers, processors, importers, distributors and store plants, plant products and regulated *(OG MN 15/2013)*** * **Rulebook on the manner of keeping records of production, processing and trade in plants, plant products and regulated object**   **(OG MN 19/2013)**   * **Rulebook amending the Ordinance on the manner of keeping records of production, processing and trade in plants, plant products and regulated object**   **(OG MN 39/2013)** | * **22.03.2013.** * **19.04.2013.** * **07.08.2013.** | * **30.03.2013.** * **26.04.2013** * **15.08.2013.** |
| **V. Import from third countries** | | | | | | | |
|  | **Commission** [**Decision 91/261/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991D0261:EN:NOT) of 2 May 1991 recognizing Australia as being free from *Erwinia amylovora* (Burr.) Winsl. *et al*. | | | |  |  | * *Possible national measures of execution* * *Fully implemented at the day of accession* |
|  | Commission [Decision 98/109/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998D0109:EN:NOT) of 2 February 1998 authorising Member States temporarily to take emergency measures against the dissemination of *Thrips palmi* Karny as regards Thailand | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread *Thrips* palmi *Karny* from Tajlanda**   **(OG MN 56/2011)** | * **25.11.2011.** | * **03.12.2011.** |
|  | **Commission** [**Directive 2004/105/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0105:EN:NOT) of 15 October 2004 determining the models of official phytosanitary certificates or phytosanitary certificates for re-export accompanying plants, plant products or other objects from third countries and listed in Council Directive 2000/29/EC | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread and control of harmful organisms and lists of harmful organisms, plants, plant products and regulated**   **(OG MN 39/2011)** | * **04.08.2011.** | * **12.08.2011.**   **04.02.2012.** |
|  | **Commission** [**Decision 2006/473/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006D0473:EN:NOT) of 5 July 2006 recognising certain third countries and certain areas of third countries as being free from Xanthomonas campestris (all strains pathogenic to Citrus), Cercospora angolensis Carv. et Mendes and Guignardia citricarpa Kiely | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread Xanthomonas campestris, Cercospora angolensis Carv.et Mendes i Guignardia citricarpa** Kiely   **(OG MN 19/2014)** | * **17.04.2014.** | * **25.04.2014.** |
|  | **Commission Implementing** [**Decision 2011/787/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0787:EN:NOT) of 29 November 2011 authorising Member States temporarily to take emergency measures against the dissemination of *Ralstonia solanacearum* (Smith) Yabuuchi *et al*. as regards Egypt | | | | * **Order prohibiting the introduction of tubers of potatoes originating in Egypt**   **(OG MN 27/2014)**   * **Rulebook on phytosanitary measures to prevent the introduction and spread bakterije *Ralstonia solanacearum* (Smith) Yabuuchi at al.**   **(OG MN 31/2014)** | * **30.06.2014** * **24.07.2014** | * **07.07.2014** * **31.07.2014** |
|  | **Commission Implementing** [**Decision 2012/219/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0787:EN:NOT) of 24 April 2012 recognising Serbia as being free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckerman and Kotthoff) Davis *et al*. | | | | * **Rulebook on phytosanitary measures to prevent the introduction and spread Clavibacter michiganensis ssp. Sepedonicus (Spieckermann et Kotthoff) Davis et all.**   **(OG MN 41/2014)** | * **03.10.2014.** | * **10.10.2014.** |
|  | **Commission Implementing** [**Decision 2012/756/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0756:EN:NOT) of 5 December 2012 as regards measures to prevent the introduction into and the spread within the Union of *Pseudomonas syringae* pv. *actinidiae* Takikawa, Serizawa, Ichikawa, Tsuyumu & Goto | | | | * **The Program of phytosanitary measures for 2014, 2015 - Official survey of** ***Pseudomonas syringae* pv. *actinidiae* Takikawa, Serizawa, Ichikawa, Tsuyumu & Goto** * *Rulebook on phytosanitary measures to prevent the introduction and spread Pseudomonas syringae pv. actinidiae Takikawa, Serizawa, Ichikawa, Tsuyumu & Goto* | * **2014** * **2015** * *IV 2018* | * **2014** * **2015** * *IV 2018* |
|  | **Commission Implementing** [**Decision 2013/92/EU**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32013D0192:EN:NOT) of 18 February 2013 on the supervision, plant health checks and measures to be taken on wood packaging material actually in use in the transport of specified commodities originating in China | | | | * **Rulebook on phytosanitary measures for wood packaging material in international trade**   **(OG MN 4/2010)**   * **The Program of phytosanitary measures for 2014, 2015 - Official survey of on wood packaging material actually in use in the transport of specified commodities originating in China** | * **24.01.2010.** * **2014** * **2015** * *2016* | * **2.02.2010.** * **2014** * **2015** * *2016* |
|  | **Commission Implementing** [**Decision 2014/237/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014D0237) of 24 April 2014 on measures to prevent the introduction into and the spread within the Union of harmful organisms as regards certain fruits and vegetables originating in India | | | | * *Rulebook on phytosanitary measures to prevent the introduction into and the spread of harmful organisms as regards certain fruits and vegetables originating in India* | * *IV 2018* | * *IV 2018* |
|  | **Commission Implementing** [**Decision 2014/422/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014D0422) of 2 July 2014 setting out measures in respect of certain citrus fruits originating in South Africa to prevent the introduction into and the spread within the Union of *Phyllosticta* *citricarpa* (McAlpine) Van der Aa | | | | * *Rulebook on phytosanitary measures to prevent the introduction and spread of Phyllosticta citricicarpa in respect of certain citrus fruit native to South Africa* | * *IV 2018* | * *IV 2018* |
|  | **Commission** [**Decision 2004/416/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0416:EN:NOT)of 29 April 2004 on temporary emergency measures in respect of certain citrus fruits originating in Argentina or Brazil | | | | * **Rulebook on phytosanitary measures to the introduction into and the spread of harmful organisms*****Guignardia citricarpa* Kiely**   **(OG MN 29/2014)** | * **08.07.2014.** | * **16.07.2014.** |
| **VI. Inspections and notification of interception** | | | | | | | |
|  | **Commission** [**Directive 94/3/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0003:EN:NOT) of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger | | | | * *Rulebook on the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger* | * *IV 2015* | * *IV 2015* * *Fully implemented at the day of accession* |
|  | **Commission** [**Directive 98/22/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0022:EN:NOT) of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries | | | | * **Rulebook on technical requirements at border crossings for phytosanitary inspection of plants**   **(OG MN 14/2012)** | * **07.03.2012.** | * **15.03.2012.** * *Fully implemented at the day of accession* |
|  | **Commission** [**Directive 2008/61/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0061:EN:NOT) of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections | | | | * **Regulation on conditions and manner of issuing licenses for the introduction of harmful organisms, plants, plant products and regulated articles for essays, research purposes or for work on varietal selections**   **(OG MN 55/2013)** | * **29.11.2013.** | * **07.12.2013.** |
|  | **Commission Implementing** [**Decision 2014/917/EU**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014D0917) of 15 December 2014 setting out detailed rules for the implementation of Council Directive 2000/29/EC as regards the notification of the presence of harmful organisms and of measures taken or intended to be taken by the Member States | | | | * *Rulebook on the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger* | * *IV 2016* | * *IV 2016* * *Fully implemented at the day of accession* |
| **CHAPTER 2**  **PLANT HEALTH – PLANT PROTECTION PRODUCTS** | | | | | | | |
| **Registration** | | | | | | | |
|  | [**Regulation (EC) No 1107/2009**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1107:EN:NOT) of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC | | | | * **Law on plant protection products as amended**   **(OG MN 51/2008)**   * **Rulebook on the content of the list of active substances authorized for use in plant protection products**   **(OG MN 67/2009)**   * **Rulebook on the rules of good agricultural practice for the plant protection**   **(OG MN 45/2014)** | * **Partly**   **2008**  **2009**  **2012**  **2014**  **24.10.2014.**   * *2015* | * **Partialy implemented**   **2008**  **2012**  **2014**  **01.11.2014.**  *2015*   * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EU) No 188/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0188:EN:NOT) of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive | | | |  |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission Implementing** [**Regulation (EU) No 540/2011**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0540:EN:NOT) of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances | | | | * **List of active substances allowed for use in Plant Protection Products**   **(OG MN 3/2015)** | * **2009-2014** * **2015** | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission** [**Decision 2007/322/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0322:EN:NOT) of 4 May 2007 laying down protective measures concerning uses of plant protection products containing tolylfluanid leading to the contamination of drinking water | | | |  |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| **Sustainable use** | | | | | | | |
|  | [**Directive 2009/128/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0128:EN:NOT) of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides | | | | * **Law on plant protection products as amended**   **(OG MN 51/2008)**   * **Rulebook on detailed conditions of space for storage and transport of pesticides**   **(OG MN 15/2013)**  **Rulebook on the content and method of keeping records on the use of plant protection products**  **(OG MN 24/2013)**   * **Rulebook on the rules of good agricultural practice for the plant protection**   **(OG MN 3/2015)** | * **24.10.2014.** | * **01.10.2014.** |
| **II. Pesticide residues** | | | | | | | |
|  | [**Regulation (EC) No 396/2005**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R0396:EN:NOT) of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC | | | | * **Rulebook on maximum level reyidua of pesticides in or on plants, plant products, food or feed**   **(OG MN 21/2015)** | * **29.04.2015.** | * **07.05.2015.** |
|  | **Commission** [**Regulation (EC) No 645/2000**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000R0645:EN:NOT) of 28 March 2000 setting out detailed implementing rules necessary for the proper functioning of certain provisions of Article 7 of Council Directive 86/362/EEC and of Article 4 of Council Directive 90/642/EEC concerning the arrangements for monitoring the maximum levels of pesticide residues in and on cereals and products of plant origin, including fruit and vegetables, respectively | | | | * **The monitoring program for pesticide residues in and on food of plant and animal origin** | * **2009** * **2010** * **2011** * **2012** * **2013** * **2014** * **2015** | * **2009** * **2010** * **2011** * **2012** * **2013** * **2014** * **2015** |
|  | **Commission** [**Directive 2002/63/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0063:EN:NOT) of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC | | | | * **Rulebook on sampling methods for determining residues of pesticides**   **(OG MN 21/2015)** | * **13.11.2014.** | * **11.05.2015.** |
|  | **Commission Implementing** [**Regulation (EU) No 400/2014**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014R0400) of 22 April 2014 concerning a coordinated multiannual control programme of the Union for 2015, 2016 and 2017 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin | | | | * **The monitoring program for pesticide residues in and on food of plant and animal origin** | * **2009** * **2010** * **2011** * **2012** * **2013** * **2014** * **2015** | * **2009** * **2010** * **2011** * **2012** * **2013** * **2014** * **2015** |
| **CHAPTER 3**  **QUALITY OF SEEDS AND PROPAGATING MATERIAL** | | | | | | | |
| **Fodder Plants** | | | | | | | |
|  | **Council** [**Directive 66/401/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31966L0401:EN:NOT) of 14 June 1966 on the marketing of fodder plant seed | | | | * *Rulebook on marketing of fodder plant seed* | * *I 2018* | * *I 2018* |
| Cereals | | | | | | | |
|  | **Council** [**Directive 66/402/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31966L0402:EN:NOT) of 14 June 1966 on the marketing of cereal seed | | | | * **Rulebook on marketing of cereal seed**   **(OG MN 13/2014)** | * **14.03.2014.** | * **22.03.2014.** |
| **Vine** | | | | | | | |
|  | **Council** [**Directive 68/193/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31968L0193:EN:NOT) of 9 April 1968 on the marketing of material for the vegetative propagation of the vine | | | | * *Rulebook on marketing material for the vegetative propagation of the vine* | * *IV 2015* | * *IV 2015* |
| **Vegetable propagating and planting material** | | | | | | | |
|  | **Council** [**Directive 2008/72/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0072:EN:NOT) of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed | | | | * *Rulebook on the marketing of vegetable propagating and planting material, other than seed* | * *2015* | * *2015* |
| **Fruit plants** | | | | | | | |
|  | **Council** [**Directive 2008/90/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0090:EN:NOT)of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production | | | | * *Rulebook on marketing of fruit plant propagating material and fruit plants intended for fruit production* | * *IV 2016* | * *IV 2016* |
| **Ornamental plants** | | | | | | | |
|  | **Council** [**Directive 98/56/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0056:EN:NOT) of 20 July 1998 on the marketing of propagating material of ornamental plants | | | | * *Rulebook on marketing of propagating material of ornamental plants* | * *II 2016* | * *II 2016* |
| **Forest reproductive material** | | | | | | | |
|  | **Council** [**Directive 1999/105/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0105:EN:NOT) of 22 December 1999 on the marketing of forest reproductive material | | | | * **Law on forest reproductive material**   **(OG MN 37/2007)** | * **2007** * *2015* | * **2007** * *2015* |
| Catalogue of varieties of agricultural plants | | | | | | | |
|  | **Council** [**Directive 2002/53/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0053:EN:NOT) of 13 June 2002 on the common catalogue of varieties of agricultural plant species | | | |  |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| **Beet seed** | | | | | | | |
|  | **Council** [**Directive 2002/54/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0054:EN:NOT) of 13 June 2002 on the marketing of beet seed | | | | * *Rulebook on marketing of* of *beet seed* | * *IV 2017* | * *IV 2017* |
| Vegetable seed | | | | | | | |
|  | **Council** [**Directive 2002/55/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0055:EN:NOT)of 13 June 2002 on the marketing of vegetable seed | | | | * *Rulebook on marketing of vegetable seed* | * *II 2017* | * *II 2017* |
| Seed potatoes | | | | | | | |
|  | **Council** [**Directive 2002/56/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0056:EN:NOT) of 13 June 2002 on the marketing of seed potatoes | | | | * **Rulebook on marketing of seed potatoes**   **(OG MN 8/2015)** | * **27.02.2015.** | * **7.03.2015.** |
| **Oil and fibre plants** | | | | | | | |
|  | **Council** [**Directive 2002/57/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0057:EN:NOT) of 13 June 2002 on the marketing of seed of oil and fibre plants | | | | * *Rulebook on marketing of marketing of seed of oil and fibre plants* | * *IV 2018* | * *IV 2018* |
| More stringent provisions as regards Avena fatua | | | | | | | |
|  | **Commission** [**Decision 74/269/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31974D0269:EN:NOT) of 2 May 1974 authorizing certain Member States to make provisions which are more strict concerning the presence of *'Avena* *fatua'* in fodder plant and cereal seed | | * **Rulebook on marketing of cereal seed**   **(OG MN 13/2014)** | | | * **14.03.2014.** | * **22.03.2014.** |
|  | **Commission** [**Directive 2006/47/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0047:EN:NOT) of 23 May 2006 laying down special conditions concerning the presence of *Avena fatua* in cereal seed | | * **Rulebook on marketing of cereal seed**   **(OG MN 13/2014)** | | | * **14.03.2014.** | * **22.03.2014.** |
| **Agricultural plant species** | | | | | | | |
|  | **Commission** [**Decision 81/675/EEC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31981D0675:EN:NOT) of 28 July 1981 establishing that particular sealing systems are 'non-reusable systems' within the meaning of Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 69/208/EEC and 70/458/EEC | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | **Council** [**Decision 2003/17/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0017:EN:NOT) of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | **Council** [**Decision 2005/834/EC**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0834:EN:NOT) of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | **Commission** [**Regulation (EC) No 217/2006**](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0217:EN:NOT) of 8 February 2006 laying down rules for the application of Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards the authorisation of Member States to permit temporarily the marketing of seed not satisfying the requirements in respect of the minimum germination | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| Fodder Plants | | | | | | | |
|  | Commission [Decision 2004/371/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0371:EN:NOT) of 20 April 2004 on conditions for the placing on the market of seed mixtures intended for use as fodder plants | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission [Directive 2008/124/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0124:EN:NOT) of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as ‘basic seed’ or ‘certified seed’ (Codified version) | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
| **Cereals** | | | | | | | |
|  | Commission [Decision 80/755/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980D0755:EN:NOT) of 17 July 1980 authorizing the indelible printing of prescribed information on packages of cereal seed | | * **Rulebook on marketing of cereal seed**   **(OG MN 13/2014)** | | | * **14.03.2014.** | * **22.03.2014.** |
|  | Commission [Decision 2010/468/EU](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0468:EN:NOT) of 27 August 2010 providing for the temporary marketing of varieties of *Avena strigosa* Schreb. not included in the common catalogue of varieties of agricultural plant species or in the national catalogues of varieties of the Member States | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| **Vine** | | | | | | | |
|  | Commission [Directive 2004/29/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0029:EN:NOT) of 4 March 2004 on determining the characteristics and minimum conditions for inspecting vine varieties | | * *Rulebook on marketing material for the vegetative propagation of the vine* | | | * *IV 2015* | * *IV 2015* |
| **Vegetable propagating and planting material** | | | | | | | |
|  | Commission [Directive 93/61/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0061:EN:NOT) of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC | | * *Rulebook on the marketing of vegetable propagating and planting material, other than seed* | | | * *2015* | * *2015* |
|  | Commission [Directive 93/62/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0062:EN:NOT) of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/33/EEC on the marketing of vegetable propagating and planting material, other than seed | | * **Law on agriculture seed material**   ***(OG MN 28 2006)***   * *Regulations on the production and marketing of Vegetable propagating and planting material* | | | * **Partly**   **2006**  **2011**  **2014**  *2015* | * **Partly**   **2006**  **2011**  **2014**   * *Fully implemented at the day of accession* |
| **Fruit plants** | | | | | | | |
|  | Commission [Directive 93/79/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0079:EN:NOT) of 21 September 1993 setting out additional implementing provisions for lists of varieties of fruit plant propagating material and fruit plants, as kept by suppliers under Council Directive 92/34/EEC | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission Implementing [Directive 2014/96/EU](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0096) of 15 October 2014 on the requirements for the labelling, sealing and packaging of fruit plant propagating material and fruit plants intended for fruit production, falling within the scope of Council Directive 2008/90/EC | | * *Rulebook on marketing of fruit plant propagating material and fruit plants intended for fruit production* | | | * *IV 2016* | * *IV 2016* |
|  | Commission Implementing [Directive 2014/97/EU](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0097) of 15 October 2014 implementing Council Directive 2008/90/EC as regards the registration of suppliers and of varieties and the common list of varieties | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission Implementing [Directive 2014/98/EU](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0098) of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| **Ornamental plants** | | | | | | | |
|  | Commission [Directive 93/49/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0049:EN:NOT) of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC | | * *Rulebook on marketing of propagating material of ornamental plants* | | | * *II 2016* | * *II 2016* |
|  | Commission [Directive 1999/66/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0066:EN:NOT) of 28 June 1999 setting out requirements as to the label or other document made out by the supplier pursuant to Council Directive 98/56/EC | | * *Rulebook on marketing of propagating material of ornamental plants* | | | * *II 2016* | * *II 2016* |
|  | Commission [Directive 1999/68/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0068:EN:NOT) of 28 June 1999 setting out additional provisions for lists of varieties of ornamental plants as kept by suppliers under Council Directive 98/56/EC | | * *Rulebook on marketing of propagating material of ornamental plants* | | | * *II 2016* | * *II 2016* |
| **Forest reproductive material** | | | | | | | |
|  | Commission [Regulation (EC) No 1597/2002](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R1597:EN:NOT) of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material | | * **Law on Forest Reproductive Material**   **(OG RMN 37/2007)**   * **Rulebook on the list of species and hybrids of which is obtained reproductive material**   **(OG MN 8/2007)** | | | * **2007** * **23.11.2007.** | * **2007** * **30.11.2007.** |
|  | Commission [Regulation (EC) No 1602/2002](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R1602:EN:NOT) of 9 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the authorisation of a Member State to prohibit the marketing of specified forest reproductive material to the end-user | |  | | |  | * *Fully implemented at the day of accession* |
|  | Commission [Regulation (EC) No 2301/2002](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R2301:EN:NOT) of 20 December 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the definition of small quantities of seed | | * **Law on Forest Reproductive Material**   **with amandmens**   * **Regulations on the criteria for general characteristics, appropriate quality and quantity, method of labeling, packaging and classification of reproductive material in the categories of end users, as well as exceptions in the marketing of small quantities of seed**   **(OG MN 46/2010)** | | | * **2007** * **6.8.2010** | * **2007** * **13.08.2010.** * *Fully implemented at the day of accession* |
|  | Commission [Regulation (EC) No 69/2004](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0069:EN:NOT) of 15 January 2004 authorising derogations from certain provisions of Council Directive 1999/105/EC in respect of the marketing of forest reproductive material derived from certain basic material | | * **Law on Forest Reproductive Material**   **with amandmens**   * **Regulations on the criteria for general characteristics, appropriate quality and quantity, method of labeling, packaging and classification of reproductive material in the categories of end users, as well as exceptions in the marketing of small quantities of seed**   **(OG MN 46/2010)** | | | * **2007** * **6.8.2010** | * **2007** * **13.08.2010.** * *Fully implemented at the day of accession* |
|  | Commission [Recommendation 2012/90/EU](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012H0090:EN:NOT) of 14 February 2012 on guidelines for the presentation of the information for the identification of lots of forest reproductive material and the information to be provided on the supplier’s label or document | | * **Law on Forest Reproductive Material**   **with amandmens**   * **Regulations on the criteria for general characteristics, appropriate quality and quantity, method of labeling, packaging and classification of reproductive material in the categories of road users, as well as exceptions in the marketing of small quantities of seed**   **(OG MN 46/2010)** | | | * **2007** * **6.8.2010** | * **2007** * **13.08.2010.** * *Fully implemented at the day of accession* |
| **Catalogue of varieties of agricultural plants**   * *National measures of execution*   *Fully implemented at the day of accession* | | | | | | | |
|  | Commission [Decision 2004/842/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0842:EN:NOT) of 1 December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Council [Decision 2005/834/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0834:EN:NOT) of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| **Beet seed** | | | | | | | |
|  | Commission Implementing [Decision 2012/340/EU](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0340:EN:NOT) of 25 June 2012 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards field inspection under official supervision for basic seed and bred seed of generations prior to basic seed | | * *Rulebook on marketing of*  *beet seed* | | | * *IV 2017* | * *IV 2017* |
| **Vegetable seed** | | | | | | | |
|  | Commission [Directive 89/14/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0014:EN:NOT) of 15 December 1988 determining the groups of varieties of spinach beet and beetroot referred to crop isolation conditions of Annex I to Council Directive 70/458/EEC on the marketing of vegetable seed | | * *Rulebook on marketing of vegetable seed* | | | * *II 2017* | * *II 2017* |
|  | Commission [Decision 90/639/EEC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990D0639:EN:NOT) of 12 November 1990 determining the names to be borne by the varieties derived from the varieties of vegetable species listed in Decision 89/7/EEC | |  | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission [Directive 2003/91/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0091:EN:NOT) of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species | | * **Law on agriculture seed material**   ***(OG MN 28 2006)***   * **Law on Amendments to the Law on Agricultural seed material**   ***(OG MN 61/2011)***   * *Rulebook on marketing of vegetable seed* | | | * **Partly**   **(2006)**  **(2011)**  **(2014)** | * **Partly**   **(2006)**  **(2011)**  **(2014)**   * *Fully implemented at the day of accession* |
|  | Commission Implementing [Decision 2012/340/EU](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0340:EN:NOT) of 25 June 2012 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards field inspection under official supervision for basic seed and bred seed of generations prior to basic seed | | * **Law on agriculture seed material**   **(OG MN 28 2006)**   * **Law on Amendments to the Law on Agricultural seed material**   **(OG MN 61/2011)** | | | * **Partly**   **(2006)**  **(2011)**  **(2014)** | * **Partly**   **(2006)**  **(2011)**  **(2014)**   * *Fully implemented at the day of accession* |
| **Seed potatoes** | | | | | | | |
|  | Commission [Decision 2004/3/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0003:EN:NOT) of 19 December 2003 authorising, in respect of the marketing of seed potatoes in all or part of the territory of certain Member States, more stringent measures against certain diseases than are provided for in Annexes I and II to Council Directive 2002/56/EC | | * **Rulebook on marketing of seed potatoes**   **(OG MN 8/2015)** | | | * **27.02.2015.** | * **7.03.2015.** |
|  | Commission Implementing [Directive 2014/20/EU](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0020) of 6 February 2014 determining Union grades of basic and certified seed potatoes, and the conditions and designations applicable to such grades | | * **Law on agriculture seed material**   ***(OG MN 28 2006)***   * **Law on Amendments to the Law on Agricultural seed material**   ***(OG MN 61/2011)***   * **Rulebook on marketing of seed potatoes**   **(OG MN 8/2015)** | | | * **Partly**   **2006**  **2011**  **2014**  **2015** | * **Partly**   **2006**  **2011**  **2014**  **2015**   * *Fully implemented at the day of accession* |
|  | Commission Implementing [DirectHYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0021"ive HYPERLINK "http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0021"2014/21/EU](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32014L0021) of 6 February 2014 determining minimum conditions and Union grades for pre-basic seed potatoes | | * **Law on agriculture seed material**   ***(OG MN 28 2006)***   * **Law on Amendments to the Law on Agricultural seed material**   ***(OG MN 61/2011)***   * **Rulebook on marketing of seed potatoes**   **(OG MN 8/2015)** | | | * **Partly**   **2006**  **2011**  **2014**  **2015** | * **Partly**   **2006**  **2011**  **2014**  **2015**   * *Fully implemented at the day of accession* |
| **Oil and fibre plants** | | | | | | | |
|  | Commission [Decision 97/125/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0125:EN:NOT) of 24 January 1997 authorizing the indelible printing of prescribed information on packages of seed of oil and fibre plants and amending Decision 87/309/EEC authorizing the indelible printing of prescribed information on packages of certain fodder plant species | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission [Decision 2004/266/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0266:EN:NOT) of 17 March 2004 authorising the indelible printing of prescribed information on packages of seed of fodder plants | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission [Directive 2008/124/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0124:EN:NOT) of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as ‘basic seed’ or ‘certified seed’ (Codified version) | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | Commission Implementing [Decision 2012/340/EU](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012D0340:EN:NOT) of 25 June 2012 on the organization of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards field inspection under official supervision for basic seed and bred seed of generations prior to basic seed | | * *Rulebook on marketing of fodder plant seed* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
| Agricultural landraces and varieties | | | | | | | |
|  | Commission [Directive 2008/62/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0062:EN:NOT) of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties | | * *Rulebook on acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
| **Vegetable landraces and varieties** | | | | | | | |
|  | Commission [Directive 2009/145/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0145:EN:NOT) of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties | | * *Rulebook on acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties* | | | * *I 2018* | * *I 2018* * *National measures of execution* * *Fully implemented at the day of accession* |
| **CHAPTER 4**  **PLANT VARIETY RIGHTS** | | | | | | | |
|  | Council [Regulation (EC) No 2100/94](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994R2100:EN:NOT) of 27 July 1994 on Community plant variety rights | | * **Law on Protection of Plant Varieties**   **(OG MN 48/2007 and 48/2008);** | | |  | * *National measures of execution* * *Fully implemented at the day of accession* |
| TITLE 7 GENETICALLY MODIFIED ORGANISMS | | | | | | | |
|  | | [**Directive 2001/18/EC**](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001L0018) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC | * **Law on Genetically Modified Organisms**   **(OG MN 22/2008)** | | | * **2008** | * **2008** * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | [Regulation (EC) N° 1830/2003](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:NOT) of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC | * **Law on Genetically Modified Organisms**   **(OG MN 22/2008)** | | | * **2008** | * **2008** * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | [Directive 2009/41/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0041:EN:NOT) of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organism | * **Law on Genetically Modified Organisms**   **(OG MN 22/2008)** | | | * **2008** | * **2008** * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | [Regulation (EC) No 1946/2003](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:320023R1946:EN:NOT) of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms | * **Law on Genetically Modified Organisms**   **(OG MN 22/2008)** | | | * **2008** | * **2008** * *National measures of execution* * *Fully implemented at the day of accession* |
| **CHAPTER 2**  **GENETICALLY MODIFIED FOOD AND FEED** | | | | | | | |
|  | | [Regulation (EC) N° 1829/2003](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1829:EN:NOT) of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. | * *Rulebook on genetically modified food and feed* | | | * *IV2018* | * *I V2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | [Regulation (EC) N° 1830/2003](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:NOT) of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC | * *Rulebook traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms* | | | * *IV2018* | * *I V2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | Commission [Regulation (EC) No 65/2004](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0065:EN:NOT) of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms | * *Rulebook a system for the development and assignment of unique identifiers for genetically modified organisms* | | | * *IV2018* | * *I V2018* * *National measures of execution* * *Fully implemented at the day of accession* |
|  | | Commission [Regulation (EC) No 641/2004](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0641:EN:NOT) of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. | * *Rulebook application for the authorization of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation*. | | | * *IV2018* | * *I V2018* * *National measures of execution* * *Fully implemented at the day of accession* |

# ANNEX II

## ACTION PLAN FOR CONTROL AND ERADICATION OF CLASSICAL SWINE FEVER IN DOMESTIC PIGS AND WILD BOARS IN MONTENEGRO, AFTER DISCONTINUATION OF VACCINATION

Podgorica, April 2015

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1. Programme of Mandatory Animal Health Protection Measures in Montenegro in 2015, Subprogram 11-Classical swine fever (Official Gazette of Montenegro 11/2015);
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**I. STATUS OF THE SWINE BREEDING SECTOR AND CLASSICAL SWINE FEVER IN MONTENEGRO**

**1. Swine breeding sector in Montenegro**

The main characteristics of the swine breeding sector are small, family holdings with a small number of pigs, with significant fluctuations throughout the year, although smaller positive structural changes towards an increase of the number of animals per holding have been noted in the past few years.

Data on the total number of pigs in Montenegro are not consistent. Namely, the system of registration of holdings with pigs and identification and registration of pigs has not yet been put in place. The beginning, i.e. the first campaign of I&R of pigs is planned for the first half of 2015 (more information in chapter: II. 1. Registration of holdings and identification of pigs) when the exact number of holdings with pigs and number of pigs will be established. Currently, we have MONSTAT data as well as data of the Veterinary Administration, on the basis of the pigs vaccinated in the course of one year.

It is important to underline the specific character of production and breeding of pigs in Montenegro. A small number of holdings keeps breeding animals (sows, boars) where piglets are produced for further breeding and fattening, and far larger is the number of holdings buying pigs in spring, mainly imported from countries in the region (Serbia, first of all), and in the second half of the year, these pigs are slaughtered for personal needs.

During the agricultural census conducted in spring and summer 2010 by the MONSTAT, the total of 47,673 pigs were registered in Montenegro.. The census was conducted in the period when pigs for fattening till autumn had been supplied, which means that this number includes also around 20,000 piglets imported from Serbia in spring, for fattening by the end of the year, which is to a large extent done on family farms for personal needs. This number of animals included swine, piglets and 756 sows in a large farm (Pantomarket doo in Spuž) which was the only intensive-type farm in Montenegro, with modern equipment and production technology, which discontinued its production in early 2012 (data from the agricultural census 2010 are given in Table 1). This contributed to the reduction in number of swine over the last two years.

**Table br. 1: Number of holdings active in the swine production sector -Source: Monstat – agricultural census 2010**

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Total | Family agricultural holdings | Business entities |
| Number of holdings | 13,469 | 13,465 | 4 |
| Total number of pigs (all categories) | 47,673 | 41,118 | 6,555 |

In the Statistical Yearbook, issued by MONSTAT, the data concerning the number of pigs for each year are processed on January 15, which means that this number does not include pigs for fattening that are seasonally kept from spring to autumn, when they are slaughtered. That is the reason for which a significant fall in number of pigs is noted compared to the data from the Agricultural census conducted in spring and summer (Table No. 2).

**Table br. 2: Data on number of pigs from 2007 to 2013,by categories and as on 15 January**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 |
| **Total number of animals** | 10,374 | 10,017 | 12,377 | 11,205 | 21,398 | 18,451 | 20,572 |
| Sows, in-pig gilts | 1,593 | 1,676 | 1,977 | 1,952 | 2,799 | 2,216 | 1,456 |
| Boars | 67 | 57 | 34 | 59 | 90 | 81 | 146 |
| Piglets, up to 19 kg |  |  |  |  | 4,182 | 4,017 | 4,598 |
| Piglets, 20 - 49 kg |  |  |  |  | 8,494 | 6,437 | 9,355 |
| Fattening piglets, 50-79 kg |  |  |  |  | 2,517 | 793 | 819 |
| Fattening swine, 80-109 kg |  |  |  |  | 1,581 | 926 | 886 |
| Fattening swine, above 110 kg |  |  |  |  | 1,589 | 3,880 | 3,167 |

**Source: MONSTAT – Statistical Yearbook for 2013**

**Note: In 2011, the framework for sample selection was changed, i.e. instead of the database from the Population and Housing, the updated/used database from the Agriculture census 2010.**

**This confirms what has been mentioned above, that a significant number of pigs is usually supplied in spring, for the private needs of a holding.**

Pig rearing is, for the most part, done on private family holdings, keeping from a few to 300 fattening pigs, throughout the country. At the annual level, significant number of piglets is bought (around 20,000) mainly from Serbia and these are fattened until reaching live weight of 100-110 kg, when they are slaughtered, mainly for personal needs.

The import of pigs is done in accordance with the procedures as given in Chapter: **II. 5. Control of trade in live pigs** of this Action Plan.

According to MONSTAT data, in most of the holdings less than 10 pigs are kept (13168). Furthermore, according to MONSTAT data, in the swine population, piglets of up to 49 kg account for 47.6% of the population, fattening swine between 50 and 110 kg account for 39.6%, while the percentage of gilts and brood sows is very low: 0.8% of gilts and 3.5% of sows, (Table No. 3).

**Table No. 3: Structure of pig keeping holdings in Montenegro**

|  |  |
| --- | --- |
| **Holding size** | **Total number of holdings** |
| >10 | 13168 |
| 10 to 49 | 277 |
| 50 to 99 | 13 |
| 100 to 149 | 1 |
| 150 to 199 | 2 |
| **Less than 200 pigs (in total)** | **13461** |
| 200 - 399 | 7 |
| 400 – 999 | 0 |
| ˃1000 | 0 |
| **TOTAL** | **13469** |

Source: MONSTAT

As already stated above, the system of identification and registration of holdings and pigs has not yet been put in place, but considering that pigs are vaccinated against classical swine fever, for which keeping records is mandatory, the Veterinary Administration has data on holdings where pigs are kept and on the number of pigs vaccinated in such holdings.

Considering the abovementioned specific character of keeping pigs – seasonal supply (spring) and fattening (end of autumn) most of the pigs are vaccinated in the period May – June, between 35,000 and 45,000 on around 12,000 holdings:

|  |  |
| --- | --- |
| 2012 | 39,219 pigs on 10,558 holdings |
| 2013 | 36,445 pigs on 10,702 holdings |
| 2014 | 31,401 pigs on 10,014 holdings |

Pork consumption has the largest share in total meat consumption in Montenegro (35%). Montenegro does not meet its own demand for pork.

Montenegro is a large consumer of pork and at the same time, as already stated above, the pig production is very low.

Most of the pigs are imported in Montenegro from the European Union and Serbia, for breeding and rearing and for slaughter, as well as fresh pork intended for further sale and processing.

Consumption of smoked ham/prosciutto produced of imported fresh hind legs of pigs, treated in a traditional manner, then smoked and air-dried has a very important share in total pork consumption. These products are consumed throughout the year.

**Table 4. Number of pigs slaughtered in registered slaughterhouses**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Number of pigs** | | | | |
| 2009 | 2010 | 2011 | 2012 | 2013 |
| 28,648 | 33,836 | 16,933 | 17,172 | 11,562 |

Source: MONSTAT, Statistical Yearbook 2014

Currently, there are no producer associations in the swine breeding sector in the country.

**2. Status of classical swine fever in Montenegro**

The Veterinary Law (Official Gazette of Montenegro 30/12) lays down the mandatory preventative measures implemented by the animal keeper, general preventative animal health protection measures, as well as special preventative measures for protection against infectious animal diseases that have to be implemented by animal keepers, veterinary organisations and veterinary services (Articles 51 to 55).

Control of classical swine fever by vaccination has been implemented continuously as a mandatory measure laid down by the law for more than 15 years, using the vaccine prepared from attenuated C strain of the virus. The marker vaccine has never been used for vaccination of animals.

The disease has occurred in the country sporadically, with the most recent confirmed case of the disease in the population of domestic pigs recorded in 2007. Classical swine fever has never been confirmed in the wild boars population.

With a view to early detection and prevention of occurrence of infectious animal diseases, the Ministry of Agriculture and Rural Development adopts at the end of every year the Programme of Mandatory Animal Health Protection for the upcoming year. The Programme of Measures lays down the type of preventative vaccination, diagnostic and other testing, scope (animal species and number), timeline, task holders, methods of reporting on measures implemented and the measures financing method.

The preventative measures laid down by the Programme of Measures are implemented by veterinary surgeries that the tasks concerned were ceded to in line with the procedures laid down and implemented in accordance with the law. The contract signed between the Veterinary Administration and veterinary surgeries lays down in detail the obligations of holders of these tasks.

The Veterinary Administration provides the veterinary surgeries with diagnostic means, vaccines and other consumables needed for the Programme implementation and performs technical monitoring over the implementation of measures.

The Diagnostic Veterinary Laboratory performs laboratory diagnostics of infectious animal diseases.

The Programme of Measures includes activities implemented in order to prevent and control classical swine fever through the measure of (Annex I) :

* vaccination of pigs (sub-programme title: *Domestic pigs vaccination),* and
* control of immunisation effectiveness and monitoring of wild boars (sub-programme title: *Monitoring of classical swine fever in wild boars*).

The funds needed for implementation of classical swine fever control as laid down by the Programme of Measures are provided from the budget of Montenegro, allocation for the Veterinary Administration.

The budget also provides the funds for damages for pig holders for dead pigs proven to have been infected with classical swine fever and for animals killed for disease eradication purposes.

The Rulebook on measures for prevention, detection, control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014); lays down the measures of control and eradication of classical swine fever implemented on the entire territory of Montenegro (Annex II).

The Rulebook was harmonised with the Council Directive 2001/89/EC on Community measures for the control of classical swine fever and the Commission Decision 2002/106/EC approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever.

The exception is the part of the legislation concerning the prohibition of vaccination of pigs against classical swine fever; namely, vaccination of domestic pigs against classical swine fever is still mandatory, and considering the planned change of policy of vaccination of pigs against classical swine fever in Montenegro, the deadline for discontinuation of vaccination has been set - 1 January 2018.

Furthermore, taking into account the fact that most of the imported pigs originate from Serbia, the policy of discontinuation of vaccination against classical swine fever will be coordinated with the measure of vaccination discontinuation in Serbia.

In case of classical swine fever outbreak, the eradication measures include depopulation of all pigs in the infected holding and contact holdings (stamping-out), restriction in trade and placing of the market of all suspected animals and products thereof, as well as all other measures that have to be implemented in order to prevent further spreading and eradicate the disease in the infected area (radius of minimum 3 km around the infected holding) and the endangered area (radius of minimum 10 km around the infected holding).

Measures that have to be undertaken in order to prevent the spreading, to control and eradicate the disease are laid down in detail by the Rulebook The Rulebook on measures for prevention, detection, control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014).

In accordance with provisions of the Rulebook on measures for control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014), the plan is to implement the control of classical swine fever on the territory of Montenegro, based on the policy of vaccination and implementation of stamping-out measure in case of disease outbreak, by 1 January 2018.

In the course of 2014, nine clinically suspected classical swine fever cases were reported and appropriate samples were delivered to the Diagnostic Veterinary Laboratory for testing.

The diagnostic testing was done using the OIE-recommended diagnostic tests and methods laid down by the Annex 1, Section E of the Rulebook on measures for prevention, detection, control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014), molecular method Real-Time PCR - kits Qiagen Amp Viral RNA Mini Kit for RNA extraction and Qiagen One-Step RT-PCR for amplification. The presence of RNA sequence of the classical swine fever virus - i.e. the disease - has not been established in any of the samples tested which were delivered to the Diagnostic Veterinary Laboratory as suspected cases of classical swine fever, i.e. there was no laboratory confirmation of the disease.

**Table 5: Number of samples tested in the laboratory for classical swine fever, originating from domestic pigs, in cases of clinically suspected disease**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Year | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
| Number of samples tested | 222 | 114 | 102 | 45 | 14 | 11 | 13 | 2 | 6 | 9 |

Table 5 above provides an overview of samples originating from domestic pigs, tested in laboratory in cases when disease is clinically suspected, while Graph 1 below gives an overview of positive classical swine fever cases in domestic pigs in the period 2004-2014, on the territory of Montenegro. The data on the number of positive cases of classical swine fever in domestic pigs in the period 2004-2006 (period when Montenegro was a part of the State Union with Serbia) refer only to the territory of Montenegro.

Classical swine fever has not been registered in Montenegro for seven years in a row. According to official data of the World Organisation for Animal Health, the disease has not been reported in countries that Montenegro imports pigs from in spring for further keeping, which, along with the regional activities aimed at eradication of this disease, provides grounds for an assumption that a favourable situation can be expected in the forthcoming period.

**Graph 1. Number of positive classical swine fever cases in domestic pigs in the period 2004 -2014 on the territory of Montenegro**

In accordance with the Programme of Mandatory Measures for 2015 (Official Gazette of Montenegro 11/2015) the occurrence of classical swine fever is prevented by vaccination against the disease in all holdings keeping or rearing pigs, using the vaccine prepared from the attenuated C strain virus. Before the vaccination, clinical examination of pigs is conducted and then only pigs in good health condition are vaccinated. Only vaccinated pigs may be placed on the market, no sooner than 15 days following the vaccination. Exceptionally, unvaccinated piglets of less than 45 days may be placed on the market if they originate from a holding free from classical swine fever, where all pigs are vaccinated, including sows and gilts.

In a specific epizootiological area, vaccination is conducted by veterinary surgeries that signed the Contract on ceding of public duties with the Administration – implementation of measures laid down by the Programme of Mandatory Animal Health Protection Measures for the current year.

The necessary quantities of vaccines are provided by the Veterinary Administration and these are distributed through the Diagnostic Veterinary Laboratory to authorised veterinary surgeries in line with instructions of the Veterinary Administration. The Diagnostic Veterinary Laboratory keeps records on quantities issued and batch numbers of vaccines.

Vaccination of domestic pigs is free of charge for pig keepers and legal persons engaged in organised animal production or keeping that provide registered veterinary services for continuous protection of health of their animals, perform vaccination on their own with a vaccine provided by the Veterinary Administration on the basis of the needs presented for the current year, i.e. on the basis of the vaccination programme submitted.

Veterinary surgeries are bound to present to the Veterinary Administration and the official veterinarian, no later than 10 days before the beginning of the measure implementation, the plan with the information on the place and date of vaccination of domestic pigs in the course of the year, as well as all subsequent changes to the plan. Furthermore, they are bound to notify the Veterinary Administration and the official veterinarian of all animal keepers who refuse implementation of vaccination.

Upon vaccination of pigs, the veterinary surgeries issue a certificate of vaccination, signed also by the pig keeper, one copy of which is retained by the pig keeper.

Veterinary surgeries deliver a report on vaccination that includes the following information: place and date of vaccination, information on the pig keeper and the number of pigs at each individual holding, along with a copy of the certificate of vaccination.

The implementation of measures is controlled by the official veterinarians in line with the Technical Instructions on the manner of performance of official controls of authorised veterinary organisations in implementation of the Programme of Measures.

**II. ACTION PLAN FOR CONTROL AND ERADICATION OF CLASSICAL SWINE FEVER IN DOMESTIC PIGS AND WILD BOARS IN MONTENEGRO**

**II. 1. Registration of holdings and identification of pigs**

Obligations of animal keepers to register holdings and identify animals are laid down by the Law on Identification and Registration of Animals (Official Gazette of Montenegro 48/07 and 73/10). The Law did not include the provisions concerning pigs, so in 2014 the work on drafting amendments to the Law began in order to develop further the existing system of identification and registration of domestic animals, primarily pigs, and for further harmonisation with the EU legislation in this field.

Identification and registration of pigs is a part of the system that would provide traceability for each pig, from the holding of birth till death, including the records on all relocations and movements, which is of critical importance for control of infectious pig diseases.

The Law on Identification and Registration of Animals (Official Gazette of Montenegro 48/07 and 73/10) lays down that the Veterinary Administration keeps the Central register of animals and holdings.

The Rulebook on identification and Registration of Pigs (Official Gazette of Montenegro 48/2014) is harmonised with the Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigsand the Commission Decision 2000/678/EC of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC*.*

This Rulebook lays down the requirements for identification of pigs, identification means (ear tags) and their application, as well as the manner of registration of pig-keeping holdings.

The Law lays down that natural persons keeping one pig for personal needs are not bound to submit the request for registration of the holding and keep the holding register.

Recognizing the importance and the need for identification of animals that sets up their traceability system, the systems of identification and registration of bovine, ovine and caprine animals, harmonised with the EU standards, have been established under the EU-funded IPA project:Animal identification and registration*.*

IPA 2011 Project Strengthening the Veterinary Service in Montenegro, developing further the already established system of identification and registration of animals and the veterinary monitoring network (Veterinary Information System), i.e. establishing an electronic database – register of pig holdings in accordance with the EU standards is underway. The Project launch was in March 2014, it will last until September 2015, and campaign of registration of holdings and identification and registration of pigs is planned in the first half of 2015 (vaccination of pigs against classical swine fever will take place simultaneously).

The final phase of development of the electronic database (web application), which has to be completed and implemented before the campaign launch is underway. Completion of the system and of the registration of holdings keeping pigs is expected by 31 December 2015.

Identification of pigs will provide conditions for control of diseases in the entire epizootiological area of Montenegro, determine the exact number of pigs and holdings keeping pigs for breeding, fattening and further sale and holdings where pigs are kept seasonally, for personal needs, as well as the categories of pigs. This will provide conditions for a better planning of preventative health protection measures for pigs, improve further this branch of livestock production and also production of wholesome and safe food.

Pigs imported into Montenegro for further keeping have to be registered in the Register of Holdings and the Electronic database within 30 days from the day of veterinary checks on the border, i.e. prior to leaving the first holding of dispatch in Montenegro.

Full implementation of the system of identification and registration of pigs as well as registration of their movement will contribute significantly to measures of control and eradication of classical swine fever, providing primarily the prompt traceability of pigs that were in direct contacts with animals infected or suspected of the disease, providing a more accurate and efficient implementation of measures in infected and endangered areas because locations of holdings keeping pigs are known.

**II. 2. Programme of monitoring of classical swine fever in domestic pigs and wild boars**

**a) Programme of control of effectiveness of immunisation in vaccinated pigs – assessment of the immunological status of domestic pig population**

The programme of monitoring of immunological status in the population of domestic pigs is based on the fact that the most recent case of classical swine fever was reported in 2007, that vaccination of all pigs against this disease has been implemented for the last 15 years at least, and that consequently, a good immune status of the domestic pig population is expected in general.

The programme objectives are the clinical monitoring of pig herds for the purpose of excluding the disease and serological monitoring of pig herds for the purpose of controlling the effectiveness of immunisation in vaccinated pigs – the assessment of the immunological status of domestic pig population in the entire territory of Montenegro.

Clinical examination of domestic pigs in a holding is done by veterinarians during the vaccination process, as well as in cases when they suspect the disease on the basis of a report of the disease.

The assessment of the immunological status of the animals is based on serological herd monitoring. A statistically representative number of samples that need to be tested is determined for the purpose of serological monitoring. Its purpose is not to prove that all herds of domestic pigs are vaccinated, but to prove that the prevalence of vaccinated herds is not lower than necessary for adequate protection against the disease. The population is considered adequately protected in cases where it is proved that 80% of the population is immune.

In order to control the effectiveness of immunisation of vaccinated pigs, blood samples are taken from vaccinated pigs in line with the technical instructions issued by the Veterinary Administration and they are delivered to the Diagnostic Veterinary Laboratory for testing for the presence of specific antibodies against the classical swine fever virus.

In line with the Technical Instructions, sampling of 1500 pigs from 300 randomly selected holdings is planned for the purpose of immunity control. Such sampling enables detection of at least one unprotected animal taking into account the following parameters: target population > 8000 pig herds of the total estimate in the country with the expected prevalence of unprotected herds of 50% and the confidence interval of 95%.

**Table 5. Number of samples by the herd size**

|  |  |
| --- | --- |
| **Herd size by number of animals** | **Number of samples needed** |
| 1-10 | All animals in a herd |
| 11-20 | 19 |
| 21-30 | 27 |
| 31-50 | 42 |
| 51-100 | 72 |
| 101-200 | 111 |
| >200 | 246 |

Upon completion of the testing, the herds are classified according to the results to: immune - all herds with more than 80% of protected animals, and - unprotected: all herds in which immunity is below 80%.

The sampling of blood for control of the immunological status is done no sooner than 35 days after vaccination. The list of veterinary surgeries taking blood samples is an integral part of the technical instructions of the Veterinary Administration.

Diagnostic Veterinary Laboratory performs laboratory testing of the presence of specific antibodies against the classical swine fever virus, using the AbELISA method; kit of the manufacturer *Index, CSFV Ab – Switzerland* was used in 2014*.*

Diagnostic Veterinary Laboratory prepares the report on results of control of the immunological status of domestic pigs and presents it to the Veterinary Administration.

In 2014, the sampling for the purpose of immunological status control was conducted on the territory of all municipalities. The total of 1131 samples taken from domestic pigs were delivered and analysed, which is 75.40% compared to the planned number of 1500 samples set by the Programme of Mandatory Measures for 2014.

Taken from the entire population of domestic pigs in the country, the percentage of seropositive pigs (successfully vaccinated domestic pigs) compared to the number of pigs tested by the random selection method, is 96.02% and it is considered satisfactory as it provides adequate protection of the population against the outbreak of the disease.

**Graph 2. Results of control of immunological status of pigs for the period 2012-2014**

The Technical guidelines for implementation of the Sampling Plan for the control of success immunization of vaccinated pigs against classical swine fever are attached in the Annex III.

In case of suspicion or clinical signs that point to the occurrence of classical swine fever, veterinarians take appropriate samples of dead or killed animals and deliver them to the Diagnostic Veterinary Laboratory for laboratory testing. The samples are delivered to the laboratory in a prescribed manner, and testing is done in accordance with the Annex I of The Rulebook on measures for prevention, detection, control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014).

**b) Monitoring of classical swine fever in wild boars**

The Programme of active monitoring of classical swine fever in wild boars has been implemented in Montenegro since 2008. So far, the circulation of the classical swine fever virus has not been proven in the wild boars population in Montenegro.

Due to a very small number of samples tested in the period 2008 – 2011, which was not sufficient for a proper epizootiological analysis, planning of further disease control measures in the country was difficult.

In order to plan further measures of control of the disease in the population of domestic pigs and wild boars, it was necessary to develop a new programme, based on actual data on wild boar population density and distribution in the country and define clear objectives and disease control strategy for the future.

The wild boar population density and distribution are based on results collected during the *IPA 2008 Project Support to Control and Eradication of Rabies and Classical Swine Fever in Montenegro* and on data delivered by the Hunters Federation of Montenegro**.**

The objective of the monitoring programme is to prove absence or presence of the disease in the population through serological monitoring. Since the disease has never been confirmed in the wild boar population, it is assumed that the risk of disease outbreak in all hunting grounds in the country is identical.

The sampling is done on the territory of 28 hunting grounds throughout the country. The estimated wild boar population in the country was 2600 animals, distributed throughout the total of 28 hunting grounds. According to the data delivered by the hunters’ organisations, around 500 wild boars are shot every year. The plan of mandatory measures lays down laboratory testing of 150 samples per annum.

The samples for the programme are collected from wild boars shot under regular hunting activities. Effort is made to collect additional information on the status of the disease also by testing samples collected from wild boars found dead.

For the time being, the entire area of Montenegro (hunting grounds and national parks) are taken as a single sampling unit for monitoring of classical swine fever in wild boar population. In the forthcoming period, the monitoring programme will be revised in order to take account of the risk factors (hunting grounds with history of the disease in wild boars, hunting grounds in the vicinity of areas with history of the disease in domestic pigs, areas in the vicinity or areas bordering the countries where classical swine fever was confirmed in domestic pigs or wild boars, etc.). On the basis of the risk status with regard to the classical swine fever (high or low), sampling units will be formed, number of samples as well as organs and/or tissues that have to be taken from a wild boar shot and delivered for laboratory testing.

The samples for the programme are collected from wild boars shot under regular hunting activities. Effort is made to collect additional information on the status of the disease also by testing samples collected from wild boars found dead. As the number of samples taken from wild boars found dead that have been delivered so far (from 2011 to date) is very low, further efforts will be made in terms of education and raising the awareness of hunters, considering that dead wild boars are among the most important indicators of change in health condition and source of information in terms of early detection of diseases, analysis of which is one of the most important elements that early detection of classical swine fever depends on.

Sampling is done continuously, throughout the year (dead wild boars) and actively during the hunting season. One sample represents one wild boar and for the purpose of programme implementation it is necessary to collect body fluids from the thoracic or abdominal cavity and organs (spleen and kidney). The samples need to be collected as soon as possible after shooting, in order to render them appropriate for laboratory testing.

The samples are taken by hunters who are bound to deliver them to the veterinary surgeries, which then forward them to the laboratory. Each sample has to be accompanied by a filled Form, it has to be properly marked in order to enable its traceability and properly packed. The sampling equipment and forms are provided by the Veterinary Administration and distributed to hunters’ organisations through the Hunters Federation.

When delivering the sample for testing for the classical swine fever, it is also necessary to take a sample of the diaphragm for trichinosis testing, which is free of charge for hunters in case the sample was delivered in line with the instructions. The trichinoscopy is done by veterinary surgeries and examination costs are paid from the budget of the Veterinary Administration in order to encourage the hunters to deliver the samples needed for implementation of the programme in the scope planned.

Particular emphasis is placed on the manner of sample delivery and the sample quality. Samples have to be presented to the veterinary surgery as soon as possible after collecting, and in case it is not possible, they have to be kept at an appropriate temperature. The details are provided in the Sampling Plan.

Veterinary surgeries have been trained for delivery of samples to the laboratory and are aware of the fact that they are not obliged to take the samples not appropriate for analysis from hunters. Samples not kept adequately are not fit for laboratory testing, which is why a part of expected information is lost and unnecessary material costs are incurred.

In case an unfit sample arrives to the laboratory, it is necessary to immediately notify the Veterinary Administration and the veterinary surgery that the sample was delivered from.

Training on proper keeping of samples was delivered to hunters and veterinarians under the *IPA 2008 Project – Control and Eradication of Rabies and Classical Swine Fever.*

The sampling plan and standard Operation Procedures for collecting of samples and the official Form accompanying the sample, are attached in the Annex IV of this Plan.

Diagnostic Veterinary Laboratory is bound to regularly inform the Veterinary Administration of all results of analyses and present the annual report on analyses. The samples are analysed using the ELISA test on samples of body fluids for the purpose of detecting seropositive animals. In case of a positive serological result, further testing is done using the RT PCR method.

**Table 6. Number of samples taken from wild boars tested for classical swine fever**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Year** | **2008** | **2009** | **2010** | **2011** | **2012** | **2013** | **2014** |
| **Number of samples tested** | 42 | 59 | 7 | 27 | 56 | 93 | 63 |

All data on implementation of the programme are distributed to hunters’ organisations and veterinary surgeries.

The data collected provide foundations for further creation of policy of classical swine fever control in the country.

Implementation of the programme of monitoring of the classical swine fever in wild boars is in entirety financed from the budget of the Veterinary Administration.

**c) Plan of implementation of the monitoring programme for classical swine fever in domestic pigs 2018.**

According to the new strategy of the control, to be implemented as of 1 January 2018, domestic pigs will not be vaccinated against classical swine fever, while in case of occurrence of the disease, strict stamping out measures will be implemented.

The final long-term objective of the new policy of classical swine fever control is eradication of this disease in domestic pigs and wild boards in the entire territory of Montenegro and confirmation and maintenance of the status of the country free from classical swine fever, without vaccination.

Specific objectives of the new Programme of monitoring will be focused on early detection of the infection, revealing of possible illegal use of the vaccine against classical swine fever and proving the absence of the disease caused by the classical swine fever virus.

In order to achieve this objective, it is important to collect and update the data on every case suspected of the disease as well as detailed data on measures subsequently taken, on the findings of the epizootiological testing as well as results of laboratory testing performed for the purpose of confirmation or exclusion of the disease. Documenting the above-mentioned activities is a precondition for proving/confirmation of the status of a country free from classical swine fever.

The national programme of monitoring of classical swine fever in 2018 will cover the pig holdings with an increased probability of disease occurrence. The programme of testing for classical swine fever will cover also the pig herds that possibly include protected animals (i.e. vaccinated against the disease by the end of 2017).

Furthermore, animals farrowed after 1 January 2018 will be subjected to testing for classical swine fever. An important part of the system of early detection of the disease are breeding pigs (considering that the infection with low pathogenic classical swine fever virus can be clinically unapparent in adult pigs, but with very high level of virus spreading). Furthermore, the testing will cover also pigs in places with history of the disease, places in vicinity of the hunting grounds where the disease was possibly determined in wild boars or in places in areas bordering states where classical swine fever was confirmed in domestic pigs or wild boars.

The data on implementation of preventative biosafety measures on pig holdings, to be collected under the Programme of monitoring of classical swine fever in domestic pigs over the next few years will contribute further to assessment and better understanding of the hazard of disease outbreak and identification of measures aimed at reducing the hazard.

Naturally, recognizing the importance of implementation of bio-safety measures, the Veterinary Administration will develop the Instructions for implementation of bio-safety measures in holdings keeping pigs, particularly in the final year of vaccination, when additional training on bio-safety measures will be implemented for pig keepers in co-operation with veterinary organisations, along with an accompanying media campaign on importance of implementation of all bio-safety measures in the period after discontinuation of vaccination.

**II. 3. Contingency Plan**

In order to control and eradicate highly dangerous infectious diseases, the Veterinary Law lays down the obligation of adoption of a Crisis management plan for specific infectious diseases, adopted by the Government (hereinafter referred to as: the Contingency Plan), as well as implementation of measures laid down by the Contingency Plan, depending on the risk assessment.

The work plan of the Government of Montenegro for 2015 envisages the adoption of the Contingency Plan for classical swine fever in the third quarter of 2015.

The draft Contingency Plan for Classical Swine Fever is in the final stage of development so the plan will be adopted by the deadline planned.

Upon adoption, the Contingency Plan will be distributed to all official veterinarians and veterinary organisations.

The Contingency Plan, along with a detailed development of measures that need to be undertaken in case of occurrence of the disease provides grounds for development of operational - local contingency plans - that would, apart from general measures in accordance with specific local circumstances to be taken into account, define also the method of implementation of measures prescribed in specific areas.

The Contingency Plan for classical swine fever includes organisation and method of implementation of measures, the means necessary, equipment, human resources and the manner of control of the plan implementation. The Contingency Plan includes activities, measures of suppression, control and eradication of classical swine fever and procedures and models for their implementation.

In addition to the Veterinary Law, the measures set by the Contingency Plan area also laid down by the Law on Animal Welfare (Official Gazette of Montenegro 14/2008), Rulebook on classification of animal diseases, manner of reporting and informing on infectious animal diseases (Official Gazette of Montenegro 5/2008), the Rulebook on measures for prevention, detection, control and eradication of classical swine fever (Official Gazette of Montenegro 18/2014), the Rulebook on safe disposal of animal carcasses (Official Gazette of Socialist Republic of Montenegro 20/83), the Programme of mandatory animal health protection measures for the current year and the Rulebook on the method of performing veterinary-sanitary checks and control of animals prior to slaughter and control of products of animal origin (Official Gazette of the Federal Republic of Yugoslavia 68/89).

The main objective of implementation of measures as laid down by the Contingency Plan is to urgently undertake all measures necessary for prevention of disease spreading, eradication of the disease and Montenegro's achieving the status of a country free from classical swine fever.

The Veterinary Administration implements control and co-ordination and provides instructions for implementation of the Contingency Plan.

The Veterinary Administration, in order to check the Contingency Plan, prepares and co-ordinates the disease outbreak simulation exercise.

**II. 4. Technical and administrative capacity of the diagnostic laboratory**

The Diagnostic Veterinary Laboratory was officially open on 1 March 2005. It is a state-owned laboratory under the supervision of the Ministry of Agriculture and Rural Development, and it is the only veterinary laboratory in Montenegro.

Pursuant to the Article 18 of the Veterinary Law (Official Gazette of Montenegro 30/12), the Laboratory performs, as duties of public interest on the epizootiological area of Montenegro, among others, the laboratory diagnostics of animal diseases in accordance with the Programme of mandatory animal health protection measures and other specific animal health protection programmes, diagnostic laboratory and patho-anatomic analyses in cases where infectious animal diseases are suspected and provides continuous laboratory diagnostics of infectious animal diseases for which it is necessary to establish the infectious disease or the cause of death without delay.

The Diagnostic Veterinary Laboratory is authorised by the Veterinary Administration of Montenegro for performing laboratory diagnostics of infectious diseases, on the basis of previously established compliance with the requirements in terms of premises, staff and equipment (Decision No. 060-323/06-0203-28/2, of 14 March 2006).

The Diagnostic Veterinary Laboratory is responsible for laboratory diagnostics of classical swine fever by conventional and molecular methods and under it, it performs laboratory diagnostic testing in case of suspecting the occurrence of the classical swine fever, as well as during the implementation of the programme of control of effectiveness of immunisation of vaccinated pigs – assessment of immunological status of the population of domestic pigs and monitoring of classical swine fever in wild boars.

The Diagnostic Veterinary Laboratory was the participant in the Project S*upport for the control and eradication of rabies and classical swine fever in Montenegro”* financed by the EU IPA programme 2008, Ref.: EuropeAid/128207/C/SER/ME.

The Diagnostic Veterinary Laboratory is accredited in compliance with the MEST ISO/IEC 17025:2011 by the National Accreditation Body of Montenegro since April 2011, and under the accreditation scope it accredited the serological AbELISA test for diagnostics of the classical swine fever.

Since 2012, the Laboratory has regularly participated in annual PT-schemes organised by the EU reference laboratory for classical swine fever in Hannover, Germany.

Staff: Two doctors of veterinary medicine (molecular and serological diagnostics) and two laboratory technicians of the Diagnostic Veterinary Laboratory work on diagnostics of classical swine fever.

Methods: In diagnostics of the classical swine fever, the Laboratory implements the methods recommended by the World Organisation for Animal Health (OIE) and the methods laid down by the Rulebook on measures for prevention, detection, control and eradication of classical swine fever – Annex 1 Section E (Official Gazette of Montenegro 18/14).

**Table 7. Methods implemented and maximum weekly number of tests compared to the staff numbers**

|  |  |  |  |
| --- | --- | --- | --- |
| **Method** | **Test duration** | **Number of tests per week** | **Number of employees needed for performing the test** |
| Immunofluorescence test (FAT) | 3 hours | 50 | 1 |
| Real time RT-PCR | 6 hours | 50 | 2 |
| Enzyme immunoessay ELISA test (antigene detection) | 5 hours | 250 | 2 |
| Enzyme immunoassay ELISA test (antibody detection) | 4.5 hours | 1000 | 1 |
| **TOTAL:** | **-** | **1,350** | **6** |

The abovementioned estimate of the maximum number of tests may be conducted with the currently employed staff within one week in case all preconditions in terms of adequate quantities of diagnostic kits and availability of staff in the laboratory are met, i.e. that employees are not engaged at the same time in other laboratory activities.

In crisis situations, such as disease outbreak, the Laboratory may hire additional staff employed by the Laboratory, primarily for the following activities:

* sample preparation,
* less technical auxiliary laboratory work,
* preparation of accompanying forms and reports of analyses.

Technical capacities

Diagnostic Veterinary Laboratory has:

* a separate room for reception of samples of cca. 10m2 with a reception desk and a personal computer used at the same time for reception of other diagnostic material;
* a separate room for preliminary examination of pathological material with a bench, disinfectants, autoclave for sterilization of the material, deep freezer for sample keeping, of cca. 24m2 used at the same time for preliminary examination of other diagnostic material received;
* a separate room for histopathology for preparation of cryostat tissue sections for FTA test, with a cryostat *(Leica);*
* a separate room for RNA and DNA extraction with class II biosafety cabinet and accompanying equipment for extraction (centrifuge, automatic pipettes, fridge, deep freezer), of cca. 15m2; used at the same time for extraction during molecular diagnostic of other viral diseases;
* a separate room for electrophoresis system for visualization, of cca. 4m2.
* a separate room for *polymerase chain reaction* (PCR) with two sterile boxes, one thermocycler (Techne TC-PLUS), two Real time PCR instruments (Applied Biosystems 7300 and 7500) and the necessary accompanying equipment (centrifuge, automatic pipettes, fridges, deep freezer);
* a separate room for serological testing with two ELISA readers and two automatic ELISA washers and accompanying equipment (centrifuge, micro-centrifuge, incubator, automatic pipettes, fridges, deep freezers) of cca. 30m2, which is at the same time used for other serological analyses.
* A separate room – dark chamber with a fluorescence microscope, of cca. 4m2

**Table 8. Plan for further development of laboratory diagnostics of classical swine fever – Plan for the period 2016/2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Measure** | **Phase** | **Tasked for implementation** | **Deadline** | **Expected price**  **€** | **To be financed by** |
| Ensuring the confidence in quality of examination | Presence of an expert from the Laboratory at the at the annual meeting of the EU CSF national reference laboratories | DVL | Annually | 800 x 2 = 1600 | DVL |
| Participation in interlaboratory comparisons testing organised by the EU reference laboratory | DVL | Annually | 800 x 2 = 1600 | DVL |
| Quality system training | DVL | Annually | 200 x 2 = 400 | DVL |
| Education on CSF and delivery of samples for analysis (lectures, leaflets,) | Intended for veterinary inspectors and doctors of veterinary medicine | In accordance with the plan of the Ministry of Agriculture/Of the Veterinary Administration | 400 | DVL |
| Equipment | Homogeniser | MARD/VA/DVL | Open public procurement procedure – tender 2016 | 15,000 | MARD/VA |
| ELISA reader | 7,000 | MARD/VA |
| ELISA washer | 5,000 | MARD/VA |
| Freezer (-80OC) | 15,000 | MARD/VA |
| Centrifuge with cooling | 10,000 | MARD/VA |
| Thermocycler | 12,000 | MARD/VA |
| Diagnostic reagents for CSF | Diagnostic reagents for CSF | DVL | 2016 and 2017 | 8,000 x 2 = 16,000 | DVL |
| IT Systems | Hardware | DVL | 2016 | 4,000 | DVL |

The abovementioned financial means necessary will be planned in the financial plan of the Diagnostic Veterinary Laboratory for 2016 and 2017 and in the Budget of Montenegro (MARD/VA).

**II. 5. Control of trade in live animals**

The conditions for trade in live animals and products thereof and conditions that need to be met by animal transporters in trade are laid down by the Veterinary Law under the Chapter Movement of consignments and veterinary checks (Articles 116-118) and Export, import and transit of consignments (Articles 123-128).

**Trade in live animals for breeding or production on the territory of Montenegro** may be done only in case animals are properly marked and registered, if they originate from holdings where prescribed veterinary measures were implemented and if accompanied by appropriate documentation in trade. The animal transporter is bound to provide the health certificate for animals transported and ensure that from the moment of leaving the holding of origin to their final destinations the animals do not come into contact with animals of a lower health status.

In cases where, in internal trade, a consignment of live animals that do not comply with the requirements laid down by the Veterinary Law (no evidence of origin, without marks, without accompanying documents, etc.) is identified, the animals are placed into quarantine for diagnostic testing and vaccination or are sent for slaughter at the expense of the person responsible for animals – the transporter.

**During imports of live pigs into Montenegro** (for slaughter or for further keeping and fattening) the first step in control of trade in pigs is the obligation of the importer to present the request for import of live animals into Montenegro. On the basis of the request submitted by the importer, the Veterinary Administration issues a decision on imports based on the previous check of the status of the exporting country in terms of classical swine fever and the guarantees presented by the competent authorities of the exporting country for the farm registered for export of live pigs. The Veterinary Administration issues the Decision on compliance of veterinary-health conditions for imports of live pigs, which includes more detailed requirements that need to be met by the consignment.

In cases where animals are imported for further keeping and fattening, the obligation is to deliver the animals to the specified quarantine facility. The pigs intended for slaughter are delivered to the slaughter facility, with the obligatory slaughter within 30 days.

The control at the border crossing is done in compliance with the instructions developed in line with the Directive 91/946/EEC laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries. The Veterinary Law stipulates that no consignment of live animals may be imported into Montenegro without previously conducted checks by the competent border official veterinarian at the designated border inspection post. The border veterinary inspector performs documentary, identification and physical checks of the consignment. In cases where the consignment does not comply with the requirements prescribed, its importing into Montenegro is not permitted. In cases where the consignment complies with the requirements prescribed, it is forwarded to the place of destination. The competent official veterinarian performs the consignment check at the place of destination, i.e. the quarantine facility and monitors the consignment during the quarantine period.

Taking into account the epizootiologial situation of the disease in Montenegro and implementation of the actual measures of control of the classical swine fever, in order to prevent the illegal movement of animals and consequently introduction and possible spreading of the disease, it is necessary to strengthen further the co-operation with the Ministry of Interior (police) with regard to trade in live animals on the territory of Montenegro.

The legal grounds for co-operation with the police in implementation of veterinary measures is provided by the Veterinary Law.

With a view to efficient and effective control and undertaking of appropriate administrative and penalty actions against offenders, it is necessary to organise, together with the Ministry of Interior meetings/education on applicable legislation and instructions concerning the controls of trade (specific documents that have to accompany a consignment of animals in trade and regulations concerning the classical swine fever).

Employees of the Ministry of Interior need to be included in the checks of documents proving that the vehicle used for transport of animals has been disinfected as well as in securing the areas where measures of eradication of classical swine fever in infected holdings are implemented, as well as in other activities prescribed in case of occurrence of the disease on the territory of Montenegro.

Police employees are bound to report all irregularities identified immediately to the competent official veterinarian for further taking of appropriate measures.

The Ministry of Interior is bound to develop an Operational Plan and to regularly present cumulative reports on all activities implemented and irregularities identified concerning the control of trade in live animals. Co-operation with the police takes place at the pace and in intensity required by the epizootiological situation in the field and in accordance with the measures in force.

A joint meeting with the Ministry of Interior is planned in order to agree in detail on the actions and co-operation in case of occurrence of the disease and the distribution of training needed for police employees for an adequate control of this measure.

The measure and activities implemented for control and prevention of illegal trade in animals are an integral part of the Strategy of the Government of Montenegro on control of grey economy.

**II. 6. Additional measures of classical swine fever control**

The Veterinary Law lays down that in case the disease occurs continuously in a specific area, additional measures and manner of their implementation may be ordered in line with the local epizootiological circumstances along with the measures laid down by the existing rulebooks.

Furthermore, if necessary, the implementation of additional measures may be expanded also to the territory of the entire country.

**II. 7. Risk factors concerning the occurrence and spread of classical swine fever and measures for risk reduction**

**Table 9. Risk factors concerning the occurrence and spread of classical swine fever and measures for risk reduction**

|  |  |
| --- | --- |
| **Risk factors** | **Measures for risk reduction** |
| **Structure of holdings keeping pigs (a large number of holdings that do not respect in entirety the biosafety measures)** | Setting up the register of holdings keeping pigs  Education for keepers  Increasing the responsibility of keepers  Strict adherence to biosafety measures |
| **Swill** | Not using swill in pig feeding |
| **Low level of knowledge and interest of animal holders on classical swine fever** | Continuous implementation of training  Increase the level of responsibility by more frequent controls and sanctions in case irregularities are established |
| **Low level of knowledge and responsibility of animal transporters and traders** | Increase the level of responsibility  Education  Increased controls and sanctions in case irregularities are identified |
| **Wild boars** | Prevention of direct and indirect contacts with wild boars (including meat and products of wild boars) |
| **Uncontrolled trade in pigs and products from pork; trade in pigs of unknown health status**  (Trade Pigs which is not in accordance with regulations- when animals are not properly marked and registered, if they don’t have a proof on origin , they are not accompanied by appropriate documentation and uncontrolled coming into to holdings) | Increase responsibility  More detailed development of requirements for placing pigs onto market  Strengthened controls of trade  Placing pigs onto market exclusively under the control of a veterinarian |
| **Illegal trade in pigs** | Avoiding/detection of any illegal trade in pigs (including illegal import of pigs and pork products) |
| **Placing pigs on the market immediately after introduction of pigs to a holding** | Avoiding placing pigs on the market at least 21 days after introduction of new pigs onto a holding or return pigs to a holding (from fairs or other places) |
| **Risky contacts**  **\*high risk** (other pigs)  **\*medium risk** (trucks transporting pigs, trucks distributing feed, shared/same equipment and tools used on a larger number of holdings keeping pigs, non-professional persons visiting a large number of holdings keeping pigs, other pig keepers)  **\* low risk** (professionals, e.g. Veterinarians or advisers, others who visit holdings keeping pigs) | **\*Prohibition / restriction** of uncontrolled entry to persons and animals into facilities where pigs are kept  **\*Washing and disinfection** of vehicles, equipment and tools, washing and disinfection of footwear and use of protective clothes  **\*Avoiding use** of shared equipment and tools; washing and disinfection of footwear and use of protective clothes |
| **Livestock markets, fairs, exhibitions, assembly centres or other pig assembly points** | Avoiding trade in pigs in livestock market, fairs; washing and disinfection of footwear and washing clothes and implementation of other hygiene measures after visiting livestock markets, fairs, etc. |

**III. COOPERATION WITH COUNTRIES – TRADE PARTNERS AND NEIGHBOURING COUNTRIES**

**III. 1. Meetings of directors of veterinary administrations**

In the period 2007- 2011, meetings of directors of veterinary administrations and their assistants had been organised on the issue of the status of classical swine fever in the region and measures undertaken.

This implies bilateral meetings of representatives of the Veterinary Administration of Montenegro with representatives of competent veterinary services from countries of the region, primarily with Serbia, considering the number of live pigs imported, but also with Croatia, and Bosnia and Herzegovina.

The conclusions of the meetings were as follows:

1. An open-type meeting provides a good opportunity to exchange information on the current status of the disease, discussion on possible problems and difficulties in implementation of measures.
2. The programmes of monitoring and crisis plans for control of classical swine fever in wild boars have to be put in place, which includes also use of the TAIEX's technical assistance.
3. The need for stepping up the controls in terms of use of swill, illegal trade in animals and setting up of electronic database – register of holdings and register of pigs as well as the pig identification obligation.
4. Eradication of the disease has to be the joint objective of countries of the region, based on a regional – European approach.

Furthermore, under the TAIEX auspices, with participation of Croatia, Serbia, Bosnia and Herzegovina, Kosovo, Macedonia, Albania and Montenegro, diseases control and eradication of which is of importance for the entire region were identified as early as 2007, and these are rabies and classical swine fever. In that regard, activities aimed at control of classical swine fever (and rabies) were implemented in all these countries, under the national IPA projects in Montenegro – IPA 2011. The objective of the regional project, implemented simultaneously with the national one, was timely exchange of information, definition of joint objectives and tasks and co-ordination of measures applied for the purpose of eradication of classical swine fever.

**III. 2. Co-ordination of measures concerning the change in policy of control of classical swine fever between Montenegro and Serbia**

Considering the intensive trade in pigs between Serbia and Montenegro, it is necessary to begin development/harmonisation of strategies of control of classical swine fever between the two countries in order to co-ordinate the discontinuation of vaccination against classical swine fever at the level of both countries.

**III. 3. Education**

In order to educate and inform veterinarians, hunters and pig keepers, the Veterinary Administration plans to organise workshops for veterinarians so they would be able to immediately identify and promptly react in case of suspicion and occurrence of classical swine fever, and also for hunters and pig keepers in order to raise their awareness on significance of classical swine fever and their role in preventing its occurrence, spread and eradication. To that end, the plan is to utilise the available technical assistance of the European Union (TAIEX, BTSF, etc.). The Veterinary Administration will develop the information material intended for pig keepers, hunters and veterinarians. All information will be available at the official web page. <http://www.vet.uprava.gov.me>. The plan is to distribute the information leaflets for animal keepers in 2017, during the last vaccination campaign.

# ANNEX II-1.

# Programme of Mandatory Animal Health Protection Measures in Montenegro in 2015 (Official Gazette of Montenegro 11/2015)

**11. CLASSICAL SWINE FEVER**

With a view to preventing the occurrence of classical swine fever, vaccination of domestic pigs is implemented in order to maintain active immunity against the classical swine fever virus, along with implementation of other measures aimed at timely detection and control of the classical swine fever.

**Institution responsible:** Ministry of Agriculture and Rural Development – Veterinary Administration, Administration for Inspection Affairs.

**Task holder:** veterinary surgeries, Diagnostic Veterinary Laboratory, Hunters’ Federation of Montenegro – hunters’ organizations, Veterinary Inspectorate.

**Scope:** all holdings where pigs are bred or kept (35,850 pigs).

**Implementation period:** throughout the year (in intensive production conditions, so that animals are permanently immune).

**11.1 Vaccination of domestic pigs and control of immunization effectiveness**

**Implementation method:**

Classical swine fever is prevented and controlled through continuous maintenance of immunity against classical swine fever in all holdings where pigs are kept and bred, by vaccination of pigs with a vaccine prepared from the attenuated C strain, in line with the manufacturer’s instructions.

In holdings keeping and breeding pigs, clinical examination of pigs is conducted before the vaccination. Only healthy pigs may be vaccinated.

Vaccination of domestic pigs for legal persons engaged in organised animal production or keeping that provide registered veterinary services for continuous protection of health of their animals, are provided with the vaccine by the Veterinary Administration on the basis of the needs presented for the current year, i.e. on the basis of the vaccination programme submitted. Vaccine application costs are borne by the legal person concerned.

Only vaccinated pigs may be placed on the market, no sooner than 15 days following the vaccination.

Unvaccinated piglets of less than 45 days may be placed on the market if they originate from a holding free from classical swine fever, where all pigs are vaccinated, including sows and gilts.

Trade in pigs may take place only in livestock market and other collection sites under permanent veterinary control.

In order to control the effectiveness of immunisation of vaccinated pigs, blood samples are taken from vaccinated pigs in line with the technical instructions issued by the Veterinary Administration and they are delivered to the Laboratory for testing for the presence of specific antibodies against the classical swine fever virus.

The sampling of blood for control of the immunological status is done no sooner than 35 days after vaccination. The list of veterinary surgeries taking blood samples is an integral part of the technical instructions of the Veterinary Administration.

The Diagnostic Veterinary Laboratory prepares the report on results of control of the immunological status of domestic pigs and presents it to the Veterinary Administration.

In case of suspicion or clinical signs that point to the occurrence of classical swine fever, the veterinarian takes appropriate samples of dead or euthanized animals in line with the instructions prepared by the Diagnostic Veterinary Laboratory and delivers them to the Laboratory for laboratory testing.

In case of occurrence of the disease, euthanasia and safe disposal of infected and suspected animals is done, along with implementation of all zoo-hygiene and bio-safety measures prescribed.

**Control method:** The implementation of measures is controlled by the official veterinarians in line with the Technical Instructions on the manner of performance of official controls of authorised veterinary organisations in implementation of the Programme of Measures.

Veterinary surgeries are bound to present, in a timely manner, the following:

* to present to the Veterinary Administration and the official veterinarian, no later than 10 days before the beginning of the measure implementation, the plan with the information on the place and date of vaccination of domestic pigs in the course of the year, in accordance with the implementation period planned, as well as all subsequent changes to the plan;
* to notify the Veterinary Administration and the official veterinarian of all animal keepers who refuse implementation of the programme of measures, in contravention of the Article 51 paragraph 1 item 5 of the Veterinary Law (Official Gazette of Montenegro 30/12);
* to present to the competent official veterinarian, no later than by the 10th day of the current month for measures implemented in the previous month, the report on measures implemented in the previous month, that includes the following information: place, date of measures implemented, name of the animal keeper and number of animals per each holding separately, along with copies of certificates of vaccination, or the report on measures and activities completed concerning the implementation of this programme, along with copies of laboratory reports for the sample delivered, accompanied by the minutes of the official veterinarian;
* upon completion of the control, present the Veterinary Administration with the report, along with the minutes of the official veterinarian.

**Payment method:** the payments are made on the basis of the timely receipt of the invoice for public activities – vaccination, detection and control of the classical swine fever, accompanied by the report on measures implemented and activities completed, copies of the certificates of vaccination, and copies of the laboratory reports for the sample delivered together with the minutes of the official veterinarian, or for the implementation of measures ordered for control of classical swine fever along with the copy of the decision of the official veterinarian, on the basis of the invoice delivered, accompanied by the report on laboratory diagnostic testing completed.

**11.2 Monitoring of wild boars for classical swine fever**

**Implementation method:**

With a view to establishing the presence of the classical swine fever virus in the nature, in the wild boars population, hunters present samples of body fluids and organs (kidneys and spleen) of wild boars) to veterinary surgeries, which then deliver these samples to the Veterinary Diagnostic Laboratory for testing for the presence of the classical swine fever antibodies. Hunters, veterinary surgeries and the Diagnostic Veterinary Laboratory perform sampling, delivery of samplings and laboratory diagnostics of samples collected and delivered in accordance with the technical instructions issued by the Veterinary Administration.

Hunters who present complete samples of wild boars for the purpose of establishing the presence of the classical swine fever virus get free-of-charge examination of presence of *Trichinella spiralis* in meat of the wild boar samples of which they delivered. Veterinary surgeries are entitled to a fee for the examination only in case the samples have been taken and delivered to the Diagnostic Veterinary Laboratory in a prescribed manner.

The Diagnostic Veterinary Laboratory produces the annual report on activities implemented concerning the monitoring of the classical swine fever in wild boars and presents it to the Veterinary Administration.

**Funds: 64.736,00 €**

**Payment method:** the payments are made on the basis of a timely receipt of an invoice from the hunters, accompanied by a certificate on the sample received, issued by the veterinary surgery.

The invoice for trichinoscopy of wild pig’s meat, issued by veterinary surgeries, has to be accompanied by the copy of the referral form for delivery of samples and the certificate of trichinoscopy conducted.

The invoice is issued by the end of the current month for the previous month.

Invoices not delivered in a timely manner and not accompanied by the completed documents shall not be taken into consideration.

|  |  |  |
| --- | --- | --- |
| **Components** | **Value, €** | |
| Vaccine supply - 33.000 doses | 0.20 | 6,600.00 |
| Testing for the presence of classical swine fever – supply of vacutainers for sampling of pigs blood and collecting of body fluids of wild boars shot - 1650 | 0.24 | 396.00 |
| Vaccination of domestic pigs - 35.850 pigs\* | 1.30 | 46,605.00 |
| Control of the immunological status of domestic pigs - blood sampling - 1500 samples\* | 2.00 | 3,000.00 |
| Control of immunological status of domestic pigs – laboratory testing ELISA test - 1500 samples | 3.90 | 5,850.00 |
| Examination of wild boars for *Trichinella spiralis* - 150 | 8.00 | 1,200.00 |
| Monitoring of classical swine fever in wild boars – laboratory testing ELISA test -150 samples | 3.90 | 585.00 |
| Post mortem examination in the field and sampling - 10\* | 15.00 | 150.00 |
| Laboratory analysis of pathological material PCR - 10 samples | 35.00 | 350.00 |
| **TOTAL**  **64,736.00** | | |

**\***transport costs included in the price set by the Programme.

**ANNEX II-2.**

Pursuant to Article 54 paragraph 6 of the Veterinary Law (*Official Gazette of Montenegro no. 30/12*), the Ministry of Agriculture and Rural Development adopted

**RULEBOOK**

**ON MEASURES FOR PREVENTION, DETECTION, CONTROL AND ERADICATION OF CLASSICAL SWINE FEVER\***

**Scope**

**Article 1**

This Rulebook lays down measures for prevention, detection, control and eradication of classical swine fever.

**Application**

**Article 2**

This Rulebook shall also apply to feral pigs.

**Definitions**

**Article 3**

Terms used in this Rulebook have the following meanings:

1. **‘holding’** means any facility or place where pigs are being bred or kept on a permanent or temporary basis, except for slaughterhouses, means of transport and fenced areas where feral pigs are bred and may be hunted;
2. **‘pig suspected of being infected with classical swine fever virus’** means any pig or pig carcase exhibiting clinical symptoms of the disease or showing characteristic post-mortem lesions or reactions to laboratory tests;
3. **‘case of classical swine fever’** (pig infected with classical swine fever virus) means any pig or pig carcase in which:
4. clinical symptoms of the disease or characteristic post-mortem lesions have been confirmed, or
5. the presence of the disease has been officially confirmed as the result of a laboratory examination carried out in accordance with Annex 1 hereto;
6. **‘outbreak’** means the occurrence of one or more cases of classical swine fever on a holding;
7. **‘primary outbreak’** means the occurrence of classical swine fever that is not epizootiologically linked to the previous outbreak of the disease within the same area;
8. **‘secondary outbreak’** means the occurrence of classical swine fever that is epizootiologically linked to the previous outbreak of the disease within the same area;
9. **‘infected area’** means part of the territory of Montenegro where, following the confirmation of one or more cases of classical swine fever in feral pigs, disease eradication measures are applied in accordance with Article 16 or 17 herein;
10. **‘primary case of classical swine fever in feral pigs’** means any case of classical swine fever in feral pigs which has been confirmed in an area in which no disease eradication measures are in place in accordance with Article 16 or 17 herein;
11. **‘meta-population of feral pigs’** means any group or subgroup of feral pigs with limited contacts with other groups or subgroups of feral pigs;
12. **‘susceptible feral pig population’** means part of feral pig population which has not developed immunity against classical swine fever virus and are susceptible to the infection with classical swine fever virus;
13. **‘owner’** means any natural or legal person, or a holder, that is authorized to permanently or temporarily keep pigs, whether or not for financial reward;
14. **‘processing’** means one of the treatments for high risk material by which the risk of spread of classical swine fever virus is avoided, in accordance with relevant regulations;
15. **‘catering waste’** means any food waste from restaurants, other catering facilities or kitchens, including industrial kitchens and kitchens in the holdings in which pigs are bred;
16. **‘pig’** means any animal of the Suidae family, including feral pigs;
17. **‘feral pig’** means a pig which is not kept or bred on a holding;
18. **‘marker vaccine’** means a vaccine eliciting specific antibodies which, following laboratory tests carried out in accordance with Annex 1 hereto, may distinguish from antibodies elicited by the natural infection;
19. **‘killing’** means painlessly killing of animal;
20. **‘slaughter’** means causing the death of pigs after stunning and bleeding;
21. **‘area with a high density of pigs’** means any geographical area with a radius of 10 km around a holding containing pigs suspected to be or known to be infected with classical swine fever virus, where there is a pig density higher than 800 pigs per km2; the holding in question must be located either in a region where there is a density of pigs kept in holdings higher than 300 pigs per km2, or at a distance of less than 20 km2 from such a region;
22. **‘contact holding’** means a holding where classical swine fever could have been introduced, whether as a result of the vicinity of infected holding (location), movement of persons, pigs or vehicles or in any other way;
23. **‘production unit (subunit)’** means part of a holding being an independent epizootiological whole, which is determined according to the geographical location and/or organization of production, where a group of pigs is kept in such a way that pigs have frequent direct or indirect contact one to the other, but are kept separated from other pigs in the same holding;
24. **‘singleton reactor (nonspecific reactors)’** means any pig which yields a positive result in serological tests for classical swine fever but which has no history of contact with classical swine fever virus and from which there is no evidence of spread of infection to in-contact pigs, and may have titre virus of neutralizing antibodies ranging from borderline to strongly positive. On re-sampling, singleton reactors may show a decreasing or constant titre.

**Classical swine fever notification**

**Article 4**

1. A suspicion of the occurrence of classical swine fever shall be notified to the administrative authority in charge of veterinary services (hereinafter referred to as the Administration).
2. When classical swine fever is confirmed, the occurrence of classical swine fever shall be notified to the World Organization for Animal Health (OIE), European Commission and Member States in accordance with Annex 2 hereto in case of:
3. confirmed classical swine fever in holdings;
4. confirmed classical swine fever in a slaughterhouse or in means of transport;
5. the primary cases of classical swine fever confirmed in feral pigs;
6. the results of the epizootiological enquiry carried out in accordance with Article 9 herein;
7. the information on other confirmed cases of classical swine fever in feral pigs in the infected area in accordance with Article 17 paragraph 1 point 1 herein.

**Measures in case of suspicion of the presence of classical swine fever on a holding**

**Article 5**

1. Where a holding contains one or more pigs suspected of being infected with classical swine fever virus, necessary measures shall be immediately taken in order to confirm or rule out the presence of the disease in accordance with Annex I hereto.
2. If the suspected presence of classical swine fever is not ruled out, veterinary inspector (hereinafter referred to as the official veterinarian) shall immediately have a holding placed under official surveillance, carry out epizootiological enquiry in accordance with Article 8 herein and order the following measures:
3. a census shall be taken of all the pigs on a holding, already sick, dead or suspected of being infected with classical swine fever virus, which shall be updated regularly, including newborn and dead pigs during the period of suspicion of the presence of classical swine fever on the holding;
4. control over vaccination operations against classical swine fever, identification and movement of pigs within the last year;
5. movement of the pigs on the holding shall be restricted so that the pigs are confined in their stalls or separated in an isolated place within the facility;
6. no pigs, or if necessary other species of animals, may enter or leave the holding and appropriate deratisation and disinfection measures shall be applied;
7. no pig carcases may leave the holding without an authorization issued by the official veterinarian;
8. no meat, pig products, semen, ova and embryos of pigs, animal feed, waste and utensils likely to transmit classical swine fever virus may leave the holding without an authorization issued by the official veterinarian;
9. no person may move to or from the holding without an authorization issued by the official veterinarian;
10. no vehicle may move to or from the holding without an authorization issued by the official veterinarian;
11. disinfectants shall be used at the entrances and exits of the buildings where pigs are kept and at the entrances and exits of holdings;
12. any person entering or leaving pig holdings shall fulfill appropriate biosafety measures necessary to reduce the risk of spread of classical swine fever virus;
13. all means of transport shall be disinfected before leaving the holding.
14. In case of an unfavorable epizootiological situation and in particular if the holding containing suspected pigs is located in an area with a high density of pigs, the official veterinarian may order that:
15. the measures referred to in Article 6 paragraph 1 herein shall be applied in the holding referred to in paragraph 2 of this Article or may limit the application of these measures only to the pigs suspected of being infected with classical swine fever or on the part of the holding where they are kept, provided that these pigs have been housed, kept and fed completely separately from the other pigs in the holding;
16. a sufficient number of samples shall be taken after killing pigs in order to confirm or rule out the presence of classical swine fever in accordance with Annex 1 hereto;
17. a temporary protection zone shall be established around the holding referred to in paragraph 2 of this Article, where the measures referred to in paragraphs 1 and 2 of this Article are to be applied.
18. The measures provided for in paragraph 2 of this Article shall be applied until the suspicion of classical swine fever has been ruled out.

**Measures in case of confirmation of the presence of classical swine fever in pigs on a holding**

**Article 6**

1. In cases where the presence of classical swine fever is officially confirmed in a holding, the official veterinarian shall, in addition to the measures referred to in Article 5 paragraph 2 herein, order application of the following measures on the infected holding:
2. all pigs on the infected holding shall be killed without delay and in such a way as to avoid the risk of spread of classical swine fever virus during transport or killing;
3. a sufficient number of samples shall be taken from the killed pigs in accordance with Annex 1 hereto, in order to establish the manner of introduction of classical swine fever virus into the holding and determine the length of time during which the disease may have existed on the holding before official notification;
4. the carcasses of pigs which have died or have been killed shall be safely disposed of;
5. raw materials and byproducts of pig origin, which have been slaughtered during the period between the probable introduction of classical swine fever virus into the holding and the taking of the measures ordered, shall be traced and safely disposed of;
6. semen, ova and embryos of pigs, which have been collected during the period between the probable introduction of classical swine fever virus into the holding and the taking of the measures ordered, shall be traced and safely disposed of in such a way as to avoid the spreading of classical swine fever virus;
7. all materials and waste matter likely to be contaminated, such as feedingstuff, must be subjected to a treatment ensuring the destruction of classical swine fever virus;
8. all single-use materials which may be contaminated, in particular those used for slaughter operations, shall be destroyed;
9. after the pigs have been safely disposed of, the buildings used for housing the pigs, the vehicles used for transporting them and the equipment, bedding and manure shall be cleaned and disinfected;
10. in the case of a primary outbreak of classical swine fever in accordance with Annex 1 hereto, the classical swine fever virus isolate shall be subject to the laboratory procedure to identify the genetic type;
11. an epizootiological enquiry shall be carried out in accordance with Article 9 herein.
12. The measures provided for in paragraph 1 of this Article shall be applied under the supervision of the official veterinarian.
13. In cases where an outbreak of classical swine fever has been confirmed in a zoo, a laboratory, a national park, a hunting area where feral pigs are kept or a fenced breeding farm where pigs are kept for scientific purposes or purposes related to conservation of rare breeds, a derogation from the measures provided for in paragraph 1 points 1 and 5 of this Article may be granted, provided that social and economic interests of Montenegro are not endangered, which is notified to the European Commission in order to investigate epizootiological situation and where necessary take appropriate measures to prevent the disease.

**Measures in the event of confirmation of the presence of classical swine fever in holdings consisting of different production units**

**Article 7**

1. In the case of confirmation of the presence of classical swine fever in a holding which consists of two or more separate production units and in order that fattening of pigs may be completed, a derogation from the measures provided for in Article 6 paragraph 1 point 1 herein may be granted on a production unit with healthy pigs provided that it is confirmed that the structure, size, distance between these production units and the production operations are such that the production units provide completely separate facilities for keeping and feeding, so that the virus cannot spread from one production unit to another.
2. In cases referred to in paragraph 1 of this Article, the European Commission shall be notified in order to investigate epizootiological situation and where necessary take appropriate measures to prevent the spreading of the disease.

**Measures in contact holdings**

**Article 8**

1. On the basis of the epizootiological enquiry carried out in accordance with Article 9 herein, the official veterinarian identifies a contact holding or the holding from which classical swine fever has been introduced or to which the disease may be introduced.
2. The measures provided for in Article 5 herein shall be applied in the holding referred to in paragraph 1 of this Article until the suspicion of the presence of classical swine fever has been officially ruled out.
3. The official veterinarian shall order application of the measures provided for in Article 6 paragraph 1 herein in the contact holdings if the epizootiological situation so requires.
4. The killing of pigs in contact holdings shall be carried out on the basis of the risk assessment in accordance with Annex 3 hereto.

**Epizootiological enquiry**

**Article 9**

1. The epizootiological enquiry shall be carried out in case of suspicion of the presence of classical swine fever or in case of outbreaks of classical swine fever.
2. Such enquiry shall include collecting data on:
3. the length of time during which classical swine fever virus may have existed on the holding before the disease was notified or suspected;
4. the possible origin of classical swine fever on the holding and the identification of other holdings in which pigs may have become infected from the same source;
5. the movement of persons, vehicles, pigs, carcasses, semen, pig products or any material which could have transported the virus to or from the holdings.
6. If the results of the enquiry referred to in paragraph 1 of this Article suggest that classical swine fever may have spread from or to holdings located in other countries, competent authorities of these countries and the European Commission shall be informed thereof.

**Infected and endangered areas**

**Article 10**

1. After the presence of classical swine fever has been officially confirmed on a holding, an infected area shall be established with a radius of at least 3 km around the outbreak site, which is a part of the endangered area covering a radius of at least 10 km around the outbreak site.
2. When establishing boundaries of the infected and endangered areas, the following shall be taken into account:
3. the results of the epizootiological enquiry carried out in accordance with Article 9 herein;
4. the geographical situation, particularly natural or artificial boundaries;
5. the location and proximity of holdings;
6. data on movements and trade in pigs and the availability of slaughterhouses;
7. data on the facilities and personnel available to control any movement of pigs within the areas, in particular if the pigs that have died or have been killed have to be moved away from their holding of origin.
8. If the infected and/or endangered area includes parts of the territory of other countries, the competent authorities of these countries shall collaborate to establish the boundaries of the infected and endangered areas.
9. Prominent signs or warning notices shall be set up on visible places and the public shall be informed through the media to ensure that all persons in the infected and endangered areas are informed about the measures provided for in Articles 11 and 12 herein and to ensure the enforcement of these measures.

**Measures in the infected area**

**Article 11**

1. The official veterinarian shall order application of the following measures in the infected area:
2. a census of the holdings in which pigs are kept and bred, identification and registration of unidentified pigs and vaccination of the pigs that have never been vaccinated or if more than six months have elapsed from the last vaccination, clinical examination of all pigs on the holdings in the infected area in order to identify the state of health of pigs within seven days from the establishment of the infected area;
3. no pigs may be moved or transported, except in cases referred to in point 7 of this Article, including the pigs coming from outside the infected area that are sent to a slaughterhouse situated in the infected area for immediate slaughter or the pigs transported by road or rail through the infected area without stopping or unloading the pigs (transit) with the approval of the transit given by the official veterinarian;
4. the vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (e.g. carcasses, feedingstuff, manure) shall be cleaned and disinfected as soon as possible after contamination;
5. no other domestic animal may enter or leave a holding without the authorization of the official veterinarian;
6. no vehicle may leave the infected area without being cleaned and disinfected and then authorized by the official veterinarian;
7. all dead or diseased pigs on a holding shall be immediately notified in order to carry out investigations in accordance with Annex 1 hereto;
8. pigs may not be removed from the holding for at least 30 days after the completion of the cleaning and disinfection of the infected holding, or 15 day after carrying out vaccination on the holding, except as provided for in paragraph 2 of this Article in case of:
9. the urgent sending for immediate slaughter to the slaughterhouse within the infected or endangered area or to the slaughterhouse designated for such purposes, or to
10. the facility for safe disposal or a suitable place where the pigs are immediately killed and their carcasses are safely disposed of under the supervision of the official veterinarian, or
11. under exceptional circumstances, to other premises located within the infected area;
12. semen, ova and embryos of pigs shall not leave the holdings situated within the infected area;
13. any person entering or leaving pig holdings shall observe appropriate bio-safety measures necessary to reduce the risk of spread of classical swine fever virus.
14. Where the measures provided for in paragraph 1 of this Article are applied beyond 30 days because of further outbreaks of classical swine fever which endanger animal welfare or impede the raising of the pigs, the official veterinarian may, following a reasoned application by the owner, authorize removal of pigs from a holding within the infected area, to be directly transported to building referred to in paragraph 1 point 7 of this Article provided that:
15. the veterinarian has carried out a clinical examination of the pigs in the holding and in particular those to be moved, including the taking of the body temperature of these animals, and a check of the register and the pig identification marks and the vaccination carried out within the last year;
16. the examinations have shown no clinical signs of classical swine fever and that the pigs have been properly identified and vaccinated and that not less than 15 days nor more than six months have elapsed from the last vaccination;
17. the pigs are transported in vehicles sealed by the official veterinarian;
18. a sufficient number of samples has been taken from the pigs to be slaughtered or killed in order that the presence of classical swine fever virus in these holdings can be confirmed or ruled out;
19. the official veterinarian has been informed at the slaughterhouse about sending the pigs to the slaughterhouse who shall upon their arrival at the slaughterhouse notify the official veterinarian who has sent the pigs for slaughter;
20. the transported pigs are kept and slaughtered at the slaughterhouse separately from other pigs;
21. a special attention is devoted to the signs typical of classical swine fever during inspection before and after slaughter and the fresh meat intended for processing shall be marked with the special stamp, and in case the consignment is sent in other establishment designated for processing, the consignment shall be sealed before dispatching and throughout the transport;
22. the vehicles and equipment used to transport the pigs are immediately cleaned and disinfected after the transport in accordance with Article 13 herein;
23. The measures shall continue to be applied in the infected area at least until:
24. cleaning and disinfection in the infected holdings have been carried out;
25. the clinical examination and laboratory testing have been carried out on all holdings in accordance with Annex 1 hereto after 30 days from the completion of preliminary cleaning and disinfection on the infected holdings.

**Measures in the endangered area**

**Article 12**

1. The official veterinarian shall order application of the following measures in the endangered area:
2. a census of the holdings in which pigs are kept and bred, identification and registration of unidentified pigs and vaccination of the pigs that have never been vaccinated or if more than six months have elapsed from the last vaccination;
3. no pig may move or be transported on public roads and roads connecting holdings, except the pigs coming from outside the endangered area that are sent to a slaughterhouse situated in the endangered area for immediate slaughter or the pigs transported by road or rail through the endangered area without stopping or unloading the pigs (transit) with the approval of the transit given by the official veterinarian;
4. no animal may enter or leave a holding during the first seven days after establishment of boundaries of the endangered area without the authorization of the official veterinarian;
5. trucks and other vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (e.g. carcasses, feedingstuff, manure, etc.) shall be cleaned and disinfected as soon as possible after contamination;
6. all dead or diseased pigs on a holding shall be immediately notified to the official veterinarian in order to carry out investigations in accordance with Annex 1 hereto;
7. no pig may be removed from the holding for at least 21 days after the completion of the cleaning and disinfection of the infected holdings, or 15 days after carrying out vaccination, except as provided for in Article 11 paragraph 2 herein in case of:
8. the urgent sending for immediate slaughter to the slaughterhouse designated for such purposes if possible within the infected or endangered area, or to
9. the facility for safe disposal or a suitable place where the pigs are immediately killed and their carcasses are safely disposed of under the supervision of the official veterinarian, or
10. under exceptional circumstances, to other premises located within the infected area;
11. semen, ova and embryos of pigs shall not leave the holdings situated within the endangered area;
12. any person entering or leaving pig holdings shall observe appropriate bio-safety measures necessary to reduce the risk of spread of classical swine fever virus.
13. Where the measures provided for in paragraph 1 of this Article are applied beyond 30 days because of further outbreaks of classical swine fever which endanger animal welfare or impede the raising of the pigs, the official veterinarian may, following a reasoned application by the owner, authorize removal of the pigs from a holding within the endangered area, to be directly transported to the building referred to in paragraph 1 point 6 of this Article under conditions specified in Article 11 paragraph 2 herein under the supervision of the official veterinarian.
14. The measures shall continue to be applied in the endangered area until:
15. cleaning and disinfection in the infected holdings have been carried out;
16. the clinical examination and laboratory testing have been carried out on all holdings in accordance with Annex 1 hereto after 20 days from the completion of preliminary cleaning and disinfection on the infected holdings.

**Cleaning and disinfection**

**Article 13**

1. Cleaning and disinfection when applying the measures laid down in Articles 5, 6, 11, 12 and 15 herein shall be carried out under the supervision of the official veterinarian in accordance with Annex 4 hereto.

**Repopulation of pig holdings following classical swine fever outbreaks**

**Article 14**

1. The reintroduction of pigs to the holding where classical swine fever has been confirmed shall take place at least 30 days after completion of the cleaning and disinfection of the holding.
2. In case of open-air pig holdings, the reintroduction of pigs shall start with the introduction of sentinel pigs which have been checked and found negative for the presence of antibodies against classical swine fever virus or come from holdings in which no measures for the control of classical swine fever have been applied.
3. The sentinel pigs which are introduced to a holding shall be sampled and tested for the presence of antibodies after 40 days from the introduction to a holding in accordance with Annex 1 hereto.
4. If the presence of antibodies against classical swine fever virus has not been confirmed, full repopulation may take place on a holding provided that no pig leave the holding before the negative results of the serological examination are available;
5. In case of other forms of rearing pigs, the repopulation of pigs shall take place in accordance with paragraphs 2 and 3 of this Article on condition that the pigs have been identified and vaccinated against classical swine fever and a period from the last vaccination shall not be less than 15 days or more than six months, or full repopulation, provided that:

* all pigs are introduced to a holding within a period of 20 days and come from holdings in which no measures for restrictions related to classical swine fever have been applied;
* blood samples are taken from all pigs at the earliest 40 days after the introduction of the last pigs and that the pigs are subjected to a serological examination in accordance with Annex 1 hereto;
* no pig may leave the holding before the negative results of the serological examination are available.

**Measures in case of suspicion and confirmation of the presence of classical swine fever in pigs in a slaughterhouse or means of transport**

**Article 15**

1. Where there is a suspicion of the presence of classical swine fever in a slaughterhouse or means of transport, the official veterinarian shall carry out epizootiological enquiry in accordance with Article 9 herein and order laboratory testing in accordance with Annex 1 herein.
2. Should a case of classical swine fever be confirmed in a slaughterhouse or means of transport, the official veterinarian shall carry out epizootiological enquiry and order application of the following measures:
3. all susceptible animals in the slaughterhouse or in the means of transport shall be killed;
4. the carcasses, offal and by-products of animal origin which may be infected and contaminated shall be processed under the supervision of the official veterinarian;
5. buildings, equipment and vehicles shall be cleaned and disinfected under the supervision of the official veterinarian;
6. the classical swine fever virus isolate shall be subject to the laboratory procedure to identify the genetic type in accordance with Annex 1 herein;
7. the measures laid down in Article 6 paragraph 1 and Article 8 herein shall be applied in the holding where the infected pigs or carcases came from or in the contact holdings;
8. no pig may be introduced for slaughter or transport before at least 24 hours have elapsed after the completion of the cleaning and disinfection.

**Measures in case of suspicion and confirmation of the presence of classical swine fever in feral pigs**

**Article 16**

1. After obtaining information that feral pigs are suspected of being infected with classical swine fever, the official veterinarian shall take necessary activities to confirm or rule out the suspicion of the presence of classical swine fever, by giving information to the owners of pigs and to hunters, including laboratory testing of all feral pigs which have been shot or found dead.
2. After a primary case of classical swine fever has been confirmed in feral pigs, in order to reduce the risk of the spread of classical swine fever virus:
3. an expert group (veterinarians, hunters, biologists and epizootiologists) shall be immediately established in order to:
4. study the epizootiological situation and define an infected area,
5. establish appropriate measures to be applied in the infected area,
6. draw up the plan for the eradication of classical swine fever from feral pigs,
7. carry out audits to verify the effectiveness of the measures applied to eradicate classical swine fever from the infected area;
8. the official veterinarian shall place under official surveillance the holdings where pigs are bred and kept in the infected area and shall order application of the following measures:
9. a census of pigs on all holdings,
10. vaccination,
11. all pigs on the holding shall be kept in such a way as to prevent them from being in direct or indirect contact with feral pigs,
12. no pigs may enter or leave the holding without the authorization of the official veterinarian,
13. disinfectants shall be used at the entrances and exits of buildings in which pigs are bred and kept and at the entrances and exits of the holdings,
14. appropriate bio-safety measures shall be applied by all persons coming in contact with feral pigs, to reduce the risk of spread of classical swine fever virus, which may include a temporary ban on entering the holding where pigs are bred and kept,
15. all dead pigs or the pigs showing clinical signs of classical swine fever shall be tested on a holding,
16. no part of any feral pig, whether shot or found dead, as well as any tools or equipment which could be contaminated with classical swine fever virus, shall be brought into a holding,
17. no pigs, their semen, embryos or ova shall be moved,
18. all feral pigs which have been shot or found dead in the infected area shall be examined and tested for classical swine fever in accordance with Annex 1 herein,
19. the classical swine fever virus isolate shall be subject to the laboratory procedure to identify the genetic type in accordance with Annex 1 herein.
20. If a case of classical swine fever has occurred in feral pigs in an area of a country close to the territory of another country, the country concerned shall collaborate with the neighboring country in the enforcement of appropriate measures.
21. The measures laid down in paragraphs 1, 2 and 3 of this Article shall be applied until the plan referred to in Article 17 herein has been approved or adopted.

**Plan for the eradication of classical swine fever from feral pigs**

**Article 17**

1. The plan for the eradication of classical swine fever from feral pigsshall contain information on:
2. the results of the epizootiological investigations and controls carried out in accordance with Article 16 herein and the geographical distribution of classical swine fever;
3. the infected area with:
4. the results of the epizootiological investigations carried out and the geographical distribution of classical swine fever,
5. the number of feral pigs in the infected area,
6. the natural or artificial obstacles to movements of feral pigs;
7. the organization and manner of cooperation between biologists, hunters, hunting organizations, the wildlife protection services and veterinary services;
8. the information campaign to be enforced to increase hunters' awareness of the measures they are to apply;
9. a manner to determine the number and location of feral pig meta-populations in and around the infected area;
10. the approximate number of meta-populations of feral pigs and their size in and around the infected area;
11. a manner to determine the extent of classical swine fever in the feral pig population, by investigation of feral pigs shot or found dead, laboratory testing and epizootiological enquiry into the frequency of the disease in certain age-stratified groups of feral pigs;
12. the measures to prevent spread of classical swine fever due to movements and/or contact between meta-populations of feral pigs, which may include a prohibition of hunting;
13. a manner of safe removal of carcases of feral pigs shot or found dead;
14. the epizootiological enquiry which is carried out on each feral pig that has been shot or found dead including the information about:
15. the geographical area where the animal was found dead or shot,
16. the date on which the animal was found dead or shot,
17. the person who found or shot the animal,
18. the age and sex of the pig,
19. the symptoms before shooting if the animal was shot,
20. the state of the carcase if the animal was found dead,
21. laboratory findings;
22. the surveillance and preventive measures that may be applied to the holdings situated in the infected area, and if necessary, in its surroundings, including the transport and movement of animals within, from and to the area;
23. the criteria to be applied for lifting the measures taken to eradicate the disease from the infected area and the holdings in the area;
24. the authority charged with supervising and coordinating the departments responsible for implementing the plan;
25. the classical swine fever monitoring measures that shall be enforced after a period of 12 months has elapsed from the last confirmed case of classical swine fever in feral pigs in the infected area.
26. The plan may be amended and supplemented subject to the level of the presence and other epizootiological indicators.
27. The plan referred to in paragraph 1 of this Article shall be transmitted to the European Commission for review and approval within 90 days from the confirmation of a primary case of classical swine fever in feral pigs, and any change of the boundaries of the infected area, epizootiological situation in the infected area and the results after implementation of the plan shall be notified to the European Commission and other countries concerned.

**Vaccination as a preventive measure against classical swine fever**

**Article 18**

1. Classical swine fever is prevented and controlled by vaccination against attenuated C virus strain in order to maintain immunity of the pigs against classical swine fever during the whole year on all holdings in which pigs are kept and bred.
2. Vaccination referred to in paragraph 1 of this Article shall be carried out in piglets from 45 to 60 days old, at the latest 15 days before their movement.

**Emergency vaccination in pig holdings**

**Article 19**

1. When classical swine fever has been confirmed in the holdings where pigs are bred and kept and the epizootiological data suggest that it threatens to spread, emergency vaccination may be introduced.
2. The emergency vaccination referred to in paragraph 1 of this Article is carried out according to the emergency vaccination plan, which shall include information on:
3. the epizootiological situation that calls for emergency vaccination;
4. the extent of the geographical area in which emergency vaccination is to be carried out and the number of the pig holdings in this area;
5. categories of pigs and the approximate number of pigs to be vaccinated;
6. the vaccine to be used;
7. the duration of the vaccination campaign;
8. the identification and registration of the vaccinated animals;
9. measures for the movement of pigs and their products;
10. the criteria that will be considered to decide if vaccination or the measures referred to in Article 8 paragraph 2 herein will be applied;
11. other measures, including the clinical and laboratory examinations to be carried out on samples taken in the vaccinated holdings and in the other holdings, in particular if a marker vaccine is to be used.
12. During the application of emergency vaccination, the following measures are ordered to be applied:
13. no pigs may leave the vaccinated area, unless to be transported for immediate slaughter to a slaughterhouse, which is situated within that area or close to that area, or to a facility for safe removal or to a suitable place where they are immediately killed and their carcasses are processed under official supervision;
14. all fresh pig meat produced from pigs vaccinated during the emergency vaccination shall be either processed or treated in accordance with Article 11 paragraph 2 point 7 herein;
15. semen, ova and embryos collected from the pigs 30 days prior to vaccination shall be traced and destroyed under official supervision.
16. The measures laid down in paragraph 3 of this Article shall be applied for a minimum of 6 months following completion of the vaccination in that area.
17. Before the end of the six-month period referred to in paragraph 4 of this Article, the following measures are ordered to be applied:
18. seropositive pigs may not leave the holding where they are kept, except for immediate slaughter;
19. semen, embryos or ova may not be taken from seropositive pigs;
20. piglets of seropositive sows may not leave their holding of origin unless being transported to:
21. a slaughterhouse for immediate slaughter,
22. a holding designated by the Administration, from which they are to be sent directly to the slaughterhouse,
23. a holding after obtaining a negative result from a serological test for antibodies against the classical swine fever virus.
24. By way of derogation from paragraph 2 of this Article, the emergency vaccination may be carried out provided that the emergency vaccination plan has been drawn up in accordance with the emergency plan laid down in Article 49 of the Veterinary Law.
25. In addition to the information referred to in paragraph 2 of this Article, the vaccination plan referred to in paragraph 6 of this Article specifies whether the pigs in the holdings where the vaccination has been carried out will be slaughtered or killed as quickly as possible in accordance with paragraph 4 point 1 of this Article, and the fresh meat produced from these pigs shall be processed and marked with the special stamp, and in case the consignment is sent in other establishment designated for processing, the consignment shall be sealed before dispatching and throughout the transport.
26. The measures provided for in paragraph 4 of this Article may be lifted after:
27. all the pigs in the holdings where vaccine has been used have been slaughtered or killed in accordance with paragraph 3 point 1 of this Article;
28. all the holdings where pigs are kept have been cleansed and disinfected in accordance with Article 12 herein.
29. Where the measures provided for in paragraph 8 of this Article are lifted, the official veterinarian shall order application of the following measures:
30. no pigs may be reintroduced into the holding for at least 10 days after completion of the cleaning and disinfection, and after all pigs in the holdings where vaccine has been applied have been slaughtered or killed;
31. clinical and laboratory examinations shall be carried out in accordance with Annex 1 hereto in order to detect the possible presence of classical swine fever virus, at least 40 days after the reintroduction, during which time pigs shall not be allowed to move from the holding.
32. The emergency vaccination of pigs shall be carried out on the basis of the risk assessment in accordance with Annex 5 hereto.
33. The plan referred to in paragraphs 2 and 7 of this Article shall be transmitted to the European Commission for review and approval prior to the emergency vaccination.
34. The plan may be amended or supplemented subject to the level of the presence and other epizootiological indicators.

**Emergency vaccination of feral pigs**

**Article 20**

1. When classical swine fever has been confirmed in feral pigs and the epizootiological data suggest that it threatens to spread, the emergency vaccination of feral pigs may be introduced.
2. The emergency vaccination referred to in paragraph 1 of this Article is carried out according to the emergency vaccination plan, which shall include information on:
3. the epizootiological situation that calls for emergency vaccination;
4. the extent of the geographical area in which emergency vaccination is to be carried out (infected area);
5. the type of vaccine to be used and the procedure of vaccination, including the young of feral pigs;
6. the expected duration of the vaccination;
7. the approximate number of feral pigs to be vaccinated;
8. the measures to avoid increasing of the feral pig population;
9. the measures to avoid the spreading of vaccine virus to pigs kept in holdings, if necessary;
10. the expected results of the vaccination and the parameters that will be considered to verify its effectiveness;
11. the authority charged with supervising and coordinating the departments responsible for implementing the plan;
12. the system established in order that the expert group can be informed and review on regular basis the results of the vaccination;
13. the enforcement of other emergency measures.
14. The plan referred to in paragraph 2 of this Article shall be transmitted to the European Commission for review and approval prior to the emergency vaccination.
15. A report concerning the results of the vaccination, epizootiological situation and the results of the implementation of the plan for eradication of classical swine fever in feral pigs shall be transmitted to the European Commission and Member States every 6 months.
16. If the infected area is close to the territory of other country where measures to eradicate classical swine fever from feral pigs are applied, consistency between the vaccination plan referred to in paragraph 1 of this Article and the vaccination plan and other measures applied in the neighboring country shall also be ensured.
17. The plan may be amended or supplemented subject to the level of the presence and other epizootiological indicators.

**Application of provisions**

**Article 21**

1. The vaccination of pigs as a preventive measure against classical swine fever in accordance with Articles 11, 12, 14, 16 and 18 herein shall be carried out by 1 January 2018.
2. The emergency vaccination of pigs shall be carried out only in emergencies starting from 1 January 2018.

**Commencement of Application**

**Article 22**

The provisions of Article 7 paragraph 2, Article 17 paragraph 3, Article 19 paragraph 11 and Article 20 paragraphs 3 and 4 herein shall apply from the date of accession of Montenegro to the European Union.

**Cessation of validity of provisions**

**Article 23**

Rulebook on measures for control and eradication of classical swine fever (*Official Gazette of the Socialist Federal Republic of Yugoslavia, no. 6/88*) shall cease to be applicable on the date of entry into force of this Rulebook.

**Entry into force**

**Article 24**

This Rulebook shall enter into force on the eighth day of its publication in the *Official Gazette of Montenegro*.

Done at Podgorica, 4 April 2014

No. 323-12/14-2

Minister

PhD Petar Ivanović, m.p.

\*Council Directive 2001/89/EC on Community measures for the control of classical swine fever has been transposed into this Rulebook and Commission Decision 2002/106/EC approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever has been transposed into Annex 2 of this Rulebook.

**ANNEX 1**

**CLASSICAL SWINE FEVER DIAGNOSIS**

**CHAPTER A**

**Differential diagnosis**

(1) Classical swine fever is caused by an enveloped RNA virus which belongs to the genus *pestivirus* of the *flaviviridae* family. Classical swine fever virus is related to the ruminant pestiviruses causing bovine viral diarrhoea (BVDV) and border disease (BDV). This relationship has serious diagnostic consequences as cross reactions occur and may lead to false positive results of the laboratory tests.

(2) Classical swine fever virus is stable in secretions and excretions of infected pigs, pig carcasses and fresh pig meat and some pig meat products. It is readily inactivated by detergents, lipid solvents, proteases and common disinfectants.

(3) The main natural route of infection is oro-nasal by direct or indirect contact with infected pigs or by feeding of virus-contaminated feed. In areas with a high density of pigs, spread of virus easily occurs between neighbouring pig holdings. Disease transmission via semen of infected boars may also occur.

(4) The incubation period in individual animals is about one week to ten days, but under certain conditions clinical symptoms may only become evident two to four weeks after virus introduction or even more if adult breeding pigs or mild strains of virus are concerned.

(5) The clinical signs of classical swine fever are extremely variable and it may be confused with clinical signs of other diseases. Severity of symptoms depends mainly on the age of the animal and virus virulence. Usually young animals are affected with more severe symptoms than older animals. In breeding pigs the course of the infection is often mild or even sub-clinical.

(6) Acute, chronic and prenatal forms of classical swine fever can be distinguished.

**Acute, chronic and prenatal forms of disease**

**Acute form of classical swine fever**

(1) Weaners and fattening pigs most often display the acute form of classical swine fever. The initial signs are anorexia, lethargy, fever, conjunctivitis, swollen lymph nodes, respiratory signs (apnea, dispnea), and constipation followed by diarrhoea.

The typical haemorrhages of the skin, are usually observed on the ear, tail, abdomen and the inner side of the limbs during the second and third week after infection until death. Neurological signs are sometimes seen, such as a staggering hind limb gait, ill coordination of movement, and convulsions.

A constant finding is fever. This is usually 40°C and higher, but in adult pigs fever may not exceed 39,5°C.

(2) Classical swine fever virus causes severe leukopenia and immunosuppression, which often leads to secondary enteric and respiratory infection.

The signs of these secondary infections can mask or overlap the most typical signs of classical swine fever and thus result in a wrong diagnosis.

Death occurs usually within one month.

Recovery with production of antibodies does occur, most often in adult breeding animals which do not display severe clinical signs of classical swine fever.

Antibodies against classical swine fever virus are detectable from 2 to 3 weeks post infection onwards.

(3) Pathological changes visible on post-mortem examination are most frequently observed in lymph nodes and kidneys. The lymph nodes become oedematous and haemorrhagic.

Haemorrhages of the kidney may vary from petechiae to ecchymotic haemorrhages. Similar haemorrhages can also be observed in the urinary bladder, larynx, epiglottis and heart and sometimes widespread over the serosa of the abdomen and chest and on heart.

A non-purulent encephalitis is often present.

Infarcts in the spleen are considered pathognomonic but are infrequently seen.

(4) The acute form of African swine fever leads to a clinical and pathological picture very similar to that of classical swine fever.

When present, haemorrhages on the skin and ears are quite easy to detect and lead to suspicion of acute form of African swine fever or classical swine fever.

Acute form of classical swine fever must also be considered in case of suspected erysipelas, porcine reproductive and respiratory syndrome (PRRS), coumarin poisoning, purpura haemorragica, post-weaning multisystemic wasting syndrome, porcine dermatitis and nephropathy syndrome, salmonella or Pasteurella infections or any enteric and respiratory syndromes with fever which do not respond to antibiotic treatment.

(5) Classical swine fever virus is shed in saliva, urine and faeces from the onset of clinical signs until death. Classical swine fever virus can also be shed via semen.

**Chronic form of classical swine fever**

(1) The chronic course of infection occurs when pigs are not able to develop an effective immune response against classical swine fever virus.

Initial signs of a chronic infection are similar to the acute infection. Later, predominately non-specific signs are present, i.e. intermittent fever, chronic enteritis and wasting. The typical haemorrhages of the skin are missing.

These pigs may show clinical signs of disease for 2 to 3 months before death.

Classical swine fever virus is constantly shed from the onset of clinical signs until death.

(2) Pathological changes are less typical, especially haemorrhages in organs and serosa may not be observed. In animals showing chronic diarrhoea, necrotic lesions are common on the ileum, the ileocaecal valve and the rectum.

(3) As clinical signs of chronic classical swine fever are rather non-specific, many other diseases must be considered for differential diagnosis. The increased body temperature is not necessarily present in every animal, but in an infected holding fever can be detected at least in some pigs.

**Prenatal form and late onset of classical swine fever**

(1) Classical swine fever virus is able to pass across the placenta of pregnant animals, and infect foetuses, but in the sows the disease is often sub-clinical.

The outcome of trans-placental infection of foetuses depends largely on the stage of gestation and viral virulence. Infection during early pregnancy may result in abortions and stillbirths, mummification and malformations.

Infection of sows at up to 90 days of pregnancy can lead to the birth of persistently viraemic piglets, which may be clinically normal at birth and survive for several months. After birth, they may show poor growth, wasting or occasionally congenital tremor. This course of infection is referred to as ‘late onset classical swine fever’. These piglets may play a crucial role in spreading the disease and in the maintenance of virus persistence within a population, as they constantly shed virus until death.

(2) Detection of classical swine fever may be particularly difficult in breeding pig holdings, as the course of the disease may be very mild and may be confused with other diseases.

Reduced fertility and abortions can be caused by classical swine fever virus as well as parvovirus infection, PRRS, Aujeszkys disease and leptospirosis.

Material aborted due to classical swine fever infection cannot be distinguished pathologically from abortions due to other disease agents.

In case of suspicion of an infectious disease of the reproductive tract, investigation for classical swine fever must be immediately carried out whenever the holding in question can be considered at risk (e.g. due to location of the holding in an area where classical swine fever occurs in feral pigs), and in any case as soon as more common infectious diseases of the reproductive tract have been excluded.

**CHAPTER B**

**Clinical and pathological findings for the recognition of a holding as a classical swine fever suspected holding**

(1) In classical swine fever suspected holding, clinical and pathological examinations, as well as epidemiological and serological tests are carried.

(2) The main clinical and pathological findings to be considered are:

1) fever with increased morbidity and mortality;

2) fever with haemorrhagic syndrome;

3) fever with neurological symptoms;

4) fever of unknown origin where treatment with antibiotics failed to improve the health state;

5) abortions and increased fertility problems during the last three months;

6) congenital tremor of piglets;

7) hronically diseased animals;

8) growth retarded (runted) young animals;

9) petechial and ecchymotic haemorrhages, especially in lymph nodes, kidneys, spleen, bladder and larynx;

10) infarction or haematomas, notably in the spleen;

11) button ulcers in the large intestine of chronic cases, particularly near the ileo-caecal junction.

(3) Epidemiological findings include data on:

1) whether pigs had direct or indirect contact to pigs from a holding proven to have been infected with classical swine fever;

2) whether a holding has supplied pigs that were subsequently shown to be infected with classical swine fever;

3) whether sows have been artificially inseminated with semen originating from a boar suspected of classical swine fever;

4) whether there has been indirect or direct contact with feral pigs of a population where classical swine fever occurs;

5) whether pigs are kept outdoors in a region where feral pigs are infected with classical swine fever;

6) whether pigs have been fed with swill and there is the suspicion that this swill has not been treated in such a way as to inactivate classical swine fever virus;

7) whether possible exposure of pigs to classical swine fever virus might have occurred, e.g. due to persons entering the holding, transports, etc.

(4) The main laboratory findings related to results of serological tests to be considered are:

1) serological reaction caused by an unnoticed classical swine fever virus infection or by vaccination[[1]](#footnote-1);

2) cross-reaction between antibodies to classical swine fever and to other pestiviruses[[2]](#footnote-2);

3) detection of singleton reactors[[3]](#footnote-3).

**CHAPTER C**

**Checking and sampling procedures**

**A. Procedures for examination and sampling on pigs in suspected holdings**

(1) In order to confirm or exclude classical swine fever, an official veterinarian orders appropriate clinical examinations, sampling and laboratory investigations to be carried out in suspected holdings and performs:

- check of the production and health records of the holding, including records on pig identification and registration;

- inspection of all pigs to select the pigs to be clinically examined.

(2) The clinical examination must include the taking of body temperature and must primarily concern the following pigs or group of pigs:

- sick or anorexic pigs;

- pigs recently recovered from some other disease;

- pigs recently introduced from confirmed outbreaks or from other suspected sources;

- pigs kept in sub-units recently visited by persons which had a recent close contact with classical swine fever suspected or infected pigs or for which other particularly risky contacts with a potential source of classical swine fever virus have been identified;

- pigs already serologically tested for classical swine fever, in case the results of these tests do not allow to rule out classical swine fever, and in-contact pigs.

(3) If the inspection in the suspected holding has not indicated the presence of the pigs or group of pigs referred to in paragraph 2 of this point, the official veterinarian, taking into account the epidemiological situation, shall carry out further examinations in the holding in question in accordance with paragraph 4 of this point or:

- ensure that blood samples for laboratory tests are taken from the pigs in the holding in question in accordance with paragraph 12 of this point and paragraph 2 point F of this Chapter;

- order carrying out of measures laid down in Article 5 of this Rulebook; or

- rule out the suspicion of classical swine fever.

(4) Additional clinical examination in the holding in question must be carried out on pigs selected at random in the production units for which a risk of introduction of classical swine fever virus has been identified or is suspected.

(5) The minimum number of pigs to be examined must allow for the detection of at least one pig with a fever if the fever occurs at a prevalence of 10 % with 95 % confidence in production units.

(6) However, in case of:

- breeding sows, the minimum number of sows to be examined sows must allow for the detection of at least one pig with a fever if the fever occurs at a prevalence of 5 % with 95 % confidence;

- at reproduction and artificial insemination centres, all boars must be examined.

(7) If dead or moribund pigs are detected in a suspected holding, post-mortem examinations must be carried out, preferably on at least five of these pigs and in particular on pigs:

- that before death have shown or are showing typical signs of classical swine fever;

- with high fever;

- recently dead.

(8) If these examinations have not shown lesions suggesting classical swine fever but, due to the epidemiological situation, further investigations are deemed necessary:

- a clinical examination and blood sampling must be carried out in the production unit where the dead or moribund pigs were kept; and

- post-mortem examinations may be carried on 3 to 4 in-contact pigs.

(9) Irrespective of the presence or absence of lesions suggesting classical swine fever, samples of the organs or tissues from pigs that have been subjected to post-mortem examination must be collected for virological tests in accordance with paragraph 1 point B Chapter D of this Annex. These samples must be preferably collected from recently dead pigs.

(10) When post-mortem examinations are carried out, the official veterinarian must ensure that:

- the necessary precautions and hygienic measures are taken to prevent any disease spread; and

- in case of moribund pigs, they are killed in a humane way.

(11) If clinical signs or lesions that may suggest classical swine fever are detected in a suspected holding by further clinical examinations, but the official veterinarian deems that these findings are not sufficient to confirm an outbreak of classical swine fever and that laboratory tests are therefore necessary, blood samples for laboratory tests must be taken from the suspected pigs and from other pigs in each production unit in which the suspected pigs are kept.

(12) The minimum number of samples to be taken for serological tests must allow for the detection of at least 10 % seroprevalence with 95 % confidence in the production unit in question.

(13) However, in the case of breeding sows, the minimum number of sows to be sampled must allow for the detection of 5 % sero-prevalence with 95 %[[4]](#footnote-4) confidence. In the case of boards in semen collection centres, blood samples must be taken from all boars. The sampling for virological tests and the type of test to be used will take into account the availability of diagnostic tests, the sensitivity of laboratory tests and the existing epidemiological situation.

(14) If the suspicion of classical swine fever virus in the holding in question is related to the results of previous serological tests, in addition to the blood samples to be taken from the pigs referred to in paragraph 2 indent 5 of this point, the following procedures shall be applied:

- if the seropositive pigs are pregnant sows, some of them, preferably not less than three, shall be euthanased and subjected to a post-mortem examination. Prior to killing a blood sample must be taken for further serological tests. The foetuses shall be subjected to examination for classical swine fever virus, virus antigen or virus genome to detect intrauterine infection;

- if the seropositive pigs are sows with suckling piglets, blood samples must be taken from all piglets and shall be subjected to examination for classical swine fever virus, virus antigen or virus genome as laid down in Chapter E of this Annex. Blood samples must also be taken from the sows for further serological tests.

(15) If, after the examination carried out in a suspected holding, clinical signs or lesions suggestive of classical swine fever are not detected, further laboratory tests are carried out as instructed by the official veterinarian to rule out classical swine fever, as laid down in paragraphs. 11, 12 and 13 of this point.

**B. Sampling procedures in a holding when pigs are killed following confirmation of disease**

(1) In order that the manner of introduction of classical swine fever virus into an infected holding and the length of time elapsed since its introduction may be established, when pigs are killed on a holding following confirmation of an outbreak in accordance with Article 6 paragraph 1 point 1 of this Rulebook, blood samples for serological tests must be taken at random from the pigs when they are killed.

(2) The minimum number of pigs to be sampled must allow for the detection of 10 % seroprevalence with 95 % confidence in pigs in each production unit of the holding[[5]](#footnote-5).

(3) In case of secondary outbreaks, it may be decided to derogate from procedures referred to in paragraphs 1 and 2 of this point and establish *ad hoc* sampling procedures, taking into account the epidemiological information already available on the source and means of virus introduction into the holding and the potential spread of disease from the holding.

**C. Sampling procedures when pigs are killed as a preventive measure on a suspected holding**

(1) In order that classical swine fever may be confirmed or ruled out and additional epidemiological information is gained, when pigs are killed on a suspected holding in accordance with Article 5 paragraph 3 point 1 or Article 8 paragraph 3 of this Rulebook, blood samples for serological tests as well as blood or tonsils samples for virological tests must be taken.

(2) Sampling referred to in paragraph 1 of this point must primarily concern:

- pigs showing clinical signs or post-mortem pathological lesions suggesting classical swine fever and their in-contact pigs;

- other pigs which might have had risky contacts with infected or suspected pigs or which are suspected to have been contaminated with classical swine fever virus.

(3) These pigs must be sampled taking into account the epidemiological situation.

(4) Pigs proceeding from each of the production units of the holding must be sampled at random[[6]](#footnote-6). The minimum number of samples to be taken for serological tests must allow for the detection of 10 % seroprevalence with 95 % confidence in the production unit in question.

(5) However, in the case of:

- breeding sows, the minimum number of sows to be sampled must allow for the detection of 5 % seroprevalence[[7]](#footnote-7) with 95 % confidence,

- boars in a semen collection centre, blood samples must be taken from all boars.

(6) The sampling for virological tests and the type of test to be used will take into account the availability of diagnostic tests, the sensitivity of laboratory tests and the existing epidemiological situation.

**D. Checking and sampling procedures before authorisation is given to move pigs from holdings located in protection or surveillance zones and in case these pigs are slaughtered or killed**

(1) In order that authorisation may be given to move pigs from holdings located in protection or surveillance zones in accordance with Article 11 paragraph 2 of this Rulebook, the clinical examination must:

- be carried out within the 24-hour period before moving the pigs;

- be in accordance with paragraph 1 point A of this Chapter.

(2) In the case of pigs to be moved to another holding, in addition to the investigations to be carried out in accordance with paragraph 1 of this point, a clinical examination of pigs must be carried out in each production unit of the holding in which the pigs to be moved are kept. In case of pigs older than three to four months, this examination must include the taking of temperature of a proportion of pigs.

(3) The minimum number of pigs to be checked must allow for the detection of fever if it occurs at a prevalence of 10 % with 95 % confidence in these production units.

(4) In case of:

- breeding sows, the minimum number of sows to be examined must allow for the detection of fever if it occurs at a prevalence of 5 % with 95 % confidence in the production unit where the sows to be moved are kept;

- boars, all boars to be moved must be examined.

(5) In case of pigs to be moved to a slaughterhouse, to a processing plant or to other places to be then killed or slaughtered,procedures in accordance with paragraph 1 of this point must be carried out. In case of pigs older than three to four months, this examination must include the taking of temperature of a proportion of pigs.

(6) The minimum number of the pigs to be checked must allow for the detection of fever if it occurs at a prevalence of 20 % with 95 % confidence in the production units in question.

(7) in the case of breeding sows or boars, the minimum number of pigs to be examined must allow for the detection of fever if it occurs at a prevalence of 5 % with 95 % confidence in the production units.

(8) In case of the pigs referred to in paragraph 5 of this point, before they are slaughtered or killed, blood samples for serological tests or blood or tonsils samples for virological tests must be taken from pigs proceeding from each of the production units from which pigs have been moved.

(9) The minimum number of samples to be taken must allow for the detection of 10 % seroprevalence or virus prevalence with 95 % confidence in each production unit.

(10) In the case of breeding sows or boars, the minimum number of pigs to be sampled must allow for the detection of 5 % of seroprevalence or virus prevalence with 95 % confidence in the subunit where these pigs were kept.

(11) The sampling for virological tests and the type of test to be used will take into account the availability of diagnostic tests, the sensitivity of laboratory tests and the existing epidemiological situation.

(12) If clinical signs and post-mortem lesions suggesting classical swine fever are detected when the pigs are slaughtered or killed, the provisions laid down in point C of this Chapter shall apply.

**E. Sampling procedures in a holding before re-population**

(1) When pigs are re-introduced into a holding in accordance with Articles 14 and 19 of this Rulebook, the following sampling procedures must be applied:

– in case sentinel pigs are reintroduced, blood samples must be taken at random from a number of pigs that allow for the detection of 10 % seroprevalence with 95 % confidence in each production unit of the holding;

– in case of total re-population, blood samples for serological tests must be taken at random from a number of pigs that allow for the detection of 20 % seroprevalence with 95 % confidence in each production unit of the holding.

(2)In the case of breeding sows or boars, the minimum number of samples to be taken must be such as to detect 10 % seroprevalence with 95 % confidence in pigs in production units.

(3) In case of any disease or death of the pigs in the holding due to unknown reasons after re-introduction of pigs, the pigs in question are immediately tested for classical swine fever before lifting restrictions.

**F. Sampling procedures in holdings in the protection zone before lifting restrictions**

(1) In order that the measures referred to in Article 11 of this Rulebook may be lifted in a protection zone, in all holdings in the zone, a clinical examination must be carried out in accordance with the procedures laid down in par. 2 and 3 point A of this Chapter and blood samples for serological tests must be taken as laid down in par. 2 and 3 of this point.

(2) The minimum number of blood samples to be taken must allow for the detection of 10 % seroprevalence with 95 % confidence in pigs in each production unit in the holding.

(3) In case of:

- breeding sows, the minimum number of samples to be taken must allow for the detection of 5 % seroprevalence with 95 % confidence;

- boars in a semen collection centre, blood samples must be taken from all boars.

**G. Sampling procedures in holdings in the surveillance zone before lifting restrictions**

(1) In order that the restrictions referred to in Article 12 of this Rulebook may be lifted in a surveillance zone, a clinical examination of pigs must be carried out in all holdings in the zone in accordance with the procedures laid down in par.1, 2 and 3 point A of this Chapter.

(2) In addition to clinical examination, blood samples for serological tests must be taken from pigs:

- in all the holdings where pigs of between two and eight months of age are kept;

- whenever the competent authority deems that classical swine fever might have spread unnoticed amongst breeding sows;

- in any other holding where sampling is deemed necessary by the competent authority;

- in all reproduction and artificial insemination centres.

(3) Whenever blood sampling for serological tests is carried out in holdings located in the surveillance zone, blood samples must be taken in accordance with par. 2 and 3 point F of this Chapter.

(4) If it is deemed that classical swine fever might have spread unnoticed amongst breeding sows, sampling may only be carried out in the production units where these animals are kept.

**H. Serological monitoring and sampling procedures in areas where classical swine fever is suspected to occur or has been confirmed in feral pigs**

(1) In the case of serological monitoring in feral pigs in areas where classical swine fever has been confirmed or is suspected to occur, the size and the geographical area of the target population to be sampled should be previously defined in order to establish the number of samples to be taken.

(2) Sample size must be established as a function of the estimated number of living animals and not as a function of shot animals.

(3) If data on population density and size are not available, the geographical area within which to sample must be identified taking into account the continuous presence of feral pigs and the presence of natural or artificial barriers efficient to prevent large and continuous movement of the animals. When such circumstances do not occur, or in case of large areas, it is recommended to identify sampling areas of not more than 200 km2, where population of about 400 to 1 000 feral pigs may usually live.

(4) The minimum number of pigs to be sampled within the defined sampling area must allow to detect 5 % seroprevalence with 95 % confidence.

(5) For this purpose at least 59 animals must be sampled in each area which has been identified.

(6) It is also recommended that:

- in areas where hunting pressure is higher and regularly performed, or selective hunting is carried out as a disease control measure, approximately 50 % of the sampled animals belong to the three months to one year age class, 35 % to one to two years age class and 15 % to more than 2 years age class;

- in areas where hunting pressure is very low or absent, at least 32 animals are sampled for each one of the three age classes;

- sampling is performed in a short time, preferably not more than one month;

- the age of sampled animals is identified according to the teeth eruption.

(7) Collection of samples for virological tests from feral pigs shot or found dead must be carried out as laid down in paragraph 1 point B Chapter D of this Annex.

(8) When virological monitoring on shot feral pigs is deemed necessary, collection of samples (organs) must be primarily carried out on animals three months to one year old.

(9) All samples to be sent to the laboratory must be accompanied by the questionnaire.

**CHAPTER D**

**General procedures and criteria for collection and transport of samples**

**A) General procedures and criteria for collection of samples**

(1) Before sampling is carried out in a suspected holding, a map of the holding must be prepared and the epidemiological production units (sub-units) of the holding must be identified.

(2) All pigs which are sampled must be uniquely marked in such a way that they can be easily re-sampled.

(3) Samples for serological testing must not be taken from piglets less than eight weeks old.

(4) All samples must be sent to the laboratory accompanied by appropriate forms. These forms will include details of the history of the pigs sampled and the clinical signs or post-mortem lesions observed.

(5) In the case of pigs kept in holdings, clear information on age, category and unique identification mark of the pigs sampled must be provided. The location of each pig sampled in the holding must be recorded together with its holding of origin.

**B) Collection of samples for virological tests**

(1) For detection of classical swine fever virus, antigen or genome from dead or euthanised pigs, tonsils, spleen and kidney tissues are the most suitable samples. In addition, it is recommended to collect two samples of other lymphatic tissues, such as the retro-pharyngeal *(retropharyngeales)*, parotid *(parotidei)*, mandibular *(mandibulares)* or mesenteric *(mesenterici)* lymph nodes and a sample of ileum. In case of autolysed carcasses, an entire long bone or the sternum is the specimen of choice.

(2) Anticoagulated blood or clotted blood samples must be collected from pigs showing signs of fever or other signs of disease.

(3) Virological tests are carried out in the case of sick animals. They are usually of limited value when used for monitoring purposes on animals which do not show clinical signs. However, if the objective of a large-scale sampling is to detect classical swine fever virus when the pigs are in their incubation period, the tonsils are the most appropriate samples.

**C) Transport of samples**

(1) The transported samples:

- are transported and stored in leak-proof containers;

- are not frozen but kept cool at refrigerator temperature;

- are delivered to the laboratory as quickly as possible;

- are kept in a package where ice packs rather than wet ice is used inside to keep them cool;

- of tissue or organs are placed in a separate, sealed plastic bag and properly labelled. They must be then placed in larger and stronger outer containers (jars, packages etc.) and packed with sufficient absorbent material to protect them from damage and absorb leakage;

- are directly transported to the laboratory by competent personnel in order that a rapid and reliable transport is ensured.

(2) The outside of the package must be labelled with the address of the recipient laboratory and the following message should be prominently displayed: “Animal pathological material; Perishable; Fragile; Do not open outside a classical swine fever laboratory”.

(3) The laboratory receiving the samples must be informed in advance of the time and mode of the arrival of the samples.

(4) For air transport of samples to the Community Reference Laboratory for classical swine fever (Institut für Virologie, der Tierärztlichen Hochschule Hannover, Bünteweg 17, D-30559 Hannover, Germany)[[8]](#footnote-8) from Member States other than Germany, the package has to be labelled according to IATA regulations.

**CHAPTER E**

**Use of virological tests and evaluation of their results**

**A) Detection – identification of virus antigen**

1. Fluorescent antibody test (FAT)

(1) The principle of the test is the detection of viral antigen on thin cryosections of organ material from pigs suspected of being infected with classical swine fever virus. The intracellular antigen is detected by using a FITC conjugated antibody. A positive result should be confirmed by repeating the staining with a specific monoclonal antibody.

(2) Suitable organs for detection are tonsils, kidney, spleen, different lymph nodes and ileum. A smear of bone marrow cells might also be used in case of feral pigs, if these organs are not available or are autolysed.

(3) The test can be performed within one day.

(4) As organ samples can only be obtained from dead animals, its use for screening purposes is limited. Confidence in the test result may be limited by doubtful staining, particularly where considerable experience in performing the test has not been acquired by a person performing the test or if the organs tested are autolysed.

*2.* ELISA for antigen detection

(1) Viral antigen may be detected by using various ELISA techniques. The sensitivity of ELISA for antigen detection should be high enough to score a positive result from animals showing clinical signs of classical swine fever.

(2) The use of ELISA for antigen detection is recommended on samples from animals with clinical signs or pathological lesions of disease.

(3) ELISA is not suitable for the investigation of individual animals.

(4) Suitable samples are leukocytes, serum, non-coagulated blood as well as suspensions of the organs referred to in sub-point 1 of this point taken from pigs suspected of being infected with classical swine fever virus[[9]](#footnote-9).

(5) The ELISA can be carried out within one day and can be performed by automatic equipment.

(6) The most important advantage of the ELISA is that large numbers of samples can be processed in a short period of time.

(7) It is recommended that ELISA antigen which give satisfactory results on reference material are used. However, it must be taken into account that, at present, all commercial ELISA are less sensitive than the virus isolation on cell culture and their sensitivity is significantly better on blood samples from piglets than from adult pigs.

**B) Virus isolation**

(1) Virus isolation is based on the incubation of sample material on susceptible cell cultures of porcine origin.

(2) If classical swine fever virus occurs in the sample, it will replicate in the cells to an amount that can be detected by immunostaining of the infected cells with conjugated antibodies.

(3) Classical swine fever specific antibodies are required for differential diagnosis with respect to other pestiviruses.

(4) The preferred samples for isolation of classical swine fever virus are leukocytes, plasma or whole blood obtained from non-coagulated blood samples or the organs referred to in paragraph 2 point A of this Chapter.

(5) Virus isolation is best suited for the investigation of samples from small numbers of animals rather than mass surveillance. The virus isolation procedure is labour intensive and requires at least three days before results are available.

(6) Two further cell culture passages may be necessary in order that a small amount of virus in the sample is detected. This may lead to an investigation time of up to 10 days before a final result is obtained. Autolysed samples can be cytotoxic to the cell culture and consequently limit its use.

(7) It is recommended to perform virus isolation also in case of previous confirmation of classical swine fever by other methods. It must be used as reference test for the confirmation of previous positive results obtained by ELISA for antigen detection, PCR and immunofluorescence, ordirect peroxidase-staining method.

(8) Classical swine fever virus isolates obtained in this way are useful for virus characterisation including genetic typing and molecular epidemiology.

(9) All classical swine fever virus isolates from all primary outbreaks, primary cases in feral pigs or cases in slaughterhouse or means of transport must be genetic typed by a national reference laboratory.

(10) Virus isolates referred to in paragraph 9 of this point must be sent to the laboratory referred to in paragraph 4 point C Chapter D of this Annex without delay.

**C) Detection of virus genome**

(1) The polymerase chain reaction (PCR) is applied to detect virus genome in blood, tissues or organ samples. Small fragments of viral RNA are transcribed into DNA fragments which are amplified by PCR to detectable quantities. Since this test detects only a genome sequence of the virus, the PCR may be positive, even when there is no infectious virus present (e.g. in autolysed tissues or samples from convalescent pigs)

(2) PCR can be used on small numbers of samples which have been carefully selected from suspect animals or on material from aborted fetuses. In carcasses from wild boar it might be the method of choice, if the material is autolysed and virus isolation is not possible any more due to cytotoxicity.

(3) Suitable sample material for diagnostic PCR are the organs described for virus isolation or unclotted blood.

(4) PCR can be performed within 48 hours. It requires appropriate laboratory equipment, separated facilities and skilled staff. The method is highly sensitive, but contamination may easily occur, which leads to false positive results. Therefore stringent quality control procedures are essential.

(5) Some methods are pestivirus rather than classical swine fever specific, requiring further confirmatory tests, such as sequencing of the PCR (polymerase chain reaction) product.

**D) Evaluation of the results of virological tests**

(1) Virological tests are essential for the confirmation of classical swine fever.

(2) Virus isolation must be considered as the reference virological test and must be used as confirmatory test when necessary. Its use is particularly recommended in case positive FAT, ELISA or PCR results are not associated with the detection of clinical signs or patho-anatomic lesions of the classical swine fever virus and in any other doubtful case.

(3) Exceptionally from paragraph 1 and 2 of this point, a primary outbreak of classical swine fever can be confirmed if clinical signs and patho-anatomic lesions of disease have been detected in the pigs in question and at least two antigen or genome detection tests have given a positive result.

(4) Exceptionally from paragraph 1 and 2 of this point, a secondary outbreak of classical swine fever can be confirmed if, in addition to the epidemiological link to a confirmed outbreak or case, clinical signs or patho-anatomic lesions of disease have been detected in the pigs in question and an antigen or genome detection test has given a positive result.

(5) A primary case of classical swine fever in feral pigs can be confirmed after virus isolation and identification or if at least two antigen or genome detection tests have given a positive result.

(6) Further cases of classical swine fever in feral pigs for which an epidemiologial link with previously confirmed cases have been found can be confirmed if an antigen or genome detection test has given a positive result.

(7) A positive result for classical swine fever to a genome or antigen detection test requires that the test in question has been performed using classical swine fever virus-specific antibodies or primers. If the test used was not specific for classical swine fever virus but only pestivirus-specific, it must be repeated using classical swine fever-specific reagents.

**E) Genetic typing of classical swine fever virus isolates**

(1) Genetic typing of classical swine fever virus isolates is achieved by determining the nucleotide sequence of portions of the virus genome, namely specific parts of the 5'noncoding region and/or of the E2 glycoprotein gene. The similarity of these sequences with those already obtained from previous virus isolates can indicate the origin of outbreaks i.e. whether or not outbreaks of disease are caused by new or already recognised strains. This can support or refute hypotheses on transmission routes that have been provided by epidemiological tracing

(2) Genetic typing of classical swine fever virus isolates is of major importance to determine the source of disease. However, a close genetic relationship between viruses obtained from different outbreaks is not an absolute proof for a direct epidemiological link.

(3) If genetic typing cannot be performed in a national reference laboratory or in any other laboratory authorised to diagnose classical swine fever within a short period, the original sample of the virus isolate must be sent to the Reference Laboratory of the European Union for typing as soon as possible

(4) The data on typing and sequencing of classical swine fever virus isolates available to the reference laboratories must be forwarded to the Reference Laboratory of the European Union in order that this information is entered into the database.

**CHAPTER F**

**Use of serological tests and evaluationof their results**

**A) Basic guidelines and diagnostic value**

(1) In classical swine fever virus infected pigs, antibodies are usually detectable in serum samples from two to three weeks after infection.

(2) In pigs that have recovered from the classical swine fever, specific neutralising antibodies can be detected for several years or even for their lifetime. Antibodies are also sporadically detectable in the terminal stage of lethally diseased animals. In some pigs with chronic form of classical swine fever, antibodies might be detectable at the end of the first month post-infection.

(3) Pigs infected *in utero* may be immunotolerant against the homologue classical swine fever virus and produce no specific antibodies. However, antibodies of maternal origin can be detected during the first days of life. The half-life of maternal antibodies in non-viraemic healthy piglets is about two weeks.

(4) If found in piglets older than three months, classical swine fever antibodies are very unlikely to be of maternal origin.

(5) The detection of antibodies against classical swine fever virus in serum or plasma samples is carried out to assist the diagnosis of classical swine fever in suspected holdings, for establishing the age of infection in case of a confirmed outbreak and for monitoring and surveillance purposes.

(6) Serological tests are of limited value for the detection of classical swine fever in the case of a recent infection in a holding.

(7) A few seropositive pigs with a low neutralisation titre can be indicative of a recent introduction of the virus into the holding (two to four weeks).

(8) Many pigs with high neutralisation titre could indicate that virus entered the holding more than one month before.

(9) The location of seropositive pigs in the holding can provide valuable information on how classical swine fever virus entered the holding.

(10) An accurate evaluation of the results of the serological tests must be carried out taking into account the whole clinical, virological and epidemiological findings, in the framework of the enquiry to be carried out in case of suspicion or confirmation of classical swine fever, in accordance with Article 9 of this Rulebook.

**B) Recommended serological tests**

(1) The virus neutralisation test (VNT) and the ELISA are the tests recommended for the serological diagnosis of classical swine fever

(2) The quality and efficiency of the serological diagnosis performed by laboratory must be checked in the framework of the inter-laboratory comparison test organised by the Reference Laboratory of the European Union..

(3) The VNT is based on the determination of the virus neutralising activity of the antibodies of the serum sample, expressed as neutralising 50 % end point (ND50).

(4) A constant amount of classical swine fever virus is incubated at 37°C with diluted serum.

(5) For quick screening purposes, the sera are initially diluted 1/10.

(6) When a full titration is necessary, two-fold dilutions of serum starting at ½ or 1/5 can be prepared. Each dilution is mixed with an equal volume of a virus suspension containing 100 infectious doses (TCID 50).

(7) After incubation, the mixture is inoculated onto cell cultures which are incubated for three to five days. After this incubation period, the cultures are fixed and any viral replication in the infected cells is detected by an immune labelling system. For that purpose, either the neutralisation peroxidase-linked antibody (NPLA) or the neutralisation-immunofluorescence (NIF) assays may be used.

(8) The results of the VNT are expressed as the reciprocal value of the initial serum dilution at which half the inoculated cell cultures (50 % end point) fail to show viral replication (no specific labelling)

(9) A point between two dilution levels is estimated. The final dilution system is based on the actual dilution of serum during the neutralisation reaction, i.e. after addition of virus, but before adding the cell suspension

(10) The VNT is the most sensitive and the most reliable test to detect antibodies against classical swine fever virus. Therefore, it is recommended for the serological examination of a single animal as well as on a herd basis. However, this test may also detect antibodies specific for other ruminant pestiviruses.

(11) When VNT is used for the detection of antibodies against bovine virus diarrhea (BVD) and border disease (BD) virus, the prescribed rules are applied for the differential diagnosis of classical swine fever.

(12) The pestiviruses strains to be used in the neutralisation tests shall be in accordance with the recommendation of the Reference Laboratory of the European Union.

(13) ELISA techniques for classical swine fever detection using monoclonal antibodies are diverse and are functionally based on competitive (blocking) or non-competitive ELISA. The competitive or blocking ELISA most commonly use monoclonal antibodies

(14) If the serum sample contains antibodies to classical swine fever virus, those antibodies will inhibit the binding of a selected peroxidase-conjugated monoclonal antibody to virus antigen, resulting in a reduced signal.

(15) In non-competitive ELISA, the binding of serum antibodies to antigen is measured directly using peroxidase-conjugated anti-pig antibodies.

(16) The national reference laboratory performs quality control on sensitivity and specificity of each batch of an ELISA, making use of the panel of reference sera provided by the Reference Laboratory of the European Union, such as:

- sera from pigs in the early phase of classical swine fever virus infection (before 21 days post infection);

- sera from convalescent pigs (after 21 days post infection);

- sera from pigs infected with ruminant pestiviruses.

(17) The ELISA to be used for the diagnosis of classical swine fever must recognise all reference sera from the convalescent pigs. All results obtained with the reference sera must be repeatable, detect all positive sera from pigs in the early phase of infection and show high specificity given the possible cross-reactions with pigs infected with ruminant pestiviruses.

(18) The results obtained with the reference sera from pigs in the early phase of infection give an indication of the sensitivity of the ELISA

(19) The sensitivity of the ELISA is regarded as lower than that of the VNT, and it is recommended to use it as a screening test on a herd basis. The ELISA require less-specialised facilities and can be performed much more rapidly than the VNT, due to automated systems.

(20) The ELISA test must ensure identification of all classical swine fever infections at the convalescence stage and needs to be as free as possible from interference by cross-reacting antibodies to ruminant pestiviruses.

**C)** **Interpretation of serological results and differential diagnosis with infections due to ruminant pestiviruses (BVDV and BDV)**

(1) In case of detection of a classical swine fever virus neutralisation titre equal to or higher than 10 ND50 in serum samples collected from one or more pigs or a positive ELISA result in serum samples from a group of pigs, the measures referred to in Article 5 paragraph 2 of this Rulebook shall immediately apply or, if they are already being applied, they shall continue to apply in the holding in question.

(2) The samples already collected from this holding must be re-tested by VNT by comparative end point titration of the neutralising antibodies against classical swine fever virus and ruminant pestiviruses.

(3) If the comparative tests show antibodies to ruminant pestiviruses and no or evidently lower (less than three-fold) antibody titres to classical swine fever virus, the suspicion for classical swine fever shall be ruled out, unless other reasons exist which warrant the continued application of the measures referred to in Article 5 paragraph 2 of this Rulebook in the holding in question.

(4) If the comparative tests show a virus neutralisation titre in more than one pig equal to or higher than 10 ND50 and this titre is equal or higher than the titres to other pestiviruses, the classical swine fever shall be confirmed, provided that epidemiological evidence of disease has been found in the holding in question.

(5) If epidemiological evidence of classical swine fever has not been found or if the results of the previous tests are inconclusive, the following activities shall be ensured in the holding in question:

- the measures referred to in Article 5 paragraph 2 of this Rulebook shall continue to apply;

- further investigations are carried out to confirm or rule out classical swine fever, in accordance with Chapter C.

(6) If the further checks referred to in paragraph 5 of this point do not allow classical swine fever to be ruled out, further blood sampling for serological testing shall be carried out in the holding after at least two weeks have elapsed from the previous checks.

(7) In the framework of further sampling, the pigs already sampled and tested shall be re-sampled for a comparative serological testing with the previously collected samples to detect sero-conversion for classical swine fever virus or for ruminant pestiviruses, if any. If these further checks do not allow classical swine fever to be confirmed, the measures referred to in Article 5 of this Rulebook may be lifted.

**CHAPTER G**

**Discriminatory tests in case of emergency vaccination**

**A) Basic principles**

(1) A discriminatory serological ELISA test (discriminatory test) is available to successfully distinguish pigs which have been vaccinated with marker vaccines, that induce antibodies only against the E2 glycoprotein of classical swine fever virus, from pigs which have been infected with the wild type of classical swine fever virus.

(2) This test is designed to detect antibodies against the glycoprotein Erns of classical swine fever virus. It is based on the principle that non-infected animals vaccinated with marker vaccines only produce antibodies against the glycoprotein E2 of classical swine fever virus, whilst animals infected with field virus react and produce antibodies against other virus antigens, too.

(3) This discriminatory test is sensitive and specific. However, also pigs which have become infected with Pestiviruses other than classical swine fever virus, such as BVD virus and BD virus, will also react Erns-positive.

(4) The sensitivity of the test is not ideal, as some marker-vaccinated and then infected animals may not react Erns-positive.

(5) The discriminatory test cannot be reliably used to test serum samples from feral pigs.

(6) The discriminatory test is a liquid phase blocking enzyme-linked immunoassay. The samples to be tested are incubated onto microtitre plates precoated with monoclonal anti-Erns antibodies together with a defined amount of Erns antigen.

(7) Any antibody specific for Erns binds to the defined amount of Erns antigen in the solution and an antigen/antibody complex is formed, which does not react with the anti-Erns antibodies on the microtitre plate. After washing of the plates to remove unbound material a peroxidase labelled anti-Erns conjugate is added which binds to the Erns antigen complexed with the antibody coated on the surface of the microtitre plate. Unbound conjugate is removed by washing and chromogen-containing substrate is added.

(8) The degree of colour, which develops, is reversely proportional to the amount of antibody specific for Erns present in the sample. If the sample does not contain antibodies (negative sample) much of the defined amount of Erns antigen that was added can bind to the anti-Erns antibodies on the plate surface and a strong colour reaction is observed. A result is obtained by comparing the optical density (OD) in wells containing test samples with those of wells containing the negative and positive controls.

**B) Guidelines for the use of the discriminatory test in the context of an emergency vaccination with a marker vaccine in pig holdings**

(1) The discriminatory test is designed to verify the presence or absence of classical swine fever virus circulation on a pig population vaccinated with a marker vaccine. The available data suggest that it can be successfully used for that purpose on herd bases, but it cannot reliably exclude that individual pigs are infected with classical swine fever virus.

(2) The specificity of the discriminatory test might not be sufficient to reliably discriminate marker vaccinated pigs from infected pigs in case of vaccination of adult pigs. In case of doubtful results, however, the pigs in question must be slaughtered or killed in a humane way and their organs tested for classical swine fever virus. Virus isolation and the PCR are the most suitable tests for that purpose. These aspects have to be taken into full account when designing an emergency marker-vaccination strategy and then interpreting the results of a classical swine fever virus survey onto the marker-vaccinated population.

(3) The procedure for sampling and testing the vaccinated pig population before lifting the restrictions to be applied in the vaccinated area in accordance with Article 19 of this Rulebook, should depend on the age of the vaccinated pigs, the category of pigs (fattening/slaughter, breeding) and the desired level of safety as regards the absence of virus circulation in the population, as an integral part of emergency vaccination strategy.

**CHAPTER H**

**Minimum safety requirements for classical swine fever laboratories**

(1) The minimum requirements laid down in Table 1 of this Chapter must be fulfilled in any laboratory where classical swine fever virus is to be manipulated, even if only in a small amount, as required by the virus isolation and neutralisation tests, including virus multiplication as well.

(2) However, post-mortem examinations, processing of tissues for FAT and serology using inactivated antigen, may be carried out at a lower containment level provided that basic hygiene and post-operational disinfection with safe disposal of tissues and sera apply.

(3) The additional requirements laid down in Table 1 of this Chapter must be fulfilled by any laboratory where procedures involving extensive multiplication of virus are carried out.

(4) The requirements laid down in Table 2 of this Chapter must be fulfilled by any laboratory where animal experiments with classical swine fever virus are carried out.

(5) All stocks of classical swine fever virus must be kept in secure storage (whether deep-frozen or freeze-dried).

(6) Freezers and refrigerators may not be used for viruses other than classical swine fever, or for other materials unrelated to classical swine fever diagnosis.

(7) All individual ampoules where the classical swine fever virus is stored must be clearly labelled, and comprehensive records maintained of virus stocks together with dates and results of quality-control checks. Records must also be kept of viruses added to stock, with details of the source, and of viruses issued to other laboratories.

(8) It is recommended that the premise for classical swine fever virus work should be additionally supported by surrounding areas where classical swine fever virus is not manipulated. These other areas should be available for the preparation of glassware, tools and other equipment (used for classical swine fever diagnosis), the maintenance and preparation of non-infected cell cultures, the processing of sera and serological testing (other than methods using live classical swine fever virus), and offices.

Table 1. Requirements for diagnostic laboratories

|  |  |  |
| --- | --- | --- |
|  | Additional requirements | Minimal requirements |
| General environment | Normal atmospheric pressure  Double HEPA filtration of exhaust air.  Dedicated rooms, used exclusively for  classical swine fever diagnostic procedures | Normal atmospheric pressure.  Dedicated rooms limited to defined procedures. |
| Laboratory clothing | Complete change of clothes on entry.  Laboratory clothing used only in the classical swine fever virus unit.  Disposable gloves for all manipulations of  infected material.  Clothing sterilised or washed within unit before removal from  unit. | Dedicated outer clothing used only in the  classical swine fever virus unit.  Disposable gloves for all manipulations of  infected material.  Outer clothing sterilised or washed within unit before removal from  unit. |
| Control of personnel | Entry to unit limited to trained personnel with entry permit.  Wash and disinfect hands on leaving unit.  Personnel not permitted near pigs for 48  hours after leaving unit | Entry to unit limited to named, trained personnel.  Wash and disinfect hands on leaving unit.  Personnel not permitted near pigs for 48  hours after leaving unit |
| Equipment | Biological safety cabinet (Class I or II) used for all manipulations of live virus should have double HEPA filtration of exhaust air.  All equipment needed for laboratory procedures to be available within the dedicated laboratory suite. | |

*Table 2.* Requirements for experimental animal rooms

|  |  |
| --- | --- |
|  | Requirements |
| General environment | Negative pressure controlled ventilation.  Double HEPA filtration of exhaust air.  Facility for complete disinfection at end of experiment.  All effluents treated to inactivate classical swine fever virus (heat or chemical). |
| Laboratory clothing | Complete change of clothes on entry.  Laboratory clothing used only in the classical swine fever virus unit.  Disposable gloves for all manipulations with infected material.  Clothing sterilised or washed within unit before removal from unit. |
| Control of personnel | Entry to unit limited to trained personnel with entry permit.  Hand washing and disinfection on exit from unit.  Full shower on exit from unit.  Personnel not permitted near pigs for 48 hours after leaving unit. |
| Equipment | All equipment required for animal procedures to be available within the unit.  All materials to be sterilised on removal from unit or, in the case of animal samples, to be double wrapped in leakproof container which is surface-disinfected for transport to the classical swine fever laboratory. |
| Animals | All animals to be slaughtered before leaving the unit, post mortem examinations to be  completed within the bio-safe area, and carcasses incinerated on completion of examinations |

**ANNEX 2**

**MANNER OF NOTIFICATION OF DISEASE TO BE PROVIDED TO THE EUROPEAN COMMISSION WHERE CLASSICAL SWINE FEVER HAS BEEN CONFIRMED**

(1) European Commission must be notified within 24 hours from the confirmation of each primary outbreak of the classical swine fever in a holding, slaughterhouse or means of transport and classical swine fever in feral pigs, by means of the Animal Disease Notification System (ADNS).

(2) The notification referred to in point 1 of this Annex must contain:

1) the date of dispatch;

2) the time of dispatch;

3) the name of the Member State;

4) the number of outbreaks or cases of classical swine fever;

5) the date on which classical swine fever was suspected;

6) the date on which classical swine fever was confirmed;

7) the methods used for confirmation of classical swine fever;

8) whether the presence of classical swine fever has been confirmed in feral pigs or in pigs in a holding, slaughterhouse or means of transport;

9) the geographical location where the outbreak or the case of classical swine fever has been confirmed;

10) the classical swine fever control measures applied.

(3) In addition to the data referred to in point 1 of this Annex, in case of primary outbreaks or cases in slaughterhouses or means of transport, the Member State must also provide the information on:

1) the number of susceptible pigs;

2) the number of dead pigs of each category on the holding, slaughterhouse or means of transport;

3) the morbidity of the disease by age (category) and the number of dead pigs in which classical swine fever has been confirmed;

4) the number of pigs killed;

5) the number of carcases processed;

6) in case of an outbreak, its distance from the nearest pig holding;

7) if classical swine fever was confirmed in a slaughterhouse or means of transport, the location of the holdings of origin of the infected pigs or carcases.

(4) In case of secondary outbreaks of classical swine fever, the information referred to in points 1 and 2 of this Annex must be forwarded on the first working day of each week.

(5) In addtition to the information referred to in points 1, 2 and 3 of this Annex, a written report must be forwarded to the European Commission and the other Member States of the European Union, including:

1) the date on which the pigs on the holding, slaughterhouse or means of transport were killed and their carcases processed;

2) the results of the tests carried out on samples taken when pigs were killed;

3) information on the number of pigs killed and processed, the number of pigs which are to be slaughtered at a later date and the date laid down for their slaughter, in accordance with Article 7 of this Rulebook;

4) any information on the possible origin of the disease or the origin of the disease if this has been ascertained;

5) in the case of a primary outbreak or a case of classical swine fever in a slaughterhouse or means of transport, the genetic type of virus responsible for the outbreak or the case of classical swine fever;

(6) in cases where pigs have been killed in contact holdings or in holdings containing pigs suspected of being infected with classical swine fever virus, notification referred to in paragraph 5 of this Annex shall contain information on:

1) the date of killing and the number of pigs killed, by age, in each holding,

2) the epidemiological link between the outbreak or case of classical swine fever and each contact holding or the reasons that have induced suspicion of classical swine fever in each suspected holding,

3) the results of the laboratory tests carried out on the samples taken from the pigs killed in the holdings.

(7) In cases where pigs in contact holdings were not killed, information must be provided on the reasons for this decision.

**ANNEX 3**

**RISK FACTORS TO BE CONSIDERED FOR THE DECISION TO KILL PIGS IN CONTACT HOLDINGS**

|  |  |  |
| --- | --- | --- |
| Criteria | Decision | |
| For killing | Against killing |
| Clinical signs suggesting classical  swine fever in the contact holdings | Yes | No |
| Movements of pigs from the outbreak  to contact holdings after the likely  time of introduction of virus in the  infected holding | Yes | No |
| Location of contact holdings in an  area with a high density of pigs | Yes | No |
| Likely spreading of virus from the  outbreak before application of measures for prevention of spreading, combating and eradication of virus | Massive/unknown | Limited |
| Location of contact holdings within  500 metres from the outbreak (in case of areas with a very high density of pigs, a longer distance must be considered) | Yes | No |
| Proximity of contact holdings to more  than one outbreak | Yes | No |
| Number of pigs in the outbreak and/or  in contact holdings | High | Low |

**ANNEX 4**

**MANNER OF CLEANSING AND DISINFECTION**

**(1) Cleansing and disinfection in prevention and combating classical swine fever on a household must include:**

1) the cleansing and disinfection operations and, where necessary, the measures to destroy rodents and insects are carried out in accordance with the instructions given by the official veterinarian;

2) the disinfectants to be used and their concentrations are officially approved by the competent authority;

3) the activity of disinfectants is to be checked before use, as activity of certain disinfectants is diminished by prolonged storage;

4) the choice of disinfectants and of procedures for disinfection is to be made taking into account the nature of the premises, vehicles and objects which are to be treated;

5) the conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular, technical parameters provided by the manufacturer (pressure, minimum temperature and required contact time) are to be observed;

6) irrespective of the disinfectant used, the following general rules are to apply;

a) thorough soaking of bedding and faecal matter (manure) with the disinfectant;

b) washing and cleaning by careful brushing and scrubbing of the ground, floors, ramps and walls after the removal or dismantling of equipment or installations, where possible, so as to achieve the fullest cleansing and disinfection effect;

c) further application of disinfectant for a minimum contact time as stipulated in the manufacturer's recommendations;

d) the water used for cleaning operations is to be disposed of in such a way as to avoid any risk of spreading the classical swine fever virus;

7) where washing is carried out with liquids applied under pressure, re-contamination of the previously cleansed parts is to be avoided;

8) washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated is to be carried out;

9) cleansing and disinfection is to be documented in the holding or vehicle register.

**(2) Cleansing and disinfection operations of infected holdings include:**

1) Preliminary cleansing and disinfection:

a) during the killing of the animals all necessary measures are to be taken to avoid or minimise the dispersion of classical swine fever virus. This is to include inter alia the installation of additional disinfection spots and equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation;

b) carcases of dead or killed animals are to be abundantly sprayed with disinfectant;

c) if the carcases must be removed from the holding for processing, covered and leak-proof containers or other means are to be used,

d) as soon as the carcases of the pigs have been removed for processing, those parts of the holding in which these animals were housed and any parts of other buildings, yards and all tools and materials contaminated during killing, slaughter or post-mortem examination are to be sprayed with disinfectants;

e) any tissue or blood which may have been spilled during slaughter or post-mortem examination and contaminated tools, equipment and surface of ground is to be carefully collected and processed with the carcases;

f) the disinfectant used is to remain on the treated surface for at least 24 hours.

2) Final cleansing and disinfection:

a) manure and used bedding are to be removed and treated in accordance with point (3)(a) sub-point a) point 3 of this Annex;

b) grease and dirt are to be removed from all surfaces by the application of a degreasing agent and the surfaces washed with water;

c) after washing with water, further spraying with disinfectant is to be carried out;

d) after seven days, the premises and surfaces are again to be treated with a degreasing agent, rinsed with water, abundantly sprayed with disinfectant and rinsed with water.

3) Disinfection of contaminated bedding, manure and slurry:

a) manure and used bedding are to be stacked to heat, sprayed with disinfectant and left for at least 42 days or destroyed by burning or burying;

b) slurry is to be stored for at least 42 days after the last addition of infective material, unless the official veterinarian authorises a reduced storage period for slurry which was actually treated in accordance with the instructions given by the official veterinarian so as to ensure the destruction of classical swine fever virus.

In case of open-air holdings, specific procedures for cleaning and disinfection may be determined, taking into account the type of holding and the climatic conditions.

**ANNEX 5**

**RISK FACTORS TO BE CONSIDERED FOR THE DECISION TO APPLY EMERGENCY VACCINATION IN PIG HOLDINGS**

|  |  |  |
| --- | --- | --- |
| Criteria | Decision | |
| For vaccination | Against vaccination |
| Number/incidence slope of outbreaks  in the previous 10-20 days | High/rising rapidly | Low/shallow or slow rise |
| Location of holdings where vaccination  might be applied in an area  with a high density of pigs | Yes | No |
| Likelihood of further outbreaks in the  area for the next two months or more | Highly likely | Not likely |
| Shortage of processing capacity | Yes | No |

**ANNEX II-3.**



**Montenegro**

**Ministry of agriculture and rural development**

**Veterinary administartion**

No: 323/15-0303-148/2

Podgorica, 09. March 2015

**TECHNICAL GUIDELINES FOR IMPLEMENTATION OF THE SAMPLING PLAN FOR THE CONTROL OF SUCCESS IMMUNIZATION OF VACCINATED PIGS AGAINST CLASSICAL SWINE FEVER**

In accordance with Programme of mandatory measures for 2015 (“Official Gazzette of MNE, no.11/2015) the emergence of Classical Swine Fever is prevented by vaccination against the disease on every holding, using the vaccine prepared from the attenuated virus of K type.

In order to exclude the classical swine fever clinical surveillance and serological surveillance is performing for the control of successful immunization of vaccinated pigs – evaluation of immunological status of domestic pig population on the whole territory of Montenegro.

Evaluation of immunological status of the animals is established on the serological surveillance of the herds. For that purpose, statistical representative number of samples that has to be examinated, has been established. The purpose is not to prove that all the herds of domestic pigs are vaccinated, but to prove that prevalence of vaccinated pigs is not lower than it is required for adequate protection from the disease. The population is adequately protected if it is proved that 80% of the population is immune.

**Legal Framework:** Veterinary Law ("Officcial Gazzette of RoM", no. 30/12), regulations which are regulating diagnostic, suppression and eradication of this disease, Programme of mandatory measures for animal health protection in 2015 ("Officcial Gazzette of MNE" no. 11/15), Programme 11- Classical Swine Fever

**Responsible Authority*:*** Veterinary Administration, Administration for Inspection Affairs

**Main Contractor:**Veterinary ambulances, Diagnostic Veterinary Laboratory, Veterinary Inspection

**Coverage:** 1500 pigs

**Period of realisation:** October 2015

**Performing Mode:**

Veterinary ambulances will conduct the blood sampling of vaccinated pigs which will be delivered to the diagnostic veterinary laboratory for examination of the presence of specific anti-bodies against classical swine fever virus.

As indicated in the Table 2 (selection of holdings has been executed based on the performed identification and vaccination in 2014) it has been provided the blood sampling of 1500 pigs on 300 randomly selected holdings. This type of sampling provides detection of, at least one unprotected animal, taking into consideration the following parameters: targeted population > 8000 pig herds from the total estimated number in the country, with expected prevalence of unprotected herds of 50% and accuracy interval of 95%.

**Table 2. Number of samples in respect of the herd size**

|  |  |
| --- | --- |
| **Herd size in respect of number of animals** | **Requested number of samples** |
| 1-10 | All animals in a herd |
| 11-20 | 19 |
| 21-30 | 27 |
| 31-50 | 42 |
| 51-100 | 72 |
| 101-200 | 111 |
| >200 | 246 |

Upon executed testings the herds are classified based on the results, on immune: all herds with more than 80% of protected animals, and not protected: all herds where immunity is lower than 80%.

Blood sampling for control of immunisation status has to be conducted not less than 35 days after the vaccination.

In case that individual holdings do not have pigs, the sampling will be conducted in the closest holding that has approximate number of pigs.

Diagnostic Veterinary Laboratory will perform the laboratory – serological examination for control of immunological status. After performing the examinations, Diagnostic Veterinary Laboratory prepares the report about results of control of immunological status on domestic pigs and delivers it to the Veterinary Administration.

In order to conduct the blood sampling, the certain number of totters (in accordance with the sampling plan) has to be issued.

**ACTING DIRECTORE**

**Biljana Blečić**

**ANNEX II-4.**

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**Goverment of Montenegro**

**Veterinary administration**

**No: 323/12-0303-1602**

**Podgorica, 09. March 2012**

**Surveillance for classical swine fever (CSF) of wild boars - sampling plan and standard operating procedures for sample collection**

**Content:**

1. Introduction

2.CSF surveillance on wild boar population

3. General considerations

Annexes

I. Standard Operating Procedures (SOPs)

II. Sample submission form

**1. Introduction**

*This sampling plan specifies the requirements for surveillance CSF on wild boars. Surveillance for CSF on wild boars is already implemented in Montenegro, but without sufficient number of samples for any future indicative epidemiological measurements. Between 2006 and 2010, 115 hunted wild boars have tested negative on virus presence for CSF. Future plan is to test all hunted and founded dead wild boars. Aim of the surveillance is to prove absence or presence of seropositive animals which will represent basis for eventual future epidemiological measurements.*

**2. CSF surveillance on wild boar population**

2. 1. Considerations

* All the wild boars killed in regular hunting activity (Hunted Animals) or found dead/killed due to clinical symptoms or suspicious behaviour (Indicator Animals) are enrolled in the CSF surveillance plan.
* CSF surveillance is continuous through all year, but particularly during the hunting season.
* Samples are expected to be submitted mainly from hunters; Indicator Animals (IAs) organs or small animal’s carcases should be submitted also from occupationally and recreationally exposed people (e.g. veterinarians, National Park [NP] rangers).
* People who find IAs should inform the hunter association in hunting area where IA was noticed or nearest veterinary ambulances.
* *Role of Hunters*
  + collect and properly store the appropriate sample material before submission for diagnosis
  + memorise, note or record all necessary information and data for completing the sample submission form, incl. precise information of the location where the animal was kill/found
  + submit the sample material to the nearest Veterinary Ambulance [VAmb] in hunting area as soon as possible after death of the animal
* *Role of Veterinary Ambulances*
  + Prepare, properly store and transport the appropriate specimen for diagnosis
  + perform, for hunter free of charge, trihinoscopy analyse, for wild boar sample, from which proper sample material for future CSF diagnosis was taken
  + collect from hunters, all necessary information and data, and complete the sample submission form, incl. the geographical coordinates of the location of the animal killed/found
  + send the specimen followed with submission forms to the DVL
* *Role of the DVL*
  + receiving specimens or carcases from CSF suspect animals from VAmb or other parties
  + perform ELISA screening on body fluid samples in purpose of finding seropositive animals
  + confirm presence of virus on positive specimen using RT PCR method
  + submit diagnostic data as well as data from the sample submission form to the VA in electronic format for which the VA provides the templates
* *Role of Veterinary Administration: Epidemiology Group of the Department for Health Protection & Animal Welfare and Inspection Supervision*
  + Data analysis and reporting, incl. distribution of test results/information and analysis outcomes
  + Temporal and spatial analysis of the CSF estimated prevalence
  + Sharing of test results and analysis outcomes with other stakeholders
  + Detection of significant epidemiological events and defining response measures
  + Review of CSF control measures based on outcomes of the CSF surveillance

2.2 Sample collection & storage

* Samples should be collected as soon as possible from founding of dead animals or after the shooting
* The following samples should be collected:
  + Body fluids from thoraces or abdominal cavity, taken during dressing killed animal, directly by open container.
  + spleen, kidney
* Containers for collecting body fluids will be provided by VA and divided by Hunting Association of MNE. In this purpose will be used standard, no additives 9ml vacumtiner with gummed cap.
* Accordingly to data of annual plan for shooting wild boars, to every hunting district and farther to hunting groups of the wild boars.
* All samples collected from an animal and putted in container and thick plastic bag, should be celery marked with the same identification tag and transported together

2.3 Completion of the sample submission forms

* Veterinarians should complete one CSF sample submission form per shoot or dead found animal. Hunters should provide necessary information to complete submission forms especially for data related of exact location and time of finding/killing animals.

2.4 Samples transport

* The transport time of specimens should be as short as possible.
* The specimens should be transported in condition in which was kept (refrigerated or frozen), and arrived in 72h in DVL after the death of animal
* To avoid accidental exposure, specimens for CSF diagnosis should be shipped with triple packaging and labelled.

2.5 Data registration

* Complete evidence of sample submitted data and diagnose results should be guided by DVL.
* A data base aggregating the data of enrolled animals (submission forms) and the laboratory results will be created by DVL based on the template provided by VA.

**3. General considerations**

3.1. Organisational, financial and legal aspects

* The responsibilities and respective organisational, financial and legal aspects for the parties involved, incl. VA, VAmb, hunters and NP rangers, will be included in the annually “National operational program of preventive measure” of VA
* This also include trihinoscopy analyses free of charge for hunters which bring properly taken and preserved sample in VAmb from hunted wild boars
* Standard 9 ml containers (vacumtainers), as a part of specific equipment for taking body fluid samples, will be provided form VA and divided to wild boar hunting groups over Hunting Association of MNE
* Remuneration for trihinoscopy analyses for VAmbs will be provided from budget of annual “National operative program of preventive measure” based on invoices issued by VAmbs and data of collected and diagnosed samples from DVL
* During the training workshops for hunters and NP rangers in October 2011 their responsibilities in the surveillance for CSF will be introduced.

**Annex I. SOPs for sample collection and management**

***For Veterinary Ambulances***

1.Animals which should be sampled

* For the surveillance of CSF the following wild boars animals should be included
  + 1. Hunted animals (HAs)

a) Animals hunted in regular hunting activity

* + 1. Indicator animals (IAs)

1. Founded dead animals
2. Animals killed due to clinical symptoms or suspicion behaviour

* CSF surveillance is continuous through all the year, but particularly during the hunting season.

*1. 2 Sample collection & storage*

* Hunters will organise the collection of wild boars samples from animals (above a.-c.)
* Body fluid taken from abdominal or thoraces cavity and spleen; kidney taken form wild boar soon as possible after killing for HAs; and spleen and kidney (in case of small animal whole body) taken from founded dead animals, represent ideal specimen for serological and virological testing for CSF.
* Body fluid should be collected from abdominal or thoraces cavity (directly) whit open container. In this purpose will be use standard, no additives 9ml PVC vacumtainer. Container should be closed with original cap.
* The sample material submitted for diagnosis should be kept at cold and refrigerated as soon as possible after the death of animal to preserve samples
* Sample material of HA can be used for diagnostic analyses for 72 hours after taken from the dead animal and arrived under refrigerator conditions. If sample material can not be submitted on analyses in this time frame, it should be frozen. Frozen samples must stay frozen during transport. After defrosting samples should be tested immediately.

*1.3 Completion of the sample submission forms*

* Veterinarians should complete one sample submission form per each received sample material. Hunters should provide the necessary information to complete submission form especially for location and environmental data

*1.4 Sample transport*

* The transport time of specimens should be as short as possible.
* During transport, samples should be kept in same temperature conditions in which it was before (refrigerated/frozen)
* To avoid accidental exposure, specimens for rabies diagnosis should be shipped with triple packaging.
* Transport time of refrigerated samples should be inaclculated in summary time frame of 72 hours during which samples are situable for analyses.
* In case of transporting frozen specimens package with dry ice should be provided
* Specimens should be accompagned with the submission forms which should be separeterly packed in order to be readable.

*1.5 Preventive measurements*

* Contact with domestic pigs should be avoided for at least 3 hours after manipulating with samples

***For hunters and National Park (NP) rangers***

*1.6 Collection of samples*

* Samples from HA or IA should be taken as soon as possible after killing/founding animal together with the sample for trihinoscopy. Sample(s) for trihinoscopy analyse should be managed(packed, transported), separately form samples for CSF surveillance
* Next samples should be taken from hunted wild boars:

1. Body fluid should be taken form abdominal or thoraces cavity
2. Spleen and kidney should be taken

Body fluids should be taken directly with open container, after which container should be closed with original cap after taking body fluids

Spleen and kidney should be taken and putted in thick plastic bag.

Container and plastic bag with organ samples should be clearly marked with same identification, so that is known that originate from same animal. After this, samples should be kept in cold and put in refrigerate condition as soon as possible.

From founded death wild boar only spleen and kidney should be taken. In case that founded animal is small, whole body should be submitted in VAmb.

* The location of killing/founding wild boar should be memorised or noted immediately after taking samples in order to correct information will be provided to the VAmb.
* Samples should be submitted in nearest VAmb in hunting area as soon as possible.
* Containers for body fluid samples will be provided by VA and divided to wild boar hunting groups by Hunting Association of MNE

*1.7 Management and transport of the samples*

* After putting samples in primary packs, it should be putted later in new thick plastic bag. Samples which originate from same animal should be putted together. Than samples should be putted in adequate carton box. Measurements should be taken in order to prevent any leaking of samples or contamination of environment (triple packing).
* In case when is necessary, for transport of samples to VAmb, beside of external plastic bag, layers of ice should be putted to preserve samples in refrigerate condition
* Only proper manipulated samples will be accepted by the VAmb. There should be no signs of major decomposition. Samples should therefore be refrigerated as soon as possible after killing. Under refrigerated conditions the samples should be submitted to the VAmb as soon as possible, having in mind that refrigerator condition can preserve the samples summary 72 hours for analyses.
* Samples should be submitted to the nearest VAmb in hunting area where animal was killed/founded.
* After hunting and taking samples all tools and equipment used in this purpose should be washed in warm water.
* Contact with domestic pigs should be avoided at least 3 hours after contact with wild boars or taking samples

***For Diagnostic Veterinary Laboratory***

*1.7 Receiving of samples*

* DVL will accept arrived samples from VAmbs.
* DVL will provide information to VA about number of received samples from each VAmb.
* **Annex II. Sample submission form**



1. If pigs have been vaccinated against classical swine fever with a conventional vaccine they can be found seropositive due to the vaccination alone, or due to a silent infection in vaccinated animals. [↑](#footnote-ref-1)
2. Under certain circumstances up to 10 % of the pigs within a herd may have antibodies against ruminant pestiviruses causing bovine viral diarrhoea and border disease. For example, when pigs have direct contact with cattle or sheep infected with BVD virus or BD virus, or when pigs have contact with materials contaminated with ruminant pestiviruses [↑](#footnote-ref-2)
3. In all of the current serological tests for classical swine fever a small proportion of sera give false/positive results either due to the lack of specificity of the test-system or due to sera from the singleton reactors. [↑](#footnote-ref-3)
4. In certain cases, e.g. when classical swine fever is suspected in a holding with a limited number of young pigs, the proportion of infected sows may be very small. In these cases a higher number of sows must be sampled [↑](#footnote-ref-4)
5. However, if the derogation provided in Article 7 of this Rulebook has been applied, sampling must concern the sub-units of the holding where pigs have been killed, without prejudice to the further examinations and sampling to be carried out on the remaining pigs in the holding. [↑](#footnote-ref-5)
6. However, if preventive killing has been limited only to the part of the holding where the pigs suspected of being infected or contaminated with classical swine fever virus were kept , in accordance with Article 5 paragraph 3 point 1 of this Rulebook, sampling must concern the sub-units of the holding where pigs have been killed, without prejudice to the further examinations and sampling to be carried out on the remaining pigs in the holding, in accordance with the instructions of the Administration. [↑](#footnote-ref-6)
7. In certain cases, e.g. when classical swine fever is suspected in a holding with a limited number of young pigs, the proportion of infected sows may be very small. In these cases a higher number of sows must be sampled. [↑](#footnote-ref-7)
8. The Reference Laboratory of the European Union Member States for classical swine fever diagnosis has an unlimited permit to receive diagnostic samples and classical swine fever virus isolates. Copy of the import permit may be requested from this laboratory before transport and attached in an envelope to the outside of the package. [↑](#footnote-ref-8)
9. Several Classical swine fever ELISA antigen are commercially available, which are validated with different types of samples. [↑](#footnote-ref-9)