VETERINARY PRACTICE ACT

Prom. SG. 87/1 Nov 2005, amend. SG. 30/11 Apr 2006, amend. SG. 31/14 Apr 2006, amend. SG. 55/7 Jul 2006, amend. SG. 88/31 Oct 2006, amend. SG. 51/26 Jun 2007, amend. SG. 84/19 Oct 2007, amend. SG. 13/8 Feb 2008, amend. SG. 36/4 Apr 2008, amend. SG. 100/21 Nov 2008, amend. SG. 27/10 Apr 2009, amend. SG. 35/12 May 2009, amend. SG. 74/15 Sep 2009, amend. SG. 95/1 Dec 2009, amend. SG. 102/22 Dec 2009, amend. SG. 25/30 Mar 2010, amend. SG. 41/1 Jun 2010, amend. SG. 8/25 Jan 2011, amend. SG. 92/22 Nov 2011, amend. SG. 77/9 Oct 2012, amend. SG. 82/26 Oct 2012, amend. SG. 97/7 Dec 2012, amend. SG. 7/25 Jan 2013, amend. SG. 15/15 Feb 2013, amend. SG. 66/26 Jul 2013, amend. SG. 68/2 Aug 2013, amend. SG. 83/24 Sep 2013, amend. SG. 99/15 Nov 2013, amend. SG. 98/28 Nov 2014, amend. SG. 14/20 Feb 2015, amend. and suppl. SG. 14/19 Feb 2016, amend. SG. 34/3 May 2016, amend. SG. 58/26 Jul 2016, amend. SG. 58/18 Jul 2017, amend. SG. 85/24 Oct 2017, amend. and suppl. SG. 17/23 Feb 2018, amend. SG. 98/27 Nov 2018, amend. SG. 24/22 Mar 2019

Chapter one.
GENERAL PROVISIONS

Art. 1. This Act shall regulate the public relations relevant to the implementation, management and control of the veterinary practice, and shall introduce the principles of the veterinary legislation of the European Union and the World Organization of Animal Health (WOAH).

Art. 2. Veterinary practice shall cover:

1. application of the veterinary requirements concerning:

a) animal health protection and animal welfare;

b) protection of human health against zoonoses;

c) production and storage of germinal products;

d) safety of raw materials and foods of animal origin during their production and transportation;

e) safety of feeding stuffs, feed additives and premixes in production, placing on the market, trade, import, export, transit, storage and use;

f) disposal of animal by-products and products, derived thereof;

g) protection of the environment against harmful effects of animal breeding activity and the related production processes;

h) placing on the market, trade and exchange of animals, germinal products, raw materials and foods of animal origin, animal by-products and products, derived thereof;

i) import, export and transit of animals, raw materials and foods of animal origin, animal by-products and products, derived there from, specific plant products, feeding stuffs, feed additives and premixes;

j) production, import, trade, storage and use of veterinary medicinal products (VMP);

k) (new – SG 7/13) production, import, trade, storage and use of in-vitro diagnostic veterinary medicinal products.

2. control on complying with the requirements laid down in item 1;

3. the veterinary medical science, laboratory activity, diagnostics and expertise;

4. the terms and rules for exercising of veterinary medical profession;

5. veterinary practice.

Chapter two.
MANAGEMENT AND CONTROL OF VETERINARY PRACTICE

Section I.
Authorities for management and control

Art. 3. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall carry out the state policy in the field of the veterinary activity through the Bulgarian Food Safety Agency (BFSA).

Art. 4. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) The official competent authority for implementing, management and control of the veterinary activity shall be the Bulgarian Food Safety Agency.

(2) (revoked – SG 08/11, in force from 25.01.2011)

Art. 5. (revoked – SG 08/11, in force from 25.01.2011)

Art. 6. (amend. – SG 08/11, in force from 25.01.2011, amend. and suppl. - SG 14/16, in force from 19.02.2016, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry shall determine by order a chief veterinary-sanitary inspector.

Art. 7. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out:

1. control on health protection in:

a) animal breeding;

b) (new - SG 14/16, in force from 19.02.2016) implementation of measures for prevention, surveillance, control and eradication of animal diseases and zoonoses;

c) (former letter "b" - SG 14/16, in force from 19.02.2016) production and storage of germinal products;

d) (former letter "c" - SG 14/16, in force from 19.02.2016) placing on the market, trade, exchange and transportation of animals and germinal products;

2. veterinary-sanitary control on production, storage, placing on the market, trade and transportation of raw materials and foods of animal origin;

3. control on the collection and disposal of animal by- products and products, derived thereof;

4. control on applying the rules for protection of animals and animal welfare;

5. (amend. - SG 97/12) control on safety of specific plant products;

6. control on the production, import, storage, trade and use of VMP;

7. border veterinary control of the subjects under item 1 - 5;

8. laboratory and scientific research activity;

9. control on the veterinary practice;

10. control on the disinfection, disinsection, deratisation and devastation;

11. control on the placing on the market of genetically modified organisms as products or food

ingredients of animal origin, genetically modified feeds and feed additives as well as veterinary medical products which consist of or contain genetically modified organisms or a combination of genetically modified organisms;

12. (new – SG 7/13) control over production, import, storage, trade and application of in-vitro diagnostic veterinary medicinal products.

(2) (new – SG 7/13; amend. - SG 99/13) Disinfection, disinsection, deratization and devastation shall be carried out by trained individuals subject to compliance with the terms and conditions and following a procedure, determined by the ordinance under Art. 62, para 2 of the Health Act.

(3) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 2 – SG 7/13) Public registers shall be maintained in BFSA for:

1. animal breeding sites;

2. traders of animals;

3. traders of germinal products;

4. traders of animal by-products and products, derived there from;

5. subjects for yield, production, processing, storage, package and repackage of raw materials and foods of animal origin, subjects for wholesale with food of animal origin as well as retail establishments placing only raw materials and foods of animal origin registered under the Food Act;

6. subjects for disposal and processing of animal by-products;

7. persons, receiving consignments of raw materials and foods of animal origin from an EU Member State, further called "member state", intended for placing on the market and trade, or persons, who by profession are distributing such consignments;

8. (amend. - SG 97/12 ; amend. – SG 7/13) transport vehicles, by which animals are being transported;

9. animal assembly or quarantine centers;

10. (amend. - SG 51/07, in force from 26.06.2007) centres for transplantation of embryos, centres for artificial insemination and centres for storage of sperm;

11. staging items for animals during transport;

12. sites, where veterinary practice is implemented, and the veterinaries working therein;

13. manufacturers of VMP;

14. licensed for use VMP;

15. wholesalers of VMP;

16. veterinary medical pharmacies;

17. persons who have the permissions for carrying out experiments with animals;

18. (amend. - SG 97/12; amend. – SG 7/13) transport vehicles, by which raw materials and food of animal origine, animals, , animal by-products and products derived therefrom are being transported;

19. laboratories, carrying out veterinary practice for the purposes of the state control;

20. (new – SG 7/13) persons, having obtained a certificate of registration of in-vitro diagnostic veterinary medicinal products;

21. (new – SG 7/13) producers and traders of animals identification means.

(4) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; prev. par. 3, amend. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The registers under para 3 shall be published on the Internet site of the Ministry of Agriculture, Foods and Forestry.

(5) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 4 – SG 7/13) The Bulgarian Food Safety Agency shall maintain computerized systems of veterinary information and shall publish bulletins.

(6) (new – SG 7/13) A list of issued permits for use of animal by-products shall be maintained in BFSA.

(7) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 5 – SG 7/13) The Bulgarian Food Safety Agency shall publish specialized magazines.

Art. 8. (1) The control under art. 7, para 1 shall be carried out by official veterinaries, inspectors and experts.

(2) (amend. – SG 08/11, in force from 25.01.2011; suppl. - SG 99/13) Persons under para 1 shall not have the right to perform or participate in activities that are subject to control by BFSA, except for the cases referred to in Art. 46g.

Art. 8a. (new - SG 14/16, in force from 19.02.2016, amend. – SG 58/17, in force from 18.07.2017) Subsequent control (verification) shall be carried out on the activities of persons under Art. 8 under conditions and procedures, specified by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 9. (1) (amend. – SG 08/11, in force from 25.01.2011) Official veterinaries are employees of the BFSA, who have been appointed under official legal relation and have been appointed by an Order of the executive director, who have the right to issue certificates and other documents in case of trade, exchange and export meeting the requirements under art. 101-107, following the performance of:

1. control on animal health protection, animal welfare and at receiving and disposal of animal by-products;

2. veterinary-sanitary control;

3. border veterinary control;

4. control on safety of feeding stuffs, feed additives and premixes.

(2) For an official veterinary in one of the directions of activity under para 1 there can be appointed a veterinary doctor, who:

1. shall have at least 3 years of practical experience in the same direction;

2. shall have passed a training course on the activity under item 1.

(3) (amend. – SG 08/11, in force from 25.01.2011) When issuing the documents under para 1, the official veterinary shall put a model stamp approved by the executive director of BFSA.

Art. 10. (1) (amend. – SG 08/11, in force from 25.01.2011) The bodies of the executive authority and local government, public organizations, individuals and corporate bodies are obliged to support the officials from BFSA when performing their obligations.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The rules and procedures of interaction between the authorities of BFSA and the Ministry of Interior shall be regulated by an Ordinance issued by the Minister of Agriculture, Foods and Forestry and the Minister of Interior.

Art. 11. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) In case of occurrence of a risk for the human health and/or animals, BFSA shall immediately notify in written the Minister of Agriculture, Foods and Forestry, the Minister of Health, the heads of other interested institutions and the respective authorities of the European Commission and WOAH.

Art. 12. (1) (suppl. - SG 7/13, former text of Art. 12, suppl. - SG 14/16, in force from 19.02.2016, amend. – SG 17/18, in force from 23.02.2018) Veterinary practice in the Ministry of Interior shall be performed by an official veterinary unit and by officials at ministry structures in

compliance with this Act.

(2) (new - SG 14/16, in force from 19.02.2016) Veterinary practice in the Ministry of Defence, structures directly subordinate to the Minister of Defence and the Bulgarian Army shall be carried out by interdepartmental veterinary unit in accordance with this Act.

Section II.
Funding of BFSA activities

Art. 13. (revoked – SG 08/11, in force from 25.01.2011)

Art. 14. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; revoked – SG 08/11, in force from 25.01.2011)

(2) (amend. – SG 08/11, in force from 25.01.2011) For the activities set out in this Act shall be paid fees according to the tariff referred to in the Act on the Bulgarian Food Safety Agency.

Art. 15. (revoked – SG 08/11, in force from 25.01.2011)

Art. 16. (amend. – SG 35/09, in force from 12.05.2009, amend. - SG 14/16, in force from 19.02.2016) In cases of widespread epizootic outbreaks the necessary means for applying the measures against the diseases shall be provided as additional budget funds provided for prevention and eradication of the results of disasters.

Chapter three.
PRACTICING OF VETERINARY MEDICAL PROFESSION

Section I.
Conditions for practicing of veterinary medical profession

Art. 17. The right to practice a veterinary medical profession in the Republic Bulgaria shall have Bulgarian citizens, who shall possess a diploma for veterinary medical education, issued by institutions in the system of the professional education and accredited universities in the country, or Bulgarian citizens graduated abroad, the diplomas wherefrom shall be recognized under the Higher Education Act.

Art. 18. (1) The right to practice a veterinary medical profession in the country shall have foreigners who have graduated a veterinary medical education in the Republic of Bulgaria.

(2) (amend. - SG 13/08, in force from 08.02.2008; amend. – SG 83/13) The right to exercise veterinary medical profession in the Republic of Bulgaria shall have foreigners and nationals of Member States of the European Union or of other states which are parties to the Agreement on the European Economic Area or of the Confederation of Switzerland, to whom the professional qualification "veterinary doctor" has been recognized under the order of the Recognition of Professional Qualifications Act.

(3) (amend. - SG 13/08, in force from 08.02.2008; new – SG 83/13) In cases of temporary or single provision of services by veterinary doctors who are nationals of Member States of the European

Union or of other states which are parties to the Agreement on the European Economic Area or of the Confederation of Switzerland, Chapter Two of the Law for recognition of professional qualifications and the provisions of the Law for the activities for provision of services shall apply.

(4) (amend. - SG 13/08, in force from 08.02.2008)

(5) (amend. - SG 13/08, in force from 08.02.2008)

Section II.
Veterinary medical science, post-graduate education and laboratory activity

Art. 19. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall plan and organize the postgraduate education, which includes:

1. (amend. – SG 08/11, in force from 25.01.2011) initial short – term education of officials when starting to work in the system of BFSA;

2. (amend. – SG 08/11, in force from 25.01.2011) periodical short – term education of officials and persons, outside the system of the BFSA on the application of the requirements under this Act;

3. (amend. – SG 08/11, in force from 25.01.2011) long – term education of officials from the system of BFSA for acquiring of specialization in the field of veterinary medicine.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall pay the expenditures for education under para 1 of its officials in case of availability of budgetary funds.

(3) (amend. – SG 08/11, in force from 25.01.2011) Officials of BFSA, who have finished the education under para 1, item 3, shall be obliged to work in the system of BFSA for at least three years following the education.

(4) In case of non-fulfillment of the obligation under para 3 the officials shall refund the expenditures, made for their education proportionately to the time of non-fulfillment, except when the non-fulfillment is due to circumstances beyond their control.

(5) (amend. – SG 36/08; amend. - SG 74/09, in force from 15.09.2009; amend. – SG 41/10, in force from 01.06.2010; amend. - SG 68/13, in force from 02.08.2013, amend. – SG 58/17, in force from 18.07.2017) The conditions and the rules for carrying out of the postgraduate education under para 1 shall be regulated by an Ordinance of the Minister of Agriculture, Foods and Forestry and the Minister of Education and Science.

Art. 20. (amend. – SG 08/11, in force from 25.01.2011) The executive director of BFSA, jointly with the Deans of the veterinary medical faculties shall apitem the units from the system of BFSA for performing the practical education of the students.

Art. 21. (1) (amend. – SG 08/11, in force from 25.01.2011) An expert council shall be established to the BFSA as a consulting body for introduction of science–application studies in its system.

(2) (amend. – SG 08/11, in force from 25.01.2011) The executive director of BFSA shall approve the rules for work of the council and shall apitem its personal membership by an order.

Art. 22. The science – research and laboratory veterinary practice shall be implemented in institutes, accredited universities and laboratories.

Art. 23. (1) The laboratory activity shall include:

1. diagnostic sample examinations of animals and germinal products for prophylactics, control and eradication of animal diseases;

2. examinations for:

a) safety of raw materials and foods of animal origin, animal by-products and products, derived there from;

b) (amend. – SG 7/13 safety of feed;

c) quality, effectiveness and safety of VMP;

3. examinations of the zoohygiene parameters in animal breeding and of the environmental pollution.

(2) (amend. – SG 08/11, in force from 25.01.2011) The laboratory activity under para 1, relevant to the state veterinary medical control shall be performed in laboratories of the BFSA under internationally recognized methods.

(3) (amend. – SG 08/11, in force from 25.01.2011) At necessity the executive director of BFSA shall conclude a contract with an accredited laboratory outside the system of BFSA for implementation of the activities under para 1.

Art. 24. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, on the basis of proposal by the executive director of BFSA, shall approve the national reference laboratories within the system of BFSA.

(2) Laboratories under para 1 shall meet the following minimum requirements:

1. to be determined for the types of examinations and analyses, that are carried out by them;

2. to meet the requirements for good laboratory practice;

3. to be capable for a quick communication with laboratories in the country, the respective reference laboratories of the Member States and the respective reference laboratory of the European Union;

4. to apply the European and international standards in force necessary for implementation of their activity;

5. to maintain a system for classified information received during the implementation of their activity.

(3) The national reference laboratories:

1. shall coordinate the scientific examinations for applying new analytical methods of animal diseases diagnostics and safety of raw materials and foods of animal origin, feeding stuffs, feed additives and premixes;

2. shall carry out methodical management of the laboratories for state veterinary medical control through:

a) coordination of the application of standards and methods for laboratory control;

b) control of the schemes for ensuring the quality of analysis;

c) providing for and approval of the use of standard methods for diagnostics of animal diseases and for safety of raw materials and foods of animal origin;

d) providing of standard reference materials and standard samples;

e) rendering of technical assistance;

3. shall conduct arbitrary analysis of the results, obtained by other laboratories;

4. shall prepare and organize comparative inter laboratory studies for the laboratories in the country and participate in such ones, conducted by the reference laboratories of the European Union and UAHP;

5. shall organize and carry out courses for higher qualification of the personnel in the

laboratories of the state veterinary medical control.

Chapter four.
TERMS AND CONDITIONS FOR CARRYING OUT VETERINARY PRACTICE AND IMPLEMENTING PROGRAMS FOR PREVENTION, SURVEILLANCE, CONTROL AND ERADICATION OF ANIMAL DISEASES AND ZOONOSES (TITLE AMEND. - SG 84/07, AMEND. - SG 14/16, IN FORCE FROM 19.02.2016)

Section I.
Terms and procedure for carrying out veterinary practice (New– SG 84/07)

Art. 25. (amend. – SG 84/07) (1) (amend. – SG 7/13) Veterinarians may practice veterinary medicine in a veterinary medical establishment, if they are entered in the register under Art. 32 and are members of the Bulgarian Veterinary Union (BVU).

(2) (revoked – SG 7/13).

Art. 26. (amend. – SG 84/07) (1) (amend. – SG 7/13) A veterinary medical establishment may be:

1. (amend. – SG 7/13) veterinary clinic (hospital);
2. veterinary surgery (office);
3. veterinary laboratory.

(2) (amend. – SG 41/10, in force from 01.06.2010; amend. and suppl. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The requirements to the sites under para 1, as well as the type and the scope of the veterinary activity, which may be performed there, and also the good veterinary medicinal practice requirements, shall be defined by Ordinances of the Minister of Agriculture, Foods and Forestry.

(3) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 713) The projects for building and reconstruction of veterinary medical establishments referred to in para 1 shall be approved after providing statements for their compliance with the veterinary medical requirements, issued by the director of the regional food safety directorate (RFSD), on the territory of which is located the site.

Art. 27. (amend. – SG 84/07) (1) (amend. – SG 7/13) A veterinary medical establishment can be established by a natural or a legal person.

(2) (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) A manager of a veterinary medical establishment can only be a veterinarian.

(3) (amend. – SG 7/13) The activity of the medical establishment – prevention, clinical diagnostics and treatment of animal diseases, shall be carried out by veterinarians and veterinary technicians, herd by the person referred to in para 1.

(4) (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) In a veterinary medical establishment may also be hired other persons according to the needs and the scope of the activity in question under the conditions, laid down in an ordinance under Art. 26, para 2.

(5) (new – SG 7/13) The stockbreeding facilities may register an independent veterinary medicinal establishment at their premises.

Art. 28. (amend. – SG 84/07; amend. – SG 7/13) In case the public interests require certain

actions to be carried out in the event of natural disasters or epizootics, the veterinarians, practicing their profession at a registered veterinary medical establishment, shall be obliged to render assistance to the competent authorities, which shall pay for the accomplished work under a concluded written agreement.

Art. 29. (amend. – SG 84/07) (1) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; revoked – SG 7/13).

(2) (revoked – SG 7/13).

(3) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The data of the veterinarians practicing the profession and the data of their own stamps shall be entered into the register referred to in Art. 7, par. 3, item 12.

Art. 30. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) For the purpose of registration of a veterinary medical establishment, the persons as per Art. 27, para 1 shall submit an application to the director of the respective RFSD according to a form containing:

1. the name, the seat of business and the management address of the applicant;

2. the permanent address, the address and the type of the veterinary establishment;

3. the names of the veterinarians, working in the veterinary medical establishment, the data from their identification documents;

4. the number and date of issue of the veterinary education diploma of the Manager and of the veterinarians working in the veterinary establishment;

5. the number and the date of issuance of the certificate of membership of the Bulgarian Veterinary Union to the veterinarians working in the veterinary establishment.

(2) (amend. – SG 17/18, in force from 23.02.2018) The application under Para. 1 shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

2. (amend. - SG 14/16, in force from 19.02.2016) contract for assigning management;

3. (amend. – SG 7/13) declarations from the manager and the veterinarians that they are not deprived from the right to practice veterinary profession;

4. declaration that the person has right of ownership or a right of use of the site;

5. (amend. – SG 08/11, in force from 25.01.2011, amend. - SG 14/16, in force from 19.02.2016, revoked – SG 17/18, in force from 23.02.2018)

6. document for paid fees in amount, specified by the tariff as per Art. 14, para 2.

(3) (amend. - SG 13/08, in force 08.02.2008) Foreigners from third countries, wishing to practice veterinary profession in Bulgaria, shall attach to the documents under para 2 also a copy of the document, by which they are granted a residence permit in the Republic of Bulgaria as well as a document under art. 18, para 2.

(4) (amend. – SG 08/11, in force from 25.01.2011, amend. - SG 14/16, in force from 19.02.2016, suppl. – SG 17/18, in force from 23.02.2018) The Director of RFSD, within 3 days period from the date of submission of the application form, shall appoint a Commission which shall check the submitted documents and the correspondence of the subject itemed out in the application form, with the veterinary requirements defined by an ordinance under art. 26, para 2, and shall ex officio verifiy the membership of the Bulgarian Veterinary Union of the veterinarians indicated in the application..

(5) In the commission under para 4 shall also be included representatives of the BVU.

(6) In the case of incompleteness of the documents submitted and/or non-compliance of the site

with the veterinary requirements, the commission shall inform in writing the applicant and shall fix a period for their correction.

(7) (amend. – SG 08/11, in force from 25.01.2011) The commission shall submit to the Director of RFSD a position on the results from the check accompanied by a proposal for registration or refusal.

Art. 31. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011;amend. – SG 7/13) The director of RDFS shall refuse registration, in case:

1. (revoked – SG 08/11, in force from 25.01.2011)

2. the irregularities have not been removed within the term under

In case when in the period under art. 28, para 6 irregularities shall not be removed Art. 30, para 6.

(2) The refusal under para 1 could be appealed under the Administrative procedure code.

Art. 32. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within a period of 14 days from the date of submitting the application as per Art. 30, para 1 the director of RFSD shall enter into a register the veterinary medical establishment and the veterinarians working there and shall issue a certificate for registration under a pattern. The term shall stop running in the cases under art. 30, para 6.

(2) The register under para 1 shall contain:

1. (amend. – SG 7/13) name and a permanent address of the veterinarians practicing their profession in the veterinary medical establishment and the unique registration number of each of them;

2. (amend. – SG 7/13) address and type of the veterinary medical establishment;

3. (amend. – SG 7/13) number and issue date of the registration certificate of the veterinary medical establishment;

4. (amend. – SG 7/13) unique registration number of the veterinary medical establishment;

5. changes in the entered circumstances;

6. date of the registration deletion.

(3) (amend. – SG 83/13, revoked – SG 17/18, in force from 23.02.2018)

(4) (amend. – SG 08/11, in force from 25.01.2011) Within 7 days from the registration of the persons referred to in para 3 the director of RFSD shall inform in writing the chairman of the respective district council of BVU of ex officio entry in the BVU register.

Art. 33. (amend. – SG 84/07; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) In the headquarters of BFSA shall be maintained a public national electronic register, containing the data from the registers of RFSD referred to in Art. 32.

Art. 34. (amend. – SG 84/07) (1) (amend. – SG 7/13) In case of change of a circumstance under art. 32, para 2, item 2, a new registration shall be carried out following the procedure laid down in Art. 30.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) At commencement of work of a veterinarian at a medical establishment, following his/her registration, as well as at termination of employment contract of a veterinarian at a medical establishment, the person under Art. 27, para 1 shall inform the director of the respective RFSD within a period of 3 working days of the entry of the change in the register as per Art. 32. The director of RFSD shall enter the change within 3 working days from the notification, and shall inform the BVU

thereof.

(3) (amend. – SG 7/13, amend. and suppl. – SG 17/18, in force from 23.02.2018) For the purpose of subsequent entry of a veterinarian for carrying out practice at a registered medical establishment shall be presented an application according to a form in which the number and date are indicated of the issuance of the copy of diploma in veterinary medicine, and a document shall be enclosed for paid fee in amount, specified by the tariff under Art. 14, para 2 where payment has not been made by electronic means.

(4) (revoked – SG 7/13, new – SG 17/18, in force from 23.02.2018) At subsequent entry under Para. 3 of a veterinarian who has already been entered in the register under Art. 32, the application shall not be accompanied by a diploma for completed veterinary education and a document for paid fee.

Art. 35. (amend. – SG 84/07) (1) (amend. – SG 7/13) Apart from the cases referred to in Art. 34, the registration shall be deleted and the registration certificate of the veterinary medical establishment is to be repealed:

1. upon a written request of a person referred to in Art. 27, para 1;

2. in case of gross or systematic offences of the requirements under this Act or the acts for its implementation.

(2) (amend. – SG 7/13) A veterinarian, carrying out veterinary practice at a veterinary medical establishment, shall be deleted from the register, in case of:

1. death;

2. placement under judicial disability;

3. deprivation of right to practice veterinary medical profession;

4. long-lasting disability to practice his/her profession under a prescription of the health authorities;

5. (suppl. - SG 14/16, in force from 19.02.2016) deletion from the regional board of the BVU register;

6. (amend. – SG 7/13) termination of the employment contract with the veterinary medical establishment.

Art. 36. (amend. – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 6/13, amend. - SG 14/16, in force from 19.02.2016) (1) In case a penalty under Art. 28, para. 1, item 3 from the Law On The Professional Organization of Veterinarians In Bulgaria has been imposed, the director of the district board of BVU shall notify in writing, within three-days term of imposing the penalty, the Director of the respective Regional Food Safety Directorate (RFSD) and the owner or user of the livestock site, with which the veterinarian has signed a contract under Art. 137a or 137b.

(2) Within three days of receiving the notification under par. 1, the Director of the RFSD shall issue an order to stop registration to practice as a veterinarian until the entry into force of the penalty under par. 1.

(3) The order under par. 2 shall be announced and may be appealed under the Administrative Procedure Code. The appeal shall not suspend the execution.

(4) Within 7 days from the entry into force of the penalty under par. , the director of the district board of BVU shall notify the Director of the respective RFSD and the owner or the user of the livestock site, with which the veterinarian has signed a contract under Art. 137a or 137b. To the notification shall be attached a copy of the act under Art. 29, para. 5 from the Law On The Professional Organization of Veterinarians In Bulgaria, and be marked "entered into force".

(5) Within three days of receipt of notification under par. 4, the Director of RFSD shall issue an order to stop registration to practice as a veterinarian until the expiration of the penalty.

Art. 37. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Bulgarian Food Safety Agency shall exercise control over the activity of the veterinary medical establishments and the veterinarians, working there, with regards to observing the requirements under this Act and the acts for its implementation.

(2) (amend. – SG 7/13) Approval of projects of setting up and reconstruction of veterinary medical establishments, and also issuance of commissioning acts shall be done upon issuance of an opinion by the respective RHSD.

(3) (new – SG 7/13) For issuance of an opinion under par. 2 a fee shall be collected of an amount, determined by the tariff under Art. 14, par. 2.

Art. 38. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011) The veterinaries who perform a veterinary practice shall have personal stamps under a pattern, approved by the executive director of RFSD and BVU.

(2) (amend. – SG 08/11, in force from 25.01.2011) The veterinary shall present a pattern of the personal stamp at the RFSD and BVU.

Art. 39. (amend. – SG 84/07) (1) (amend. – SG 7/13) The managers of veterinary medical establishments shall:

1. (amend. – SG 7/13) put a price list of the veterinary medical services and working time schedule at a visible place in the medical establishment;

2. (amend. – SG 08/11, in force from 25.01.2011) notify immediately the mayor of the municipality, the mayoralty and the RFSD of irregularities found during collecting animal corps and burying animals;

3. (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) keep a register according to a model. approved by the executive director of BFSA, of animal breeding sites which are of concern of the respective veterinary medical establishment;

4. (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) control the fulfillment of the measures, carried out by the medical establishment subject to compliance with the program for prophylaxis, supervision, control and eradication of animals diseases and zoonoses.

(2) The veterinarians carrying out veterinary medicinal practice shall:

1. (amend. – SG 08/11, in force from 25.01.2011) undertake restrictive measures and shall notify immediately the RFSD, the BVU and the mayor of the municipality in case of suspicion or rising of epizootics and/or in the event of large number of dead animals;

2. (amend. – SG 08/11, in force from 25.01.2011) execute the orders of RFSD concerning the prevention, restriction and eradication of epizootic diseases and other large-scale diseases;

3. enter in the daily register of the animal breeding site:

a) date of the treatment with VMP;

b) name, number of the lot, date of expiry and the withdrawal period of VMP;

4. notify the owners of animals of the withdrawal periods of VMP or of medicated feeding stuffs for the health effects at their non-observing;

5. (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) keep an ambulatory daily register on an approved form;

6. (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) forward periodically to the RFSD reports, information and protocols on a form;

7. (amend. – SG 08/11, in force from 25.01.2011, amend. - SG 14/16, in force from

19.02.2016) submit upon a request of BFSA, the documentation maintained by them;

8. (amend. – SG 08/11, in force from 25.01.2011) submit to the BFSA a report according to a model on assumed and serious or unexpected unfavourable reactions and unfavourable reactions in humans and animals after the use of VMP;

9. respect the requirements concerning the use of hormonal products, beta-agonists and thyreostatics and/or other VMPs and substances in production animals for treatment and zoo-technical purposes;

10. perform post-mortem animal examination and send samples for laboratory analysis for diagnosis confirmation when necessary;

11. issue prescriptions;

12. (amend. – SG 7/13) observe the Good Veterinary practice requirements and Professional Ethics of Veterinarians;

13. (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) issue veterinary medical documents for movement on the territory of the state of animals and leathers and wool, produced from animals, kept for private consumption in an approved form of BFSA, upon assignment by the RFSD;

14. (new – SG 7/13) enter into the BFSA Integrated Information System:

a) the information about the carried out by them prophylactic, therapeutic and diagnostic activity;

b) (amend. - SG 14/16, in force from 19.02.2016) the carried out measures under the program for prophylaxis, supervision, control and eradication of animals diseases and zoonoses;

c) information about the identified animals;

d) information about newborn, purchased, sold, slaughtered and dead animals of the species subject to identification.

Art. 40. (amend. – SG 84/07) (1) The veterinary technicians shall be entitled to perform:

1. manipulations, prescribed by the veterinary, under whose control they are working;

2. taking samples for laboratory testing;

3. ordinary and orthopedic activity;

4. disinfection, disinsection, deratisation, deodorization of sites and devastation of pasture terrains – after passing a specialized course;

5. primary and secondary examinations of animals without making a final diagnosis;

6. (new – SG 7/13) identification of animals and entering of information into the Integrated information system of BFSA.

(2) The activities referred to in para 1 shall be carried out under the supervision of a veterinarian.

(3) The veterinary technicians:

1. (amend. – SG 08/11, in force from 25.01.2011) shall notify immediately the veterinary, under whose control they are working, or the respective RFSD in case of suspicion or occurrence of epizootics and/or in the event of a large-scale animal death;

2. shall observe and fulfill the instructions of the control authorities in the field of selection and reproduction when performing artificial insemination of agricultural animals.

Art. 41. (amend. – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The director of RFSD shall notify in writing the mayors of the veterinary medical establishments and the veterinarians, employed there, that are registered on the territory of the municipality.

Art. 42. (amend. – SG 84/07) In case a registered veterinary is absent, he/she shall be obliged to place a notification at a visible place about the period of his/her absence.

Art. 43. (amend. – SG 84/07; revoked – SG 7/13)

Art. 44. (amend. – SG 84/07) (1) (amend. – SG 08/11, in force from 25.01.2011) In case any irregularities have been found in a veterinary medical establishment, the following measures shall be undertaken by the director of RFSD, depending on their type and weight:

1. giving prescriptions;

2. temporarily stopping the exercising of the veterinary practice of the medical unit until the irregularities are removed.

(2) In case any violations of the veterinary medical requirements have been found by the veterinarians, employed in a medical establishment, shall be issued:

1. a prescription;

2. an order for deletion from the register under Art. 32.

(3) (amend. – SG 08/11, in force from 25.01.2011) The acts referred to in para 2, item 1 shall be issued by the official veterinarian, and the ones under para 2, item 2 – by the director of the RFSD.

(4) The act imposing a measure under para 1 and 2 shall be subject to appeal according to the Administrative Procedure Code. The appeal shall not stop the enforcement.

(5) In case an order under para 2, item 2 has been issued, the veterinarian can register according to the common procedure for practicing the profession at a medical establishment after expiration of two months from the date on which the order, imposing the measure, has entered into force.

Art. 45. (amend. – SG 84/07; amend. – SG 35/09, in force from 12.05.2009; amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency should order to the veterinaries outside its system the performance of certain functions for prevention, limitation and eradication of animal diseases and for carrying out of veterinary assistance in case of disaster, following a coordination with the BVU.

Art. 46. (amend. – SG 84/07) The veterinarians are members of BVU according to conditions and following a procedure, specified by the Act on the Professional Organization of Veterinarians in Bulgaria.

Section II.
Terms and conditions of assigning the implementation of measures under the program for prophylaxis, supervision, control and eradication of animals' diseases and zoonose (new – SG 84/07; title amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016)

Art. 46a. (new – SG 84/07; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) Bulgarian Food Safety Agency shall inform the European Commission and the competent bodies of the Member States of the implementation of measures for prevention, supervision, control and eradication of animal diseases and zoonoses according to veterinary legislation of the European Union.

Art. 46b. (new – SG 84/07; amend. – SG 7/13, revoked - SG 14/16, in force from 19.02.2016)

Art. 46c. (new – SG 84/07, amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) (amend. – SG 58/17, in force from 18.07.2017) The prices at which is paid the carrying out of measures under the programme for prevention, supervision, control and eradication of animal diseases and zoonoses shall be determined in a tariff, approved by the Council of Ministers on a proposal by the Minister of Agriculture, Foods and Forestry. The tariff shall be published in the State Gazette and online on the website of the Ministry of Agriculture, Foods and Forestry.

(2) The prices determined under par. 1 can only be changed in accordance with the inflation index, established by the National Statistical Institute.

Art. 46d. (new – SG 84/07; amend. – SG 7/13) (1) (suppl. - SG 99/13, amend. - SG 14/16, in force from 19.02.2016) The expenses for the carrying out of the programs, referred to in Art. 46h and 46i, and also Art. 118, par. 1 included, for sampling and transporting of samples, required for the tests, shall be provided as a state aid through the State Fund "Agriculture", except for the costs of purchasing in vitro diagnostic veterinary devices necessary for laboratory tests to be borne by the accredited laboratories.

(2) The State Fund "Agriculture" shall provide the state aid under par. 1 subject to the terms and conditions of the Law for the State Aid.

Art. 46e. (new – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) The persons carrying out the measures under the programs in Art. 46h, 46i and Art. 118, para. 1 shall be veterinary doctors.

Art. 46f. (new – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) Measures under programs in Art. 46h, 46i and Art. 118, para. 1 in the sites, registered in the order of Art. 137, shall be carried out be the registered veterinarians who have concluded an agreement under Art. 137a.

(2) (amend. - SG 14/16, in force from 19.02.2016) The measures under the programs in Art. 46h, 46i and Art. 118, para. 1 in the facilities, where animals for personal needs only are being bred, shall be fulfilled by registered veterinary doctors, having concluded an agreement subject to compliance with the provision of Art. 137b.

Art. 46g. (new – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13; amend. - SG 99/13, amend. - SG 14/16, in force from 19.02.2016) Where necessary, the Executive Director of BFSA shall issue an order for the implementation of the measures under the program for prophylaxis, supervision, control and eradication of animal diseases and zoonoses by veterinarians from BFSA or veterinary specialists outside BFSA.

Art. 46h. (new - SG 14/16, in force from 19.02.2016) (1) The National Program for prevention, supervision, control and eradication of animal diseases and zoonoses with significance for the European Union shall contain the data of Art . 12, paragraph 2 of Regulation (EU) № 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of costs, associated with the food chain, animal health and welfare, plants health and plant reproductive material,

amending Directives 98/56/EC, 2000/29/EC and 2008/90/EC of the Council, of regulations (EC) № 178/2002, (EC) № 882/2004 and (EC) № 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and of Regulation (EC) № 1107/2009 of the European Parliament and of the Council and repealing decisions 66/399/EEC, 76/894/EEC and 2009/470/EC of the Council (OJ, L 189/1 of 27 June, 2014), hereinafter referred to as "Regulation (EU) № 652/2014".

(2) (amend. – SG 58/17, in force from 18.07.2017) The program on par. 1 shall be submitted to the Minister of Agriculture, Foods and Forestry for approval by April 15 of the year, preceding the year for its implementation.

(3) The Bulgarian Food Safety Agency shall send the program under par. 1 to the European Commission for approval by 31 May of the year, preceding the year for its implementation.

(4) On the implementation of the program under par. 1, the Bulgarian Food Safety Agency shall prepare a report to the European Commission according to Art. 14 of Regulation (EU) № 652/2014.

Art. 46i. (new - SG 14/16, in force from 19.02.2016) The Bulgarian Food Safety Agency shall draw up a program for prevention, supervision, control and eradication of animal diseases and zoonoses of national significance which shall be approved under Art. 46h, para. 2.

Art. 46j. (new - SG 14/16, in force from 19.02.2016) (1) Measures of programs under Art. 46h and 46i shall be included in the program under Art. 118, para. 1.

(2) When the programs under Art. 46h and 46i are approved for a period, shorter than the period of the program under Art. 118, para. 1, the measures, referred to therein, shall be implemented in the period, for which they are approved.

(3) Where programs under Art. 46h and 46i are approved for a period, longer than the period of the program under Art. 118, para. 1, the measures, referred to therein, for the period after the expiry of the program's period, shall be included in the program for the next period.

Chapter four "a".
CARRYING OUT OF VETERINARY PRACTICE AT HIGHER EDUCATION ESTABLISHMENTS (NEW - SG 14/16, IN FORCE FROM 19.02.2016)

Art. 46k. (new - SG 14/16, in force from 19.02.2016) (1) Veterinary practice under Art. 2, item 3 shall take place in a veterinary clinic, veterinary office (surgery) or veterinary laboratory at an establishment of higher education.

(2) (revoked - SG 34/16, in force from 03.05.2016)

Art. 46l. (new - SG 14/16, in force from 19.02.2016, amend. – SG 58/17, in force from 18.07.2017) The terms and conditions for carrying out of activities under Art. 46k, para. 1, as well as the subsequent control, shall be determined by an ordinance, issued jointly by the Minister of Agriculture, Foods and Forestry and the Minister of Education and Science.

Chapter five.
VETERINARY MEDICAL REQUIREMENTS FOR ANIMALS, GERMINAL PRODUCTS, RAW MATERIALS AND FOODS OF ANIMAL ORIGIN AND ANIMAL BY- PRODUCTS

Section I.
Veterinary medical requirements for animals and germinal products

Art. 47. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Bulgarian Food Safety Agency shall implement measures for prophylactics, limitation and eradication of certain particularly dangerous contagious diseases, indicated in an order of the Minister of Agriculture, Foods and Forestry.

(2) (amend. – SG 08/11, in force from 25.01.2011) The measures under para 1 shall be imposed by an order of the executive director of BFSA and shall include killing of animals, bans on movement of people, animals, raw materials and foods of animal origin, feed materials, compound feeding stuffs, feed additives, premixes and Articles through which infectious agents can be transferred.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The measures for prophylactics, limitation and eradication of diseases under para 1, as well as the terms and rules for their application shall be determined by ordinances of the Minister of Agriculture, Foods and Forestry.

(4) (amend. – SG 08/11, in force from 25.01.2011) By an order the executive director of BFSA, except the cases under para 2, shall prohibit the movement of animals, germinal products, animal by-products and products derived from them, raw materials and foods of animal origin, feed materials, compound feeding stuffs, feed additives and premixes for a part or for the whole territory of the country, when there is a risk for human health and animal health of occurrence or spreading of contagious disease or an environmental pollution.

(5) (amend. – SG 08/11, in force from 25.01.2011) The executive director of the BFSA shall repeal by an order the imposed bans under para 2 and 4.

(6) (Amend. – SG 17/18, in force from 23.02.2018) The orders under para 2, 4 and 5 shall be published on the website of the Bulgarian Food Safety Agency.

(7) Orders under para 2 and 4 shall not be repealed.

Art. 48. (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall draw up a contingency plan, which is to be applied at a suspicion or occurrence of a disease under art. 47, para 1.

Art. 49. (1) The prophylactic vaccinations against diseases under art. 47, para 1 shall be prohibited with the exception of the vaccination against avian Newcastle disease.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) At a danger of large spreading of some of the diseases under art. 47, para 1, the Minister of Agriculture, Foods and Forestry, under a proposal of the executive director of BFSA, following a consultation with the European Commission, can provide for a vaccination through an order.

Art. 50. (1) (amend. – SG 08/11, in force from 25.01.2011) The diseases under art. 47, para 1 that have occurred in the country, are to be subjected to an obligatory notification and registration by the executive director of BFSA.

(2) The information about the notification of the diseases under para 1 shall be forwarded to the European Commission through a specialized information system for notification of animal diseases.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The rules and the method for notification and registration of the diseases under art. 47, para 1 shall be regulated by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 51. (amend. – 7/13) (1) (Suppl. – SG 17/18, in force from 23.02.2018) The animals are to be subjected to official identification, and the animal breeding sites – to a registration in the order of Art. 137 of the BFSA.

(2) The Bulgarian Food Safety Agency is the competent body for the control over the official

identification of animals.

(3) (amend. – SG 99/13) The Bulgarian Food Safety Agency shall maintain Integrated information system with information about the identified animals and about the animal breeding facilities and shall provide access to the information to:

1. the European Commission upon request;

2. the breeding organizations under Art. 8 of the Stock-Breeding Act.

(4) The numbering system of the means, used for official identification, shall be determined by the BFSA.

(5) (amend. – SG 58/17, in force from 18.07.2017) The requirements to the means of official animal identification and their use, terms and conditions and the procedure and control over collection, entering, maintenance and application of the information in the system under par. 3 shall be determined by an ordinance of the Minister of Agriculture, Foods and Forestry.

(6) The terms and conditions and the procedure of identification of heavy ruminants are established by Regulation (EC) No. 1760/2000 of the European parliament and of the council of 17 July 2000 establishing a system for identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council regulation (EC) No. 820/97, herein after referred to as Regulation (EC) No. 1760/2000.

(7) (suppl. - SG 14/16, in force from 19.02.2016) The terms and conditions and the procedure of identification of sheep and goats are established by Regulation (EC) No. 21/2004 of 17 December 2003 establishing a system for identification and registration of ovine and caprine animals and amending Regulation (EC) N0. 1782/2003 and Directives 92/102/EEC and 64/432/EEC, hereinafter referred to as "Regulation (EC) № 21/2004".

(8) (amend. - SG 14/16, in force from 19.02.2016) The terms and conditions for identification of whole-hoofed animals shall be defined by Regulation for implementation (EU) 2015/262 of the Commission of 17 February 2015 laying down rules in accordance with directives 90/427/EEC and 2009/156/EC of the Council on methods for identification of whole-hoofed animals (Regulation of equine passport) (OB, L 59/1 from 3 March, 2015), hereinafter referred to as "Regulation (EU) 2015/262.

(9) (amend. – SG 58/17, in force from 18.07.2017) The terms and conditions and the procedure of identification of animals, for which no requirements are provided in a European Union regulation, shall be established by ordinances of the Minister of Agriculture, Foods and Forestry.

(10) The cost of the means for official identification and the cost of animal identification shall be provided as a state aid through the State Fund "Agriculture".

(11) The State Fund "Agriculture" shall provide the state aid under par. 10 subject to the terms and conditions of the Law for the State Aid.

(12)(amend. – SG 80/09; amend. - SG 66/13, in force from 26.07.2013; amend. – SG 98/14, in force from 28.11.2014) With regard to the maintenance of the Integrated Information System referred to in par. 3, BFSA shall have the right to access to the national data base "Population" of the General Directorate "Civil registration and administrative services" in the Ministry of Regional Development and Public Works.

Art. 51a. (new – SG 7/13; amend. – SG 99/13, in force from 01.01.2014, amend. - SG 14/16, in force from 19.02.2016) The official animal identification shall be carried out by their owners or by veterinarians authorized by them, by veterinary technicians or breeding organizations under Art. 8 of the Stock-Breeding Act within maximum periods pursuant to Art. 4a of Regulation (EC) № 1760/2000, Art. 4, paragraph 1 of Regulation (EC) № 21/2004 and Art. 12, paragraph 1 of Regulation (EU) 2015/262 and the terms according to the ordinance under Art. 51, para. 9.

Art. 51b. (prev. text of Art. 51a – SG 99/13, in force from 01.01.2014) The means for official identification of animals shall be manufactured and/or traded only by persons, registered in the register under Art. 7, par. 3, item 21.

(2) (Amend. – SG 17/18, in force from 23.02.2018) To make an entry in the register, the producers and dealers of means for identification of the animals shall submit an application form to the Executive Director of the Bulgarian Food Safety Agency, stating the UIC under the Act on the Commercial Register and the Non-Profit Legal Entities Register or the BULSTAT code. The application shall be filed personally, through proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 17/18, in force from 23.02.2018) unified identification code according to Art. 23 of the Law for the Trade Register or a document of actual status, issued by a competent body of another state, if applicable;

2. a copy of an employment agreement with a person to register the circulation of the identification means in the Integrated Information System of BFSA, where the applicant is not registering the information personally;

3. a declaration in an approved form, that the manufacturer, respectively the trader will replace at their expense a damaged or non-readable identification mean within its warranty period within 20 days after the notification of the damage;

4. twenty pieces of samples of an identification means and the device for its application, where the applicant is a manufacturer or a trader, launching on the market identification means for the first time;

5. (suppl. – SG 17/18, in force from 23.02.2018) a document of a paid fee for entering into the register in an amount, determined by the tariff referred to in Art. 14, par. 2 when the payment is not made electronically.

(3) The Managing Director of BFSA by an order shall appoint a commission for revision of the attached to the application documents and of the samples of the identification means under par. 2, item 4, which are to be manufactured or traded, for their compliance with the requirements of the ordinance under Art. 51, par. 5.

(4) Within 14 days after filing of the application, the commission under par. 3 shall submit to the Managing Director of BFSA a protocol with an opinion on the compliance of documents and samples with the requirements. One copy of the protocol shall be handed over to the manufacturer or the trader.

(5) Within three days after the receipt of the opinion under par. 4, the Managing Director of BFSA shall issue an order for entering into the register or for a refusal for entering. In case of entering into the register, the applicant shall be granted a certificate by the Managing Director of BFSA.

(6) The issued Certificate shall become invalid and the entering into the register shall be deleted by an order of the Managing Director of BFSA:

1. upon a written request by the manufacturer or the trader;

2. in case of use of identification means which are not approved by BFSA;

3. in case of non-compliance with the requirements of the ordinance under Art. 51, par. 5;

4. in case of non-reported circulation of identification means.

(7) The refusal under par. 5 and the order under par. 6, items 2, 3 and 4 shall be advised and may be appealed following the provisions of the Code of Administrative Procedure.

(8) The persons registered in the register under Art. 7, par. 3, item 21 shall be obliged to keep record of the circulation of animal identification means subject to compliance with the terms and provisions and following the procedure of the ordinance under Art. 51, par. 5.

Art. 51c. (new – SG 7/13; prev. text of Art. 51b – SG 99/13, in force from 01.01.2014)) (1) (amend. – SG 99/13, in force from 01.01.2014) Manufacturers and traders of official animal identification means shall be obliged to offer on the market only identification means with approved samples following the procedure of Art. 51b.

(2) Where manufacturers and traders, registered into the register under Art. 7, par. 3, item 21 wish to launch on the market official identification means, different from these referred to in par. 1, they shall submit to BFSA an application in an approved form, to which they shall attach 20 pieces of samples of the new identification means and the device for their application.

(3) The Managing Director of BFSA by an order shall appoint a commission for revision of the samples of the new identification means. Within 10 days after filing of the application under par. 2, the commission shall submit to the Managing Director of BFSA an opinion on the compliance of the samples with the requirements of the ordinance under Art. 51, par. 5.

(4) The Managing Director of BFSA shall advise in writing the persons under par. 2 of the results of the inspection under par. 3.

Art. 52. (In force from January 1 2007) (1) Movement and transportation of animals and germinal products between the Republic of Bulgaria and Member States shall be carried out providing that:

1. they are originating from an animal site, a center for production and storage of germinal products or from an area, the health status of which comply with the requirements for prophylactics, limitation and eradication of certain diseases in the different animal species;

2. (amend. – SG 08/11, in force from 25.01.2011) they are transported in mechanically cleaned and disinfected transport vehicles, registered in BFSA;

3. (amend. – SG 08/11, in force from 25.01.2011) they have been subject to veterinary checks, carried out by the authorized bodies of BFSA;

4. (amend. – SG 08/11, in force from 25.01.2011) traders of animals and germinal products have been registered in BFSA;

5. (amend. – SG 08/11, in force from 25.01.2011) germinal products have been produced by organizations, centers or teams, registered in BFSA.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The diseases under para 1, item 1, in regards to which the health status of a animal site, production and storage center for germinal products or an area is to be determined, shall be identified by an order of the Minister of Agriculture, Foods and Forestry.

Art. 53. (In force from January 1 2007; amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry by an order shall determine the diseases for each animal species, for which during an exchange the Republic of Bulgaria can request from a Member State additional health status guarantees for the animal breeding sites or the areas, wherefrom the animals originate.

Art. 54. (In force from January 1 2007; amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements for defining of the health status of sites under art. 52, para 1, item 1, the additional guarantees under art. 53 and the other health requirements for movement or transportation of animals and germinal products between the Republic of Bulgaria and the Member States shall be regulated by ordinances of the Minister of Agriculture, Foods

and Forestry.

Art. 55. (amend. – SG 08/11, in force from 25.01.2011) The owners, keepers, transporters and traders of animals shall be obliged to notify immediately the authorities of BFSA in case of suspicion of a contagious disease under art. 47, para 1, art. 52, para 2, and art. 53.

Art. 56. (In force from 01.01.2007) (Amend. – SG 88/06, in force from 31.10.2006) (1) Import of animals and germinal products in the Republic of Bulgaria shall be allowed, provided that:

1. they originate from a third country, part of a third country or a region, which are included in the list of animal species and germinal products of the European Commission;

2. they originate from centers for production and storage of germinal products, included in the list of the European Commission;

3. they are accompanied by a model of certificate of the European Union for each kind of animals and germinal products;

4. they shall meet the veterinary medical requirements for import in the European Union.

(2) (amend. – SG 36/08, amend. – SG 58/17, in force from 18.07.2017) Veterinary medical requirements for import of animals and germinal products shall be determined by ordinances of the Minister of Agriculture, Foods and Forestry.

Section II.
Veterinary medical requirements for raw materials and foods of animal origin

Art. 57. (1) Raw materials and foods of animal origin shall be placed on the market if they meet the requirements of this Act, Foodstuffs Act and the secondary legislation for their implementation.

(2) Raw materials and foods of animal origin intended for placing on the market shall be obtained from animals:

1. which meet the health requirements and have passed a veterinary medical control;

2. for which there are no imposed bans or restrictions because of suspicion or occurrence of a disease under art. 47, para 1.

(3) The requirement under para 2, item 2 shall not be applied, where the raw materials and foods of animal origin are marked by a special mark or are handled or processed by methods, which shall guarantee an eradication of the respective disease agents.

(4) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The health requirements to the animals, from which the raw materials and foods have been obtained, shall be determined in ordinances of the Minister of Agriculture, Foods and Forestry.

Art. 58. (1) Raw materials and foods of animal origin intended for placing on the market shall be marked with a health or identification mark for identifying their origin.

(2) The veterinary registration number of the production and storage site, where from they originate, shall be entered into the veterinary medical and/or other documents, accompanying the raw materials and foods of animal origin during their transportation.

Art. 59. General requirements of production, transportation and placing on the market of foods

shall be regulated by the ordinance under art. 17, para 2 of the Foodstuffs Act.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) Specific requirements in production, transportation and placing on the market of raw materials and foods of animal origin shall be regulated by ordinances of the Minister of Agriculture, Foods and Forestry.

Art. 60. (1) (In force from January 1 2007) (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Bulgarian Food Safety Agency shall submit to the Member States and the European Commission information about all sites included into the register under art. 7, para 3, item 5, as well as an information about the changes made in it.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall submit the information under para 1 to other countries upon request.

Art. 61. (Amend. – SG 88/06, in force from 31.10.2006) (1) (In force from 01.01.2007) Import of raw materials and foods of animal origin, animal by-products and products, derived from them, shall be allowed by observing the following requirements:

1. to originate from third countries, parts or regions of them, which are included in the lists of the European Commission;

2. to be manufactured in establishments situated on the territory of the counties, parts of the countries or regions under item 1 and to be included in the lists of the establishments, approved by the competent authorities of the country of origin for import into the European Union;

3. the consignment is to meet the veterinary requirements for import of raw materials and foods of animal origin into the European Union;

4. each consignment is to be accompanied by a veterinary certificate and/or other model documents provided by the European Union, issued by the competent authorities of the country of origin.

(2) (amend. – SG 84/07; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The veterinary medical requirements in case of import, exchange and trade of raw materials, foods and products of animal origin shall be determined by ordinances of the Minister of Agriculture, Foods and Forestry.

Section III.
General veterinary medical requirements concerning the subjects of control

Art. 62. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out control on:

1. contaminants of the environment in animals, raw materials and foods of animal origin, feed materials, feed additives, compound and medicated feeding stuffs, drinking water, which is entering into contact with raw materials and foods of animal origin, and water in the sites for rearing and breeding of fish and other aquaculture organisms;

2. VMP residues in raw materials and foods of animal origin, and water in sites for rearing and breeding of fish and other aquaculture organisms;

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The control measures on the sites under para 1 shall be determined by an ordinance of the Minister of Agriculture, Foods and Forestry.

(3) (amend. – SG 08/11, in force from 25.01.2011) Annually the BFSA shall develop and

implement a National monitoring program in order to carry out the control under para 1

(4) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall present the program under para 3 for the current year, for approval by the European Commission.

(5) (amend. – SG 08/11, in force from 25.01.2011) Annually the Bulgarian Food Safety Agency shall inform the European Commission about the results from the implementation of the program during the previous year.

Art. 63. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 7/13) The maximum residue limits of VMP in raw materials and foods of animal origin shall be determined by Regulation (EC) No. 37/2010 of the Commission of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ, L 15/1 of 20 January 2010), herein after referred to as Regulation (EC) No. 37/2010.

Art. 64. (1) Production, placing on the market and trade of the following raw materials and foods of animal origin shall be prohibited:

1. produced from animals, treated with VMP, before the expiry of their withdrawal period, thyreostatics and beta-antagonists;

2. produced from dairy cows, treated with somatotrophin;

3. in which there is detected presence of contaminants and residues of VMP above the maximum established limits.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The hormonal VMP, thyreostatics and beta-antagonists approved by the European Commission, which can be used as an exception for therapeutically and zoo-technical purposes, shall be determined by an order of the Minister of Agriculture, Foods and Forestry, which is to be published in the State Gazette.

(3) Products under para 2 shall be licensed for usage.

Art. 65. (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall apply measures for prophylactics, limitation and eradication of the zoonoses.

Art. 66. (1) Animal by-products and products derived from them, shall be collected, transported, kept, handled, processed or destroyed in a manner, that shall guarantee full safety of the final product and shall prevent the occurrence of a risk for human and animal health and for contamination of the environment.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements for carrying out the activity under para 1, as well as for the usage, placing on the market and transit of animal by-products and products, derived from them shall be regulated by an ordinance of the Minister of Agriculture, Foods and Forestry agreed upon with the Minister of Environment and Waters.

Section IV.
Veterinary medical checks concerning the exchange of animals, germinal products, animal by-products and products, obtained from them with the EU Member States (In force from

January 1 2007)

Art. 67. (In force from January 1 2007) (1) The veterinaries under art. 8, para 1 shall perform the clinical examinations and checks for animal health control during movement and transport of animals, germinal products, animal by-products and products, derived there from at an exchange between the Member States and the Republic of Bulgaria.

(2) The veterinaries under art. 8, para 1 shall be obliged to carry out clinical examination and veterinary medical checks on the place of origin of the animals, germinal products, animal by-products and the products, derived there from for:

1. compliance with the veterinary medical requirements for identification of animals;

2. (amend. - SG 14/16, in force from 19.02.2016) implementation of the program for prevention, supervision, control and eradication of animal diseases and zoonoses;

3. compliance with the veterinary medical requirements in centers for production and storage of germinal products, on markets and assembly centers for animals and premises for cleaning and disinfecting of transport vehicles;

4. compliance with the veterinary medical requirements during transportation of animals, germinal products, animal by-products and products, derived from them;

5. implementation of the obligations of the owners at each stage of breeding, production and trade in animals, germinal products, animal by-products and products, derived from them;

6. veterinary certificates and other documents, accompanying the subjects under para 1.

(3) The veterinaries under art. 8, para 1 shall have the right to carry out an epizootic investigation, other additional checks and shall prohibit the movement of subjects under para 1, when during the checks arises a suspicion or it is detected that:

1. the veterinary medical requirements are not being observed;

2. the issued certificates and other documents do not correspond to the actual status of the subjects under para 1;

(4) On the delivery place of the subjects under para 1 the veterinaries shall perform the checks in one and the same manner, irrespective of whether the consignment is originating from the Republic Bulgaria or from a Member State.

(5) During transit passing of the subject under para 1 the veterinaries shall perform checks, upon suspicion for a violation of the veterinary medical requirements.

(6) During checks the veterinaries shall be allowed to take samples for laboratory analysis of animals, germinal products, animal by-products and products, derived from them.

(7) The veterinaries shall have the right to put under quarantine animals that are originating from Member States and for which no veterinary medical requirement of the European Union exist.

Art. 68. (In force from January 1 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) When during a check, carried out on the place of arrival of the consignment, or during its transportation a disease is being detected, which represents a hazard for the human and animal health, or a contamination of infectious agents, the authorized bodies of the BFSA shall carry out an epizootic investigation and can order a destruction of the subjects under art. 67, para 1 or their utilization after a waste disposal.

(2) The expenditures for destruction of the consignment shall be charged to the consignor or to his representative.

(3) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall notify the competent veterinary authorities of the Member States and the European Commission of the findings under para 1 and on the measures undertaken.

Art. 69. (In force from January 1 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) During an exchange with other Member States of subjects under art. 67, para 1 the executive director of the BFSA shall order the undertaking of urgent measures, where:

1. during the check on the place of the delivery of the subjects, the veterinary:

a) has a suspicion for a disease under art. 47, para 1, a zoonose or another reason, which represents a hazard to the human and/or animal health;

b) has a suspicion, that the subjects under art. 67, para 1 originate from a region, where a particularly dangerous contagious disease is being detected under art. 47, para 1;

c) it is detected, that the subjects under art. 67, para 1 do not meet the veterinary medical requirements under this Act;

2. on the territory of Republic Bulgaria a disease under art. 47, para 1, a zoonose or another reason, that represents a hazard for the human and/or the animal health is being detected;

3. The European Commission has made available information about the presence on the territory of a Member State of a disease under art. 47, para 1, a zoonose or another reason, which represents a hazard for the human and/or the animal health.

(2) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para 1 the executive director of the BFSA shall notify the European Commission and the Member States of the measures undertaken.

Art. 70. (In force from January 1, 2007; amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements for carrying out of checks on animals, germinal products, animal by-products and products, derived from them, during an exchange between Republic Bulgaria and the Member States shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 71. (In force from January 1 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) Traders, who are receiving consignments of animals, germinal products, animal by-products and products derived from them from Member States, shall be registered at RFSD.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The traders under Para 1 shall submit in the RFSD an application for registration, conformed to a specimen, in which the UIC is stated under the Act On The Commercial Register And The Non-Profit Legal Entities Register. The application shall be filed personally, by proxy, electronically under the conditions and by the order of art. 5 and 22 of the Electronic Governance Act or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 7/13, amend. and suppl. – SG 17/18, in force from 23.02.2018) a document of actual status, issued by a competent body of another state, if applicable;

2. (revoked – SG 17/18, in force from 23.02.2018)

3. (suppl. – SG 17/18, in force from 23.02.2018) a document of a paid fee, at the amount determined in the tariff under art. 14, para 2, when payment is not done electronically.

(3) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. and suppl. – SG 17/18, in force from 23.02.2018) In a three-day period from the submission of the application form, the director of the RFSD shall officially check the registration of the site in which the activity is carried out, shall enter the person in the register under art. 7, para 3, items 2-4 and shall issue a certificate of registration or shall justify its rejection.

(4) (amend. – SG 08/11, in force from 25.01.2011) In case of incompleteness of the documents under para 2, the director of the RFSD within a period of seven days shall notify in writing the

applicants about their adjustments.

(5) Until the adjustment of the omissions the period under para 3 shall stop running.

(6) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 3 may be appealed according to the rules of the Administrative procedure code.

Art. 72. (In force from January 1 2007) (1) The registration under art. 71, para 1 shall be deleted, and the issued certificate shall be invalidated upon termination of the activity of the trader.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) Upon change of the circumstances in the documents under art. 71, para 2, items 1, the person in a 14-days term shall notify in writing the director of the RFSD for entering of the changes into the register.

Art. 73. (In force from January 1, 2007; amend. – SG 7/13) The registers under art. 71, para 3, items 2-4 shall contain the following:

1. name, address of management and head office of the person;
2. location and type of the unit;
3. number and date of the registration certificate;
4. number and date of the order for deletion of the registration;
5. changes of entered circumstances.

Art. 74. The persons under art. 71, para 1:

1. shall keep a daily register, in which each consignment received shall be entered;
2. (amend. – SG 08/11, in force from 25.01.2011) shall notify the RFSD of the arrival of the consignments in order to perform veterinary medical checks;
3. (amend. – SG 08/11, in force from 25.01.2011) shall keep at least one year from the date of receiving of the consignment the certificates and the other documents, which are accompanying it and shall make them available to the authorities of the BFSA upon request.

Art. 75. (in force from 01.01.2007; amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall maintain a computerized system of exchange of information with the veterinary services of the Member States for veterinary certificates and other documents issued.

Section V.
Veterinary medical checks in trade with raw materials and foods of animal origin with the Member States of the European Union

Art. 76. (In force from January 1, 2007) (1) The raw materials and the foods of animal origin, intended for trade between the Republic of Bulgaria and the Member States, shall be checked according to the rules under this Section.

(2) For trade shall be offered raw materials and foods of animal origin, which :

1. have been produced according to the requirements under this Act, the Foodstuffs Act, the regulating acts, issued for their application and the decisions of the European Union, concerning the Republic of Bulgaria;
2. (suppl. - SG 14/16, in force from 19.02.2016) are to be accompanied to the final consignee

by certificates, invoices and/or other documents, including accounting related, relevant to the consignment;

(3) In the establishments, where the raw materials and foods of animal origin have originated, good manufacturing practices (GMP) and a system of hazard analysis and critical control items (HACCP) of the raw materials and the foods must be implemented.

(4) (amend. – SG 08/11, in force from 25.01.2011) The Headquarters of BFSA shall carry out control on the activity of the veterinaries by performing periodical checks in the establishments, wherein the raw materials and foods have originated, for complying with the requirements under para 2, item 1.

Art. 77. (1) Where by one and the same transport vehicle at one and the same time, raw materials and foods of animal origin intended for several consignees are to be transported, the raw materials and the foods shall be detached in as many separate consignments, as the number of the consignees is.

(2) Each consignment under para 1 must be accompanied by a separate certificate and/or other documents, indicated in the ordinances under Art. 59.

(3) (In force from January 1, 2007) Where the raw materials and the foods of animal origin are intended for exporting to a third country, the consignment shall remain under customs supervision till the departure of the territory of the European Union.

Art. 78. (In force from January 1 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall inform immediately the European Commission and the Member States, when in the Republic of Bulgaria an import under special conditions of raw materials and foods of animal origin from third countries is being carried out.

(2) When in the Republic of Bulgaria an import under special conditions has been carried out, the veterinaries shall permit the dispatch of the imported raw materials and foods of animal origin on the territory of another Member State only in the case where the same special conditions have been introduced, under which the import in the Republic of Bulgaria has been carried out.

(3) When through the territory of the Republic of Bulgaria raw materials and foods of animal origin, intended for another Member State are transit passing and are being imported under special conditions, the border veterinaries shall perform only a check of the documents, accompanying the consignment.

Art. 79. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) When from the Republic of Bulgaria a consignment is being dispatched to another Member State, the BFSA shall carry out checks and shall guarantee to the competent authorities of the Member State, that the consignment is meeting the veterinary medical requirements of production, transportation and placing on the market of the raw materials and the foods of animal origin.

(2) The checks under para 1 of raw materials and foods of animal origin for which requirements of the European Union exist, shall be carried out in one and the same manner, irrespectively whether these raw materials and foods are intended for trade in the European Union or for trade on the national market.

(3) Raw materials and foods of animal origin, for which no requirements of the European Union exist, may be dispatched on the territory of another Member State, if they meet the requirements for production and placing on the market of the Republic of Bulgaria and of the Member State, for which they are intended.

(4) (amend. – SG 08/11, in force from 25.01.2011) When carrying out the checks under para 1,

the BFSA shall undertake the respective administrative, administrative penalty and other legal measures, when detecting, that:

1. the requirements under this Section are not being met;

2. the certificates and/or other documents issued do not correspond to the actual state of the raw materials and the foods of animal origin;

3. on the raw materials and the foods of animal origin, which do not comply with the requirements under para 1, a health or identification marking has been placed.

Art. 80. (In force from January 1, 2007) When in the Republic Bulgaria consignments of raw materials and foods of animal origin from other Member State arrive, the veterinaries shall perform on – spot checks at the place of delivery of the consignments for compliance with the requirements under art. 76-78 in one and the same manner as for raw materials and foods of animal origin produced in the Republic of Bulgaria.

Art. 81. (In force from January 1, 2007) During the transportation of consignments of raw materials and foods of animal origin, intended for the Republic Bulgaria or which are transit passing, the veterinaries shall perform checks of the consignments and of the means of transport, when there is a suspicion, that the veterinary medical requirements have not been met.

Art. 82. (In force from January 1, 2007) (1) When the raw materials and the foods are originating from another Member State and are subject to veterinary control, the veterinaries shall permit the introduction in the establishment only of those, which are meeting the requirements for health marking and are accompanied by certificates and/or other documents.

(2) Where for the raw materials and the foods no veterinary medical requirements of the European Union exist, the veterinaries shall allow them in the establishment only if they are accompanied by a veterinary certificate conformed to a specimen.

Art. 83. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) Individuals and corporate bodies, that are receiving consignments of raw materials and food of animal origin from another Member States, intended for placing on the market and trade or that by profession distribute such consignments, shall be registered in the RFSD, on the territory of which the establishment is located.

(2) (amend. – SG 08/11, in force from 25.01.2011) The persons under para 1 shall make an application conformed to a specimen to the director of the RFSD.

(3) The register under para 1 shall contain:

1. name, address of management and headquarters of the applicant;

2. veterinary registration number of the establishment;

3. number and date of the certificate of registration ;

4. number and date of the act of deletion of the registration;

5. changes of the circumstances entered.

Art. 84. (In force from January 1, 2007) When carrying out the activity the persons under Art. 83, para 1:

1. shall keep a daily register, where the data from the documents, accompanying the

consignments is entered;

2. (amend. – SG 08/11, in force from 25.01.2011) in the cases under art. 82 shall immediately notify RFSD of the arrival of such consignments, with the purpose of carrying out of veterinary medical control;

3. shall keep for at least six months from the date of delivery, the certificates or the documents, that have accompanied the consignment and shall present them to the veterinaries upon request.

Art. 85. (amend. – SG 08/11, in force from 25.01.2011) Persons, who by profession distribute consignments of raw materials and foods of animal origin from another Member State, shall be obliged before the distribution of the consignments to check the health marking and the accompanying documents, and at a non-compliance to inform immediately the respective RFSD.

Art. 86. (amend. – SG 08/11, in force from 25.01.2011) Persons, who are receiving consignments of raw materials and foods of animal origin from another Member State in the establishment, that is not under permanent veterinary control, shall be obliged before the placing of the consignments on the market to check the health or identification marking and the accompanying documents, and upon detecting of a non-compliance to inform immediately the respective RFSD.

Art. 87. (In force from January 1, 2007) When the consignments of raw materials and foods of animal origin from another Member State are intended for consignees, other than those under art. 85 and art. 86, as well as in the cases where the consignment is unloaded partially during its transportation, each part of the consignment shall be accompanied by an original certificate.

Art. 88. (In force from January 1, 2007; amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out unexpected checks on implementation of the obligations under art. 85 и art. 86.

Art. 89. Where the raw materials and the foods originate from an establishment in a Member State, for which no veterinary medical requirements of the European Union exist, the veterinary medical requirements, provided for in the Bulgarian legislation shall be applied.

Art. 90. (In force from January 1, 2007) (1) The veterinary shall order a destruction of the consignment or its use after processing in such a way, that shall guarantee its safety, where at a check, carried out on the place of receiving of the consignment, or during its transportation through the country has been detected:

1. a presence of a zoonose, other disease, or other reason, representing a danger to the human or animal health;

2. that the raw materials or the foods of animal origin are coming from a region with a detected contagious disease, which is subjected to obligatory notification and registration.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall notify the competent authorities of the other Member States and the European Commission of the findings under para 1, the measures undertaken and the reason for their imposing.

Art. 91. (In force from January 1, 2007) (1) Where at a check, carried out on the place of receiving of the consignment or during its transportation through the territory of the Republic of Bulgaria, the veterinary has found, that the raw materials and the foods of animal origin do not meet the veterinary medical requirements of the European Union, and when such are missing – are violated the requirements of the Bulgarian legislation, and if there is no danger to the human or to the animal health, he shall propose in writing to the consignor or to his representative to choose one of the following possibilities:

1. destruction of the consignment;

2. use of the consignment for other purposes;

3. return of the consignment, if a permission is received by the competent authorities of the country of origin.

(2) The consignor or his representative shall notify in writing the veterinary in seven days period from receiving of the proposal for the possibility selected under para 1.

Art. 92. (In force from January 1, 2007) (1) When the veterinary has found, that the certificate and/or the other documents, which are accompanying the consignment contain discrepancies, he shall fix a term to the consignor or his representative for their adjustment not longer than 14 days.

(2) When in the fixed period the discrepancies are not adjusted, and the veterinary concludes that there is no danger for the human or animal health, he shall propose in writing to the consignor or to his representative to choose one of the possibilities under art. 91, para 1.

Art. 93. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) In the cases under art. 91, para 1 and art. 92, para 2, the BFSA shall notify in writing the competent authorities of the Member State of origin for the measures undertaken.

(2) (amend. – SG 08/11, in force from 25.01.2011) When the BFSA assesses, that the measures undertaken by the competent authorities of the Member State of origin are ineffective, it shall jointly with these authorities take a decision for changing of the measures, and where necessary - for carrying out checks on the place of origin.

(3) (amend. – SG 08/11, in force from 25.01.2011) Where in the cases under art. 90 and art. 91, notwithstanding the measures undertaken by the authorities of the country of origin, repeated breaches are being found, the BFSA shall inform the European Commission and the competent authorities of the other Member States.

Art. 94. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall notify in writing the consignor or his representative and the competent authorities of the Member State of origin about the measures undertaken under art. 90, para 1 and art. 91, para 1 and the reasons for their application and shall specify the rules for appeal under the Bulgarian legislation.

(2) (amend. – SG 08/11, in force from 25.01.2011) When the consignor or his representative and the competent authorities of the Member State of origin do not agree with the decision of the BFSA and by consent of the parties at issue within a period of one month from the issuing of the decision, shall bring the case for decision to the European Commission.

(3) The decision of the European Commission shall be obligatory to the parties at issue.

Art. 95. (In force from January 1, 2007) The expenditures on returning, storage, usage for other purposes or destroying of the consignment shall be charged to the consignor.

Art. 96. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall inform immediately the Member States and the European Commission upon occurrence of non-contagious diseases or any other reasons, that can represent a danger for the human or animal health.

(2) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para 1, the BFSA shall immediately undertake measures for prophylactics, restrictions and eradication of the diseases, for elimination of the reasons, and where necessary shall undertake other measures.

Art. 97. (In force from January 1, 2007; amend. – SG 08/11, in force from 25.01.2011) Where through the Republic of Bulgaria transit passing of raw materials and foods of animal origin is carried out and upon check under art. 80 a danger to the human or animal health is being detected, the BFSA shall undertake the measures, provided for in the veterinary legislation of the European Union.

Art. 98. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) When the Republic of Bulgaria is a consignee country and upon check of the consignment under art. 80 a danger to the human and animal health is being detected, the BFSA shall immediately inform the European Commission and the Member States.

(2) (amend. – SG 08/11, in force from 25.01.2011) Upon announcing of the decision of the European Commission, the BFSA shall undertake temporary protective measures with regard to the establishments, where the raw materials and foods of animal origin, received are being processed, stored or placed on the market, and in the case of a contagious disease – shall determine restrictive zones, provided for in the Bulgarian legislation.

(3) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall inform immediately the European Commission and the other Member States of the measures undertaken under para 2.

(4) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para 2, the BFSA can request or the European Commission on its own initiative can sent its representatives on the spot for joint examination of the measures undertaken and presentation of an opinion regarding them.

(5) The measures, approved by the European Commission shall be obligatory.

Art. 99. (In force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall inform the European Commission and the Member States about the types of control, which is being carried out on raw materials and foods of animal origin, for which no requirements of the European union exist.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall notify to the European Commission and the Member States information on the requirements, which are being applied in the trade with raw materials and foods under para 1.

Art. 100. (In force from January 1, 2007) (1) Where consignments of raw materials and foods of animal origin, produced in the Member States shall pass through a border inspection veterinary post (BIVP) the official veterinaries shall carry out only a documentary check of the origin of the

consignment.

(2) In the cases of regularly executed deliveries of consignments of raw materials and foods of animal origin, transported directly between two Member States, a documentary check shall not be performed.

Section VI.
Issue of veterinary medical documents for animals, germinal products and raw materials and foods of animal origin

Art. 101. (1) The veterinary medical documents, by which the compliance with the veterinary medical requirements for movement, transportation, exchange, trade, exportation or placing on the market of animals, germinal products, raw materials and foods of animal origin is being certified, shall be issued by official veterinaries.

(2) The official veterinaries shall:

1. not have an interest, arising doubt in their impartiality with regard to the animals, raw materials and the foods of animal origin upon issuing of the veterinary medical documents;

2. know the specificity of each veterinary medical document, which they issue;

3. have the necessary knowledge on the animal health protection, the veterinary-sanitary control and the border veterinary medical control;

4. be acquainted with the requirements, procedures and examinations, that are carried out before filling of the veterinary medical documents, and which are required under the Bulgarian veterinary legislation or of the legislation of the consignee-country.

(3) (amend. – SG 08/11, in force from 25.01.2011) The official veterinaries must have passed training, organized by the BFSA for acquiring of the knowledge under para 2, item 3 and 4.

Art. 102. The official veterinaries can issue veterinary documents, based on information, obtained by veterinaries or veterinary technicians, that:

1. meet the requirements under art. 101, para 2, item 3 and item 4;

2. can certify the authenticity of the information supplied through documents issued by them.

Art. 103. (1) When issuing the veterinary medical documents, the official veterinary shall be obliged:

1. not to certify data, for which he does not have knowledge or the authenticity of which he can not ascertain;

2. not to sign:

a) unfilled or partially filled forms;

b) documents of animals, germinal products, raw materials or foods of animal origin, which have not been inspected by him or the inspection has not been carried out under his control.

(2) When the official veterinary shall issue veterinary medical document, based on another document, he shall be obliged to get acquainted with its content before its signing.

Art. 104. (amend. – SG 08/11, in force from 25.01.2011) The official veterinary may issue a veterinary medical document based on data, which he has obtained from monitoring programs, good production practices and trade in foods, procedures, based on systems for self-control of raw materials and foods of animal origin and/or from a system for epizootic surveillance, approved by the BFSA.

Art. 105. Before issuing of certificates and other documents of movement or transportation of animals and germinal products on the territory of the European Union, the official veterinaries shall carry out the checks under art. 67, para 2.

Art. 106. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall establish and maintain a system of traceability and control of the issued veterinary medical documents, based on:

1. the identification number of the document;

2. (amend. – SG 08/11, in force from 25.01.2011) the signature of the veterinary, his personal stamp and the stamp of the respective RFSD.

(2) (amend. – SG 08/11, in force from 25.01.2011) A copy of each veterinary medical document shall be kept in the respective RFSD for a period of 3 years from the date of its issuing.

Art. 107. (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out checks of the issued veterinary medical documents for compliance with the requirements, related to their issuing.

Section VII.
Funding of activities for covering epizootic risks

Art. 108. (1) (amend. – SG 15/13, in force from 01.01.2014, amend. – SG 58/17, in force from 18.07.2017) The resources for covering of the expenses, related to epizootic risks, shall annually be provided from the budget of the Ministry of Agriculture, Foods and Forestry.

(2) The resources under para 1 shall be spent on:

1. (amend. - SG 14/16, in force from 19.02.2016) compensation of the owners of animals, in the cases under Art. 47, para 1;

2. (amend. - SG 14/16, in force from 19.02.2016) equipment of laboratories for diagnostics of the contagious diseases under Art. 47, para 1;

3. elaboration and implementation of national programs for prophylactics, control and eradication of the contagious diseases under Art. 47, para 1;

4. (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) application of the measures as per the program under Art. 118, para 1;

5. (amend. - SG 14/16, in force from 19.02.2016) application of the measures of the program for prevention, supervision, control and eradication of animal diseases and zoonoses;

6. (amend. – SG 7/13) maintenance and development of the Integrated information system under Art. 51, para 3;

7. application of the measures under Art. 117, para 1, item 11;

8. (suppl. - SG 14/16, in force from 19.02.2016) storage and processing of animal by-products under the control and eradication of the diseases under Art. 47, para 1.

Art. 109. The Council of Ministers shall adopt an ordinance on the conditions and order for spending the funds under Art. 108, Para 1.

Section VIII.
Financing of the veterinary medical checks and inspections

Art. 110. (revoked – SG 08/11, in force from 25.01.2011)

Art. 111. (revoked – SG 08/11, in force from 25.01.2011)

Art. 112. (In force from January 1, 2007; revoked – SG 08/11, in force from 25.01.2011)

Art. 113. (revoked – SG 08/11, in force from 25.01.2011)

Art. 114. (revoked – SG 08/11, in force from 25.01.2011)

Section IX.
Cooperation between the Republic of Bulgaria and the Member States in the veterinary - medical field

Art. 115. (1) The NVS shall cooperate with the veterinary services of the Member States and the European Commission upon implementation of its activity under this Act.

(2) The NVS shall assist the representatives of the European Commission upon execution of checks in the Republic of Bulgaria.

Art. 116. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The terms and the rules of the cooperation under art. 117, para 1 shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Chapter six.
CONTROL OF THE HEALTH PROTECTION OF THE ANIMALS

Section I.
Measures of control on the animal health protection

Art. 117. (1) (amend. – SG 08/11, in force from 25.01.2011) When carrying out control of the animal health protection, the BFSA shall apply the following measures of prophylactics, limitation and eradication of the animal diseases:

1. clinical checks, diagnostic examinations and epizootic investigations;
2. laboratory examinations;
3. immune-prophylaxis and chemoprophylaxis;
4. chemotherapy and immunotherapy;
5. quarantine;
6. isolation;
7. ban;

8. eradication of animals and germinal products, raw materials and foods of animal origin, feed raw materials, feeds additives and finished feeding stuffs; and inventory, that can not be disinfected;

9. waste disposal or processing of animal by-products;

10. diagnostic slaughter;

11. sanitary slaughter;

12. disinfection, insect control , pest control and devastation;

13. establishing of protected zones for control of the spreading of diseases on animals;

14. sanitary shooting of wild animals.

(2) (new - SG 14/16, in force from 19.02.2016) The Executive Director of BFSA shall determine with an order teams to confirm or reject the suspicion of an outbreak of diseases, for which there is a risk of rapid and mass spread or which lead to causing significant economic losses. Teams shall operate if there is anything suspicious.

(3) (new - SG 14/16, in force from 19.02.2016) The requirements towards the performance of the teams under par. 2 shall be determined by an instruction of the Executive Director of the BFSA

(4) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, former par. 2 - SG 14/16, in force from 19.02.2016, amend. – SG 58/17, in force from 18.07.2017) The terms and the rules for application of the measures on the different types of diseases shall be determined by ordinances of the Minister of Agriculture, Foods and Forestry.

Art. 118. (1) (amend. – SG 14/16, in force from 19.02.2016) (1) The Bulgarian Food Safety Agency shall draw up a program for prevention, supervision, control and eradication of animal diseases and zoonoses.

(2) (in force from 01.01.2018, amend. – SG 58/17, in force from 18.07.2017) The program as per par. 1 shall cover a period of three years, to be developed and submitted for approval by the Minister of Agriculture, Foods and Forestry until 31 July of the year, preceding the period, for which the program shall apply.

(3) (in force from 01.01.2018, amend. – SG 58/17, in force from 18.07.2017) The program as per par. 1 shall be approved by the Council of Ministers following a proposal by the Minister of Agriculture, Foods and Forestry until 31 October in the year of its preparation, and it shall contain:

1. a list of diseases, against which the BFSA carries out measures for prevention, supervision, control and eradication of animal diseases and zoonoses;

2. the species and the number of animals, for which the measures, foreseen in it, shall be applied;

3. the types of measures under item 1, the schemes for their implementation and deadlines for their implementation;

4. the necessary funds for its implementation.

(4) (Amend. – SG 17/18, in force from 23.02.2018) The program under Para. 1 shall be published on the website of the Bulgarian Food Safety Agency.

(5) The owners, respectively users of the livestock sites, are obliged to establish an organization and assist veterinarians to implement measures under the program on par. 1.

(6) If any of the measures under the program on par. 1 is not fulfilled due to violation of par. 5, the Director of the RDFS shall notify in writing the respective regional directorate of the Agriculture State Fund within 7 days of the found violation.

(7) State and local authorities are obliged to contribute according to their competence for the implementation of the measures under the program on par. 1.

Art. 119. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, revoked - SG 14/16, in force from 19.02.2016)

Art. 120. (amend. – SG 7/13, revoked - SG 14/16, in force from 19.02.2016)

Art. 121. (amend. - SG 14/16, in force from 19.02.2016) The program under Art. 118, para. 1, if necessary, may be amended and supplemented pursuant to its approval, indicating the additional funds for its implementation.

Art. 122. (revoked – SG 7/13)

Art. 123. (revoked - SG 14/16, in force from 19.02.2016)

Art. 124. The contagious diseases of the animals, detected in the country, shall be subjected to an obligatory registration and notification under the procedures, stipulated in the ordinance under art. 50, para 3.

Art. 125. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) A Commission on zoonoses shall be established, as permanently acting consultative body at the Minister of Agriculture, Foods and Forestry and the Minister of Health, for coordination of the application of the measures upon the execution of the epizootic and epidemiological control.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry and the Minister of Health shall approve the statutes of work of the commission and shall appoint its members by a joint order.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry and the Minister of Health shall issue joint ordinances for prophylactics, control and eradication of the zoonoses.

Art. 126. (1) (amend. – SG 08/11, in force from 25.01.2011) In the case of an occurrence of a contagious disease, the executive director of the BFSA shall issue an order, wherein the measures on restriction and eradication of the disease shall be indicated.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) In the cases of particularly dangerous contagious diseases, including the diseases under art. 47, para 1, which spreading may cause considerable economic damages, the measures under para 1 shall be introduced over a part or throughout the territory of the country by an order of the Minister of Agriculture, Foods and Forestry upon a proposal by the executive director of the BFSA, in coordination with the Minister of Interior.

(3) (amend. – SG 08/11, in force from 25.01.2011) Upon occurrence of diseases, for which there is no danger of fast and mass spreading and causing of considerable economic damages the order under para 1 shall be issued by a director of the respective RFSD.

(4) (amend. – SG 08/11, in force from 25.01.2011) The orders under para 1 and 2 shall be forwarded to the directors of RFSD and the respective regional governors.

(5) (New - SG 17/18, in force from 23.02.2018) The measures imposed under Para. 1 shall be revoked by an order of the competent authority when the need to apply them is no longer present.

Art. 127. (1) For the purposes of organization, coordination and financial securing of the measures for prophylactics, control and eradication of specifically contagious deceases, including the deceases under art. 47, para 1, which spread could cause significant economic losses, a Central Epizootic Council shall be established at the Council of Ministers.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) The Council shall be chaired by Deputy Prime Minister, deputy chairman shall be the Minister of Agriculture, Foods and Forestry, and the secretary shall be the Executive director of BFSA.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 7/13; amend. – SG, 14/2015, amend. – SG 58/17, in force from 18.07.2017) Members of the Council shall include representatives of the Ministry of Interior, Ministry of Defense, Ministry of Finance, Ministry of Health, Ministry of Transport, Information Technology and Communications, Ministry of Environment and Waters, Ministry of Economy and the Ministry of Agriculture, Foods and Forestry.

(4) The Prime-minister shall approve the rules for the work of the Council.

Art. 128. (1) To the regional governors and the mayors of municipalities constantly acting epizootic commissions for application of the measures on animal health protection shall be established.

(2) The regional governor, respectively the mayor of the municipality shall determine by an order the list of the names of the members of the commission and the rules for its work.

Art. 129. (1) The control of health protection shall be carried out in the following establishments with epizootic importance:

1. animal breeding sites;
2. establishments for processing of animal by-products;
3. waste collection items;
4. (amend. - SG 14/16, in force from 19.02.2016) animal carcass pits;
5. centers of production and storage of germinal products;
6. establishments for production, trade and storage of feed raw materials, feed additives, premixes and finished feeding stuffs; units of trade and use of VMP, products, used in the veterinary medicine;
7. pastures and watering-places;
8. markets and sites, where exhibitions and competitions of animals are being carried out;
9. transport means, by which animals, animal by-products and products derived from them, feed raw materials, feed additives and finished feeding stuffs are being transported;
10. places, where wild animals are being grown;
11. units for production, processing and storage of raw materials and foods of animal origin;
12. (new – SG 7/13) sites for feeding up of carrion birds.

(2) The control on health protection shall also be carried out on the activity of the veterinaries, who have been registered for execution of a veterinary practice.

Art. 130. The health control shall be carried out through:

1. veterinary medical checks of the establishments under art. 129 and of the documentation therein;
2. clinical examinations, killing and autopsy of animals with a diagnostic purpose;
3. testing and sending of samples for laboratory examinations;
4. issuing of veterinary medical documents;
5. imposing of measures of prophylactics, limitation and eradication of the animal diseases and notifying of the interested physical and corporate bodies;
6. imposing of compulsory administrative measures;
7. conducting of epizootic study for detection of the reasons for the occurrence of the disease.

Art. 131. (1) When upon carrying out checks at the establishments under art. 129, the control authorities identify breaches, depending on their type and severity, they shall undertake one or several of the following measures:

1. shall give binding prescriptions, wherein deadlines for the elimination of the breaches shall be fixed;

2. shall impose bans;

3. shall order an eradication or a redirection for a thermal or a chemical re-processing of raw materials and foods of animal origin, animal by-products and products, derived from them, feed raw materials, feed additives and finished feeding stuffs.

(2) The measures under para 1 shall be imposed, as follows:

1. under item 1 - by a prescription;

2. under item 2 и 3 - by an order.

(3) A copy of the enactments under para 2 shall be handed to the owner of the establishment or to his representative.

(4) In a three-days period after expiration of the deadline for the elimination of the breaches, indicated in the prescriptions, the veterinary, who had issued it, shall perform a check and in case the breaches have been eliminated, shall reflect this in the prescription by endorsing a date, signature and seal.

(5) Where the breaches, indicated in the order under para 2, item 2 have been eliminated before the expiration of the determined time limit, the owner or the beneficiary of the establishment shall notify the veterinary, who in a period of three days shall carry out a check, and in case the breaches have been eliminated shall repeal the ban.

(6) Upon implementation of the order under para 1, item 3, the veterinary shall note this in the order, entering a date, signature and seal.

Section II.
Obligations of the local government authorities, the individuals and the corporate bodies

Art. 132. (amend. – SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) The owners, respectively users of livestock sites with farm animals shall:

1. provide veterinary medicine servicing of animals, bread by them, by concluding contracts under Art. 137a, respectively Art. 137b;

2. comply with the requirements for human treatment of animals;

3. comply with the veterinary medicine requirements for breeding, movement and transportation of animals;

4. within three days notify in writing the veterinarian, servicing the animal-breeding site, about the new born or purchased animals of breeds, subject to identification:

5. immediately notify in writing of any dead animals the veterinarian, servicing the animal-breeding site, the mayor of the residential place and the facility for safe disposal of animal by-products, servicing the respective territory;

6. within 24 hours prior to transportation, change of ownership or slaughtering of animals of breeds, subject to identification, meant for personal consumption, notify in writing the veterinarian, servicing the animal-breeding site;

7. within three days after the birth of animals of breeds, subject to identification, notify in writing the veterinarian, servicing the animal breeding site:

a) to carry out official identification of the newly born animals and to make a record of the

identification data in the Integrated information system of BFSA, or

b) (amend. – SG 99/13) about the official identification of the newly born animals carried out by presenting the identification data in order to be entered in the Integrated information system of BHSA;

8. maintain a register of the animals in the animal breeding site, where to register the newly born, slaughtered, dead, sold and acquired animals; the register shall be kept for a period of minimum three years after the last record;

9. sign and keep the passport of bovine and solid-hoofed animals and shall submit them to the monitoring bodies upon request;

10. (amend. - SG 14/16, in force from 19.02.2016) be responsible for the official identification and cooperate for the execution of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses;

11. (amend. - SG 14/16, in force from 19.02.2016) not have the right to move and trade in animals, which are not identified and for which the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses, and also in raw materials and foods, produced from such animals;

12. submit by a protocol issued by the veterinarian, servicing the animal breeding site:

a) the official identification means and the passport of the slaughtered for personal consumption bovine and solid-hoofed animals;

b) (amend. - SG 14/16, in force from 19.02.2016) the resources for official identification which have been damaged, for scrapping and which are available at the owner, respectively user of the live stock sites at the time of cessation of its activities, to be destroyed and the fact reflected in the Integrated Information System of the BFSA;

c) the official identification means of the slaughtered for personal consumption swine, ovine and caprine;

13. shall keep a record book in a standard form, wherein the veterinarian, servicing the animal-breeding site shall register the carried out medical preventive activities, and also the date of provision of VMP, description of VMP; applied quantities; batch number and withdrawal term of VMP; name and address of the supplier, identification number of the treated animal; the record book shall be kept for 5 years from the last record, including in cases where the activity on the site is terminated prior to the expiration of this term;

14. keep for a period of minimum three years from the date of issue of the documents for movement of animals;

15. (amend. - SG 14/16, in force from 19.02.2016) give, under Art. 259, para. 1 or 2, to a site the dead animals, their passports and the animal by-products; in cases where dead animals are disposed of outside a site as per Art. 259, para. 1, shall submit their passports to the respective official veterinarian, for which a protocol shall be drawn and signed;

16. keep the withdrawal term, fixed for the VMP and/or medicinal fodders, when launching on the market raw materials and food, produced from treated productive animals;

17. comply with the dozes and duration of treatment of animals with medicinal fodder prescribed in a veterinarian prescription;

18. provide permanent access to the animal-breeding site to the monitoring bodies of BFSA and other competent bodies;

19. (amend. - SG 14/16, in force from 19.02.2016) not let to the site animals, which are not identified under Art. 51, to which the measures from the program for prevention, supervision, control and eradication of animal diseases and zoonoses have not been applied;

20. shall follow the prescriptions of the veterinarians, relevant to the application of the measures for prophylactics, limitation and eradication of animal diseases;

21. carry out in an annual basis in the period from 1 to 20 October inventory taking of the

animals on the site and shall submit to the official veterinarian, responsible for the respective municipality, a declaration in a standard form, approved by the Managing Director of BFSA;

22. maintain and keep a list of employees, servicing the site, registered subject to compliance with the provision of Art. 137;

23. comply with the requirements of Attachment III to Regulation (EC) No. 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.

24. (new - SG 14/16, in force from 19.02.2016) immediately notify the veterinarian, servicing the livestock site, and the official veterinarian for animal health, who is responsible for the respective municipality, for deteriorating health of animals in the facility.

(2) (amend. – SG 99/13, suppl. - SG 14/16, in force from 19.02.2016) The information under par. 1, items 4, 5, 7, 8 and 13, and Art. 39, para. 2, item 14 shall be recorded by the veterinarian servicing the animal breeding site, in the Integrated information system of BFSA within 7 days after the date of notification under par. 1 of the event.

(3) The persons referred to in par. 1, shall evidence the ownership on big bovines, solid-hoofed animals, small bovines and swine:

1. for newly born:

a) (amend. - SG 14/16, in force from 19.02.2016) big bovines - with passport under Regulation (EC) № 1760/2000 by an official veterinarian;

b) (new - SG 14/16, in force from 19.02.2016) whole-hoofed animals - with passport under Regulation (EU) 2015/262; where the issuing authority is not the BFSA, the passport shall be certified by an official veterinarian; the Executive Director of BFSA shall give and revoke authorization to issue a passport to other issuing authorities under the conditions of Regulation (EU) 2015/262;

c) (former letter "b" - SG 14/16, in force from 19.02.2016) small bovine animals and swine – by a declaration by the owner of the mother animal;

2. for animals acquired in a different way – by a contract for transfer of the ownership or by another document, certifying the acquisition of ownership on animals.

(4) (amend. - SG 14/16, in force from 19.02.2016) The persons under para. 1 shall submit to the official veterinarian, monitoring the site, a copy of the document under par. 3, item 1, letter "c" and item 2 within three days after its issuance.

Art. 133. (amend. – SG 7/13) (1) (New - SG 17/18, in force from 23.02.2018) Municipal councils shall determine with an ordinance the volume of livestock activities and sites for breeding of farm animals within the meaning of the Stock-Breeding Act in the territory of the relevant municipality.

(2) (Previous text of Art. 133 - SG 17/18, in force from 23.02.2018) The mayors and mayoral administrators:

1. shall assist for the implementation of the measures for prophylactics and imitation and eradication of animal diseases;

2. shall divide into districts the pastures and the watering-places depending on the epizootic situation, and if necessary shall prohibit their use;

3. shall undertake measures for not letting animals enter waste landfills;

4. shall organize the collection of dead ownerless animals according to the requirements of Regulation (EC) No. 1069/2009 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 (Animal by-products Regulation) (OJ, L 300/1 of 14 November 2009), herein after referred to as "Regulation (EC) No. 1069/2009";

5. (amend. - SG 14/16, in force from 19.02.2016) shall organize safe disposal of animal by-products out of sites under Art. 259, par. 1 and 2 and installations under Art. 259a in the cases, determined in Ordinance No. 22 of 2006 for the terms and conditions and the procedure for safe disposal

of animal by-products and of derived products thereof, and of specific hazardous materials out of the sites registered in RVMS (SG 21/06);

6. (amend. - SG 14/16, in force from 19.02.2016) shall undertake measures not to allow the use of municipal pasture grounds and drinking pools by animals, which have not been identified and to which the measures of the program for prevention, supervision, control and eradication of animal diseases and zoonoses have not been applied;

7. shall undertake measures not to allow free movement of animals in the streets of residential places;

8. shall fix the route of movement of animal flocks in the roads in residential places.

9. (new - SG 17/18, in force from 23.02.2018) shall exercise control over observance of the ordinance under Para. 1.

Art. 134. (1) (amend. – SG 08/11, in force from 25.01.2011) The physical and corporate bodies that organize exhibitions and competitions shall notify in writing the director of the respective RFSD, indicating the place and the time of the activity and of the species of the animals, that shall take part.

(2) The notification under para 1 shall be submitted at least seven days before the date of carrying out the activity.

(3) (amend. – SG 08/11, in force from 25.01.2011) The director of RFSD, by an order, shall determine a veterinary for carrying out of control on the health status of the animals that are to take part in the exhibition or the competition.

(4) (amend. – SG 08/11, in force from 25.01.2011) In cases of adverse epizootic conditions the director of RFSD shall notify the persons under Para 1 in writing for the postponement of the exhibition or the competition.

Art. 135. (1) (amend. – SG 7/13) The projects for construction or reconstruction of animal-breeding site shall be assessed under the rules and procedures of the Spatial Development Act.

(2) (amend. – SG 7/13) The assessment of the projects under para 1 shall be carried out in compliance with the ordinance under art. 137, para 10.

(3) (amend. – SG 08/11, in force from 25.01.2011) Representatives of RFSD shall take part in the list of the experts on the spatial planning when assessing the projects under para 1.

Art. 136. (1) The putting into operation of the animal-breeding sites shall be carried out under the order and the conditions of the Spatial Development Act.

(2) (amend. – SG 08/11, in force from 25.01.2011) When the site shall undergo an acceptance by a state accepting commission, a representative of the respective RFSD shall be included in its member list.

(3) (amend. – SG 08/11, in force from 25.01.2011) When the site shall not undergo an approval by a state accepting commission, its putting into exploitation shall be carried out after an opinion by the respective RFSD is being provided.

Art. 137. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) The owners or users of animal-breeding sites shall submit an application for registration, conformed to a specimen to the director of the respective RFSD, which specifies the number and date of issue of the document for putting into operation of the site, when required by the Spatial Development Act. The application shall be filed personally, by proxy,

electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. copy of a document of ownership or right of use of the site;

2. (revoked – SG 17/18, in force from 23.02.2018)

3. copy of a contract with a veterinarian for prevention, therapy and diagnostics of diseases on animals to be bred on the site;

4. (suppl. - SG 17/18, in force from 23.02.2018) document of a paid fee to an amount determined by the tariff under Art. 14, para 2, when the payment is not made electronically.

(2) (amend. – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within a time period of up to 7 days from the submission of the application, the director of RFSD by an order shall appoint a commission for carrying out of a check for compliance of the sites with the veterinary medical requirements on animal breeding and welfare.

(3) (amend. – SG 08/11, in force from 25.01.2011) The commission shall in a period of 3-days present to the director of the RFSD the opinion with a proposal for a registration or a refusal.

(4) When upon the check it is being found out that the site does not meet the veterinary medical requirements, the commission shall give a written prescription to the applicant, wherein shall fix a deadline for removal of the omissions.

(5) (amend. – SG 08/11, in force from 25.01.2011) When the applicant has removed the omissions before the expiry of the indicated in the prescription deadline, he shall inform in writing the director of RFSD, who within a period of seven-days shall send the commission for a re-check of the site. The commission shall draft a record of the results of the check and shall submit it to the director of RFSD.

(6) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within a period of three-days from the submission of the opinion under para 3 or the record under para 5, the director of RFSD shall enter the animal-breeding site in the register and shall issue a certificate of registration or shall justify the refusal of the registration if the site does not meet the requirements laid down in the ordinance under para 10.

(7) (amend. - SG 30/06, in force from 12.07.2006; suppl. – SG 7/13) The refusal under para 6 shall be communicated and may be appealed according to order of the Administrative procedure code;

(8) The issued certificate shall be permanent.

(9). The register under para 6 shall contain the following:

1. number and date of the certificate issued;

2. the veterinary registration number of the site;

3. (suppl. – SG 7/13) name and permanent address of the owner or user of the site;

4. address/location and type of the site;

5. (suppl. – SG 7/13) capacity of the site, except for the apiaries, for which number of bred honey-bee families is being recorded;

6. type, category and use of the animals in the site;

7. technology of breeding of the animals;

8. number and date of the order for deletion of the registration;

9. changes in the circumstances entered.

(10) (new – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) Veterinary medicinal requirements to the animal-breeding sites shall be determined by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 137a. (new – SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) On an annual basis by 1 November the owners or users of sites, registered in compliance with the provision of Art. 137, shall conclude with registered veterinarians contracts for prevention, therapy and diagnostic of

diseases on animals and for the implementation of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses. The form of the contract in the part related to the implementation of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses shall be approved by the Managing Director of BFSA upon agreement with the BVU.

(2) By 15 November the veterinarian shall prepare a list of the sites to provide services to pursuant to the concluded contracts. The list and a copy of the contracts shall be submitted to the official veterinarian of the respective municipality.

(3) (amend. - SG 14/16, in force from 19.02.2016) In case of termination of the contract, the owner or the user of the animal breeding site shall be obliged within 7 days after its termination to conclude a contract with another veterinarian and to send a copy of the contract in the part related to the implementation of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses, to the official veterinarian of the respective municipality.

(4) Replacement of the veterinarian under par. 1 at the discretion of the owner or the user of the animal breeding site may take place up to two times within a calendar year in January, respectively in June, provided that the owner or the user of the animal breeding site has paid the due amounts under the contract referred to in par. 1 to the veterinarian, having serviced the animal breeding site as to that time.

(5) An owner or a user of an animal breeding site wishing to replace their veterinarian under par. 1, shall notify in writing the Director of the respective RDFS within minimum 7 days prior to the date of conclusion of a contract with another veterinarian.

(6) The Director of RDFS by an order shall appoint a commission which within the term referred to in par. 5 shall review the documentations, related to the veterinarian medicinal servicing of the animal breeding site.

(7) The members of the commission referred to in par. 6 shall include the official veterinarian in charge of health care for animals in the respective municipality, the head of Animals Health Care department in the RFSD and an officer from the same department in charge of servicing of the Integrated information system of BFSA.

(8) The commission of par. 6 shall draw up a protocol, containing findings from the inspection. The protocol shall be made in three copies – one for the RHSD, the veterinarian having serviced the animal breeding site by that time and for the veterinarian with whom a new contract will be concluded.

(9) In the presence of the commission under par. 6 the veterinarian, having serviced the animal breeding site by that time by a protocol shall submit the veterinary medical documentation of the site to the veterinarian with whom a new contract will be concluded.

(10) The Director of the respective RFSD shall make a list of veterinarians, having concluded contracts under par. 1, which shall be sent to the Central Administration of BFSA for publication on the Internet site of BFSA.

Art. 137b. (new – SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) On the sites where animals for personal needs only are being bred, the prevention, therapy and diagnostics of the diseases on animals and the implementation of measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses shall be implemented by registered veterinarians, having concluded a contract with the animals owner.

(2) The provisions of Art. 137a shall apply to the contracts referred to in par. 1.

Art. 137c. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) In case where by 31 October the owners or users of sites, registered under Art. 137, or the owners of animals, kept for personal use only, have not concluded a contract under Art. 137a, respectively Art. 137b, the BVU shall,

in coordination with the director of the RFSD, name a veterinarian, with whom to conclude contracts.

Art. 138. (1) Registration shall be deleted, and the certificate be invalidated:

1. at request of the applicant, that has received the certificate of registration;

2. at serious or regular breaches of veterinary medical requirements.

(2) (new - SG 14/16, in force from 19.02.2016) Upon violations under par. 1, item 2, found in animals, which provide raw materials and food, having caused immediate danger to the health of people or animals, the director of RFSD shall issue an order, which shall include ordering the killing of animals on site and directing the disposal of animal by-products at a disposal site.

(3) (new - SG 14/16, in force from 19.02.2016) Killing shall be carried out in the presence of a commission, appointed by order under par. 2, which members shall include the registered veterinarian, contracted under Art. 137a or 137b.

(4) (new - SG 14/16, in force from 19.02.2016) For carrying out the killing, the commission shall draw a protocol on a form.

(5) (new - SG 14/16, in force from 19.02.2016) The commission under par. 3 shall do the delivering of animal carcasses to a site for the disposal of animal by-products.

(6) (new - SG 14/16, in force from 19.02.2016) The director of the RFSD shall notify in writing the Executive Director of the BFSA within 7 days from the cancellation of the certificate.

(7) (new - SG 14/16, in force from 19.02.2016) The Executive Director of the BFSA shall send written information to the Agriculture State Fund for the cancellation of the certificate.

(8) (amend. - SG 30/06, in force from 12.07.2006, amend. - SG 8/11, in force from 25.01.2011, former para. 2, suppl. - SG 14/16, in force from 19.02.2016) In the cases under par. 1, item 2, the order of the director of the RFSD may be appealed under the Administrative Procedure Code. The appeal shall not stop the execution.

Art. 138a. (new – SG 51/07) (1) The procedures under Art. 137, Para 1 – 8 shall apply also to approval of the organizations and centres for transplantation of embryos, the centres for artificial insemination and the centres for storage of sperm.

(2) The circumstances referred to in Art. 137, Para 9, Items 1 – 4, 8 and 9 shall be entered into the register of the sites under Para 1.

Art. 138b. (new – SG 51/07) (1) (amend. – SG 08/11, in force from 25.01.2011) Procurement and storage of embryos and ova shall be carried out only be teams approved by the BFSA.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) For approval of the teams under Para. 1, the team leader shall submit a standard application form to the Director of the Regional Food Safety Directorate. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. a copy of the diploma for higher veterinary medical education of the head of the team or a document acknowledging the right to exercise veterinary medical profession in the Republic of Bulgaria, if the head is a foreigner;

2. copies of the diplomas for higher or secondary stock farming or veterinary medical education of the members of the team;

3. declarations for training passed by the members of the crew in the field of disease control and procedures for work in sterilized premises;

4. declarations that the members of the team are not deprived of the right to exercise the profession under Item 2;

5. description of the equipment in the laboratory (mobile or stationary) for inspection,

processing and packaging of embryos, including description of the premises of the stationary laboratories;

6. document certifying the right to use of contract/contracts for work of the team in the laboratory under Item 5;

7. copy of a contract with a stationary laboratory for supplying the necessary materials and sterilization of the instruments and equipment, when the activity will be carried out in a mobile laboratory;

8. (suppl. – SG 17/18, in force from 23.02.2018) document for paid fees in amount determined in the Tariff under Art. 14, Para 2, when the payment is not made electronically.

(3) (amend. – SG 08/11, in force from 25.01.2011) The Director of RFSD shall determine in an order a commission for inspection of the supplied documents and for the compliance of the laboratory with the requirements of the ordinance referred to in Art. 54 and Art. 56, Para 2, which shall draw up a protocol.

(4) In case of incompleteness and invalidity of the documents referred to in Para 2 and/or non-compliance of the laboratory with the veterinary medical requirements the Commission shall notify the applying person in writing thereof and shall determine a term for correcting them.

(5) (amend. – SG 08/11, in force from 25.01.2011) Within 20 days from submission of the application or from expiration of the term referred to in Para 4 the Director of RFSD shall enter the team in a register and issue an order of approval according to sample, or shall make a motivated refusal.

(6) The refusal under Para 5 may be appealed by the order of the Administrative Procedures Code.

(7) The register referred to in Para 5 shall contain:

1. number and date of the order of approval;
2. veterinary registration number of the team;
3. names, unified civil number and permanent address of the head and the members of the team;
4. address of the stationary laboratory, where the activity will be carried out;
5. number and date of deletion of the registration;
6. changes in the registered circumstances.

Art. 138c. (new – SG 51/07) The registration under Art. 138 shall be deleted and the order of approval – invalidated in case of:

1. severe or systematic infringements of the veterinary medical requirements;

2. suspension of the activity of the team upon an application by its head;

3. termination of the contract for use with the stationary laboratory, where the activity is carried out.

Art. 138d. (new – SG 51/07) In case of finding infringements of the requirements in the centres of procurement and storage of embryonic products and in the sites referred to in Art. 138a, Para 1 the official veterinary doctors:

1. shall take the measures under Art. 131, Para 1, Items 1 and 2;
2. shall order destruction of the embryonic products.

(2) In case of applying the measures under Para 1 the provisions of Art. 131, Para 2 – 5 shall apply.

Art. 139. (1) Prohibited shall be:

1. (amend. - SG 14/16, in force from 19.02.2016) the breeding, movement or transport of animals, to whom a formal identification has not been carried out, and of animals, to whom the

measures, envisaged in the program for prevention, supervision, control and eradication of animal diseases and zoonoses, have not been fulfilled;

2. (suppl. - SG 14/16, in force from 19.02.2016) the removal or unregulated replacement of individual ear tags and other means of identification and deletion of markers on hives;

3. transportation of animals without a veterinary medical certificate, and for the bovine and the solid-hoofed animals – also without a veterinary medical passport;

3a. (new - SG 14/16, in force from 19.02.2016) the release of animals outside of the livestock site unaccompanied (owner and breeder), unless the animals are located in fenced pastures;

4. the breeding of animals at waste collection items;

5. the feeding of animals with waste from waste collection items;

6. the movement or transportation of sick or contact animals, except for in the cases, where it is under the order of a veterinary ;

7. the nutrition with food scraps of farmed animals, except for animals, bred for skin production;

8. (amend. - SG 14/16, in force from 19.02.2016) the use of communal pastures and water pools by unidentified animals and those not covered by the program for prevention, supervision, control and eradication of animal diseases and zoonoses;

9. the pasture rearing of pigs, except for East-Balkan breed and its hybrids;

10. (amend. – SG 7/13) feeding of agricultural animals with vegetation mass in the meaning of Art. 11, paragraph 1, item "c" of Regulation (EC) No. 1069/2009;

11. the carrying out of veterinary medical treatments on animals by persons, who have no veterinary medical education;

12. the slaughter of sick or the skinning and the autopsy of animals, which have died of rabies or anthrax;

13. the use and application to animals of active substances intended for production of VMP or other substances, that may be used as VMP;

14. the production, import and export of skins of dogs and cats;

15. (new – SG 84/07) rearing of pigs with the purpose of trade at sites, which do not meet the veterinary medicinal requirements;

16. (new – SG 7/13) trading in raw materials and foodstuffs, produced from animals, bred on sites, which are not registered under Art. 51.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The terms and the rule of pasture rearing of pigs of the East Balkan breed and its hybrids shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 139a. (new – SG 84/07; amend. – SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) In case of identified violation under Art. 139, para 1, items 1, 2 and items 4-9, the official veterinarians immediately shall notify in writing the director of the respective RFSD, who shall issue an order on a form to withdraw animals in favor of the state or to kill them on site and direct them for disposal at a disposal facility of animal by-products.

(2) Mortification of animals shall be done by a commission, appointed by the order referred to in par. 1.

(3) The commission of par. 2 shall issue a protocol in a standard form for the carried out mortification.

(4) The commission of par. 2 shall carry out the delivery of the carcasses to animal by-products safe disposal facility.

(5) The order under par. 1 may be appealed following the provisions of the Code of Administrative Procedure. The appealing of the order shall not suspend its execution.

Art. 139b. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) In case of violations of Art. 139, para. 1, items 3 and 3a, found in animals which provide raw materials and food, official veterinarians shall inspect for performed official identification and implementation of measures, envisaged in the program for prevention, supervision, control and eradication of animal diseases and zoonoses, and clinical examination of the animals, and shall immediately notify in writing the director of RFSD who, depending on the results of the inspection and examination, shall:

1. issue an order form for withdrawal of animals in favor of the state, their killing at the site and directing them for disposal at a site or facility for disposal of animal by-products - in the absence of official identification and/or failure to implement the measures, envisaged in the program for prevention, supervision, control and eradication of animal diseases and zoonoses, and/or abnormalities in animal health status; animal killing and their directing for disposal shall be made in accordance with Art. 139A, para. 1-4;

2. issue an order form for withdrawal of animals in favor of the state and directing them for slaughter in a slaughterhouse - in the presence of official identification in implementing the measures, envisaged in the program for prevention, supervision, control and eradication of animal diseases and zoonoses, and no deviations in the health status of the animals.)

(2) In the cases under par. 1, item 2, the director of RFSD shall organize:

1. (amend. - SG 24/19, in force from 01.01.2020) the stay of the animals until sending them to food bank organizations or to providers of social services;

2. notification of the organizations under item 1 presented in the area, within two hours of the issuance of the order under par. 1, item 2;

3. ensuring data continuity of information on the food chain of animals, targeted for slaughter;

4. gratuitous transferring of animals to organization under item 1.

(3) If, after 12 hours of notification under par. 2, item 2, a representative of an organization under par. 2, item 1 has not arrived, the director of the RFSD shall take the actions under Art. 139a.

(4) When it is established that the information under par. 2, item 3 cannot be provided within 24 hours of detention of animals, the director of the RFSD shall take the actions under Art. 139a.

(5) Upon the issuance of an order for withdrawal of animals in favour of the state and their directing for slaughter in a slaughter house, a veterinary certificate for transport of animals shall not be issued.

(6) The order under par. 1 may be appealed under the Administrative Procedure Code. The appeal shall not stop the execution.

Art. 139c. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) For the transfer of animals shall be drawn an acceptance protocol form, signed by a representative of the organization under Art. 139b para. 2 item 1 and of the RFSD.

(2) The organization, to which the animals have been transmitted, is required, within three days of their slaughtering, to inform in writing the director of the RFSD, who issued the order under Art. 139b, para. 1, item 2, when and in which slaughterhouse the slaughtering has taken place and to whom were given the products, provided by the animals and intended for human consumption.

Art. 139d. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) When a violation of Art. 139, para. 1, items 10-16 has been found, depending on its type and severity, the following shall be issued:

1. an act to implement a measure under Art. 131, para. 1 – by the official veterinarian;

2. an instruction to terminate the activities of the livetock site in cases under Art. 139, para. 1, item 15 - by the director of the respective RFSD.

(2) Upon applying the measure under par. 1, item 2, the animals from the livestock site shall be directed for slaughter.

(3) The costs for the slaughter under par. 2 shall be borne by the owner of the animals.

(4) The acts under par. 1 may be appealed under the Administrative Precedure Code. The appeal shall not stop the execution.

Art. 139e. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) Costs for disposal of carcasses of killed animals under Art. 139a, the costs under art. 139b, para. 1, item 1 and par. 2, items 1-3, and disposal costs of animal by-products, derived from the slaughter of the animals, shall be covered by the budget of the Bulgarian Food Safety Agency.

(2) Responsibility for the animals and costs after delivery shall be borne by the organization, to which they have been delivered.

Art. 139f. (New - SG 14/16, in force from 19.02.2016) (1) In the cases under Art. 139b, para. 1, when in connection with an equine animal, injected with electronic transponder within the meaning of Art. 2, letter "n" of Regulation (EU) № 2015/262, director of the respective RFSD shall immediately make a written request to the mayor/deputy mayor of the township to provide accommodation for the animal within 72 hours in a suitable room, and after performing a check in the Integrated information system of the BFSA, shall inform the animal's owner about its whereabouts.

(2) To deliver the animal under par. 1, an acceptance protocol shall be drawn, signed by the owner or by a person, authorized by him, and a representative of the town-hall. The owner or the authorized person shall give a copy of the acceptance protocol to the registered veterinarian, with whom there is a concluded contract under Art. 137a or Art. 137b, who shall introduce him/her to the Integrated Information System of the Food Safety Agency.

(3) If, within the term under par. 1, the owner or the authorized person has not received the animal, the director of the RFSD shall issue an order under Art. 139b, para. 1, item1.

Section III.
Order for indemnification

Art. 140. (1) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA or determined by him officials shall provide by an order for:

1. the eradication of sick, suspicious sick or contact animals;

2. the destruction of germinal products, raw materials and foods of animal origin, animal by-products and products, produced from them, feed raw materials, feed additives and end feeding stuffs and inventory in an epizootic outbreak, that pose a danger to the human and animal health.

(2) The order under para 1, shall be executed after a written notification of the mayor of the municipality or a person appointed by him.

Art. 141. (1) (amend. – SG 08/11, in force from 25.01.2011) The owners of animals shall be compensated with budget funds of the BFSA and under art. 108, para 1 for:

1. (amend. - SG 14/16, in force from 19.02.2016) animals who died of deseases as per Art. 47, para. 1;

2. animals, which have been killed for determining of the diagnosis;

3. infected and contact animals, destroyed purposely upon eradication of the diseases under item 1;

4. animals, treated with immune-biological VMP against the diseases under item 1:

a) animals, which have died as a result of an unpredictable risk;

b) urgent slaughtered animals before expiry of the withdrawal period;

5. (amend. – SG 08/11, in force from 25.01.2011) dead or urgent slaughtered animals after imposing of a ban by the BFSA;

(2) (amend. – SG 08/11, in force from 25.01.2011) The owners of germinal products, raw materials and foods of animal origin, animal by-products and products, derived there from, feed raw materials, feed additives and end feeding stuffs and equipment, destroyed upon eradication of diseases under para 1, item 1 shall be compensated with budget funds of the BFSA and with state budget funds.

Art. 142. (1) Indemnification shall not be paid to owners of animals, who:

1. (amend. - SG 14/16, in force from 19.02.2016) have not provided their animals for identification and implementation of measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses;

2. have violated bans, imposed by the veterinary medical authorities;

3. have violated the veterinary medical requirements upon breeding of the animals.

(2) The breaches under para 1 shall be established by a penalty act, by which a fine or a proprietary sanction at an amount above 100 BGNis being imposed, enforced not later than one year from the eradication of the animals or the subjects under art. 141.

Art. 143. (1) (amend. – SG 08/11, in force from 25.01.2011) The eradication of animals and the subjects under art. 141, para 2 shall be carried out in the presence of a commission, appointed by an order of the Director of the respective RFSD.

(2) (amend. – SG 84/07; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) In the commission under para 1 three officials of the respective RFSD, a representative of the municipality administration shall be included.

(3) (amend. - SG 14/16, in force from 19.02.2016) When pedigree animals and bee families from apiaries, registered under Ordinance № 47 of 11 November, 2003 on production and marketing of elite and pedigree queen-bees and branches (swarms) and the order for keeping a register (prom. SG 103 of 2003; amend. SG 26 of 2008,SG 67 of 2011 and SG 94 of 2012) are destroyed, the commission shall include a representative of the territorial unit of the Executive agency for selection and reproduction in animal breeding.

(4) The commission under para 1, in the presence of the owner, shall draft records conformed to a specimen for the eradication of the animals and/or the subjects under art. 141, para 2.

(5) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The records shall be signed by the commission and shall be stamped with the stamp of RFSD.

(6) (amend. – SG 08/11, in force from 25.01.2011) The records shall be drafted in 4 uniform copies - one for the headquarters of the BFSA, two – for RFSD and one – for the owner.

(7) In the cases, where the carcasses of animals are being transferred to plants for processing of animal by-products the plant shall issue a confirmation document.

(8) The document under para 7 shall contain the following:

1. name /title of the owner of the animals;

2. veterinary registration number of the animal-breeding site;

3. identification number of the animals, that are to be identified;

4. type, number and total weight of the animals of one species.

Art. 144. (1) (amend. - SG 14/16, in force from 19.02.2016) Compensation for animals shall be determined by:

1. the market prices for the month, preceding the occurrence of disease, or

2. (amend. – SG 58/17, in force from 18.07.2017) assessment, including breed affiliation and breeding value, made by the Executive agency for selection and reproduction in animal breeding for animals, which are subject to a breeding program, approved by the Minister of Agriculture, Foods and Forestry or by a competent authority in another Member State.

(2) In cases where products, derived from slaughtered animals, are subject to selling, the proceeds shall be deducted from the compensation amount.

Art. 145. (1) The indemnification for equipment, the total market value of which at the time of the eradication is above 500 BGN, shall be paid after its determining by a licensed valuer, and under this value – at market prices.

(2) (amend. – SG 08/11, in force from 25.01.2011) The fee of the licensed valuer shall be charged to the BFSA.

Art. 146. (amend. - SG 14/16, in force from 19.02.2016) The compensation for germinal products, raw materials and foods of animal origin, animal by-products and products, produced thereof, feed raw materials, feed additives and finished feeding stuffs shall be determined according to the market price per type of animals, provided by the National Statistical Institute for the month, preceding the occurrence of the disease.

Art. 147. (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) For the payment of a compensation the owners within 3 working days from the date of death or destroying of animals, germinal products, raw materials and foods of animal origin, animal by-products and products, derived from them, feed materials, feed additives, premixes, compound and medicated feeding staffs shall submit an application form to the director of the respective RFSD, whereto shall be attached:

1. (amend. – SG 08/11, in force from 25.01.2011) a document, issued by a meat processing and/or milk processing establishment, where to the raw materials of animal origin are directed by RFSD for processing;

2. a veterinary medical passport for the big ruminants and equine animals;

3. document under art. 143, para 7.

(2) To the documents under para 1 officially shall be attached:

1. the documents under art. 143, para 1 and 4;

2. a letter with the result of the laboratory – diagnostic examination;

3. the penalty decree under art. 142, para 2.

(3) (amend. – SG 08/11, in force from 25.01.2011) In the cases, where there have not been attached some of the documents under para 1 or omissions have been found, the director of RFSD in three-days period from the submission of the documents shall notify in writing the applicant and shall fix a deadline for taking away the irregularities.

(4) The notification under para 3 shall be personally given to the applicant against signature or shall be sent by registered mail with a back receipt.

(5) (amend. – SG 08/11, in force from 25.01.2011) When the irregularity is not being removed in the fixed deadline, the director of RFSD shall terminate the procedure of payment of compensation by a motivated order.

(6) (amend. - SG 30/06, in force from 12.07.2006) The order under para 5 shall be subject to appeal according to the Administrative procedure code.

Art. 148. (amend. – SG 08/11, in force from 25.01.2011) On the basis of the documents of art. 147, the director of RFSD:

1. (suppl. - SG 14/16, in force from 19.02.2016) shall draft an enactment for a compensation conformed to a specimen and shall pay the compensation within 30 days from the date of death or their destroying.

2. shall not pronounce decision on pending administrative punishing proceeding for breaches under art. 142;

3. shall refuse the payment of compensation by a motivated order in the cases under art. 142.

Chapter seven.
PROTECTION OF ANIMALS AND ANIMAL WELFARE

Section I.
Requirements of protection of animals and animal welfare

Art. 149. (1) The animals shall be breed and used in a manner complying with their growth and purpose in conformity with their physiological needs and ethological specificities.

(2) Manipulations or surgery interventions, which are causing or may cause substantial pain to the animals, shall be carried out by application of anesthesia.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The minimum requirements of protection and welfare by breeding, using, selling, slaughter and killing of the different animal species of shall be arranged by ordinances of the Minister of Agriculture, Foods and Forestry.

Art. 150. (1) The owners and the persons, taking care of the animals, as well as the managers of the animal breeding sites shall be obliged to:

1. take care of the animals and not to abandon them;

2. provide for each animal, depending on its species, age and bred:

a) habitation place and conditions, consistent with its needs

b) the necessary space and freedom of movement;

c) enough quantity of feed and water;

d) free access to the places of nutrition and drinking;

e) an appropriate micro climate;

f) regular prophylaxis veterinary medical treatment and immediate treatment in case of sickness or injuring ;

g) appropriate feeding and drinking utensils, installed in a such way, that shall not allow their contamination and reducing to a minimum the aggressive competition among the animals;

3. shall undertake all measures for the prevention of the flight of animals.

(2) The persons, taking care of the animals shall check at least once a day their general status.

Art. 151. It shall be prohibited:

1. (suppl. – 92/11) to cause fear, injuring, pain, suffering, distress or death to the animals, except for the cases referred to in Art. 117, Para 1, Items 10, 11 and 12, art. 159, para 3, art. 160, para 2 and 179, para 3 or at self-defense;

2. (amend. – 92/11) using of animals for performances, resulting in pain, hurting, injuring or death of the animal;

3. instigation of animals one against the other;

4. training of animals in a manner, which causes any pain or suffering;

5. putting animals under physical pressures, that have not taken into consideration their anatomic or physiological capabilities;

6. gathering of animals in a way, which is causing them any pain, suffering or injury;

7. breeding of the animals in permanent darkness or permanent tethered;

8. walking on the streets of wild animals for the purposes of show or trade;

9. carrying out of veterinary medical treatments and administration of VMP by persons without the necessary qualification;

10. the application of anesthetic substances or substances that harm the health of the animals, except for the cases where these are medically justified or for treatments in the framework of an allowed experiment;

11. the use of stimulating substances for animals aiming to higher sport results;

12. natural or artificial insemination, that results in or creates a hazard for the health of the animals;

13. intervention in the litter process through application of treating, that are incompatible with the veterinary - medical science and practice;

14. feeding of animals with feeding stuffs, which contain harmful substances, or feeding stuffs, which are nor appropriate to their species, age or health status;

15. accommodation at one place of incompatible species of animals or of animals of the same species, where this can rise aggressiveness;

16. amputation of the tail of big ruminants and solid hoofed;

17. carrying out of the following surgery manipulations without anesthesia:

a) amputation of the tail of lambs, goat kids, pigs, calves and the dogs over eight – months age;

b) amputation of additional fingers of dogs over eight-days age;

c) amputation of horns of calves under eight-weeks age at cauterization or extirpation in a surgical way;

d) amputation of horns of calves of over eight-weeks age;

e) castration of pigs of over two-weeks age;

f) castration of calves of over four –weeks age;

g) castration of lambs and rabbits of over eight-weeks age.

Section II.
Animals, used for experiments

Art. 152. (1) (prev. text of Art. 152 – SG 13/08, in force 31.01.2008) Experiments with animals shall be carried out where it shall not be possible to be applied alternative methods.

(2) (new – SG 13/08, in force 31.01.2008) Experiments with animals shall be carried out with the purpose of:

1. (amend. – SG 08/11, in force from 25.01.2011) development and production of safe medicinal products for the veterinary and human medicine, of food and food supplements and of fodder and fodder supplements;

2. disease diagnostics and trials of new methods for treatment of diseases;

3. research, regulation and modification of physiological functions of people, animals and plants;

4. education in professional gymnasiums and high schools;

5. protection of the environment.

Art. 153. (1) (amend. – SG 08/11, in force from 25.01.2011) Experiments with animals shall be carried out in experimental centers of research institutes, manufacturing establishments, laboratories, secondary and high schools, after a received permission by the executive director of the BFSA.

(2) The experimental centers under para 1 shall be registered in compliance with art. 137.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements for using of animals for experiments and the centers, wherein the experiments with animals shall be carried out, the centers of breeding and/or delivery of experimental animals shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 154. (1) (amend. – SG 08/11, in force from 25.01.2011) To the executive director of the BFSA shall be established a Commission on ethics towards the animals as a permanently operating consultative body.

(2) (amend. – SG 08/11, in force from 25.01.2011) The executive director by an order shall appoint the staff of the commission on a proposal by the relevant authorities and organizations, and shall approve the rules of its work.

Art. 155. (1) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The owners or the managers of registered centers, wherein experiments with animals shall be carried out, shall submit to the executive director of the BFSA an application form conformed to a specimen for issuing of a permission to use animals in experiments. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 08/11, in force from 25.01.2011, revoked – SG 17/18, in force from 23.02.2018)

2. a list of the species and the number of animals, that shall be used and a justification of their choosing, the place and the manner of taking care of the animals after termination of the experiments;

3. a list of the persons, taking part in the conducting of the experiment and a copy of the document of their professional qualification;

4. a copy of the document for the paid fee at the amount, specified in the tariff under art. 14, para 2.

(2) (amend. – SG 08/11, in force from 25.01.2011, suppl. – SG 17/18, in force from 23.02.2018) The executive director of the BFSA by an order shall appoint a commission, that shall check ex officio the registration of the test base and the submitted documents.

(3) Where deficiencies in the submitted documents are found in a 14-days period of their submission the commission shall notify in writing the applicant and shall fix him a period for their correction.

(4) After submission of the necessary documents the commission immediately shall forward them to the Commission on ethics towards the animals.

(5) (amend. – SG 08/11, in force from 25.01.2011) In one-month period from the submission of the application form the Commission on ethics towards the animals shall submit an opinion to the executive director of the BFSA for issuing of permission for carrying out of the experiment or for a refusal.

(6) (amend. – SG 08/11, in force from 25.01.2011) In a seven-days period from the receiving of the opinion the executive director of the BFSA shall issue a permission for the carrying out of the experiment or shall justify the refusal of its issuing.

(7) The permission of using of animals in experiments shall be issued for a period of 5 years.

(8) (amend. - SG 30/06, in force from 12.07.2006) The refusal referred to in para 6 may be appealed under the Administrative procedure code.

(9) (amend. – SG 08/11, in force from 25.01.2011) The owners or the managers of the centers, where the experiments with animals are carried out, shall be obliged to notify on a three–days period the BFSA for any change in the initially indicated circumstances. Upon a change a new permission shall be issued.

Art. 156. (amend. – SG 08/11, in force from 25.01.2011) The issued permissions under art. 155, para 6 shall be entered in a register of the BFSA, that shall contain:

1. name and address of the holder of the permission;
2. type and location of the center;
3. species of the experimental animals;
4. name of the experiment.

Art. 157. (1) (amend. – SG 08/11, in force from 25.01.2011) The executive director of the BFSA by an order shall suspend the issued permission:

1. where it have been found, that the data of the documents submitted is not real ;
2. where there have been found gross or systematic breaches of the Law.

(2) The order under para 1 shall be forwarded to the holder of the permission.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order under para 1 may be appealed under the Administrative procedure code.

Art. 158. Prohibited shall be:

1. using of stray and domestic dogs and cats as experiment animals;
2. the enforcement of secondary and high school students to carry out experiments with animals, where are caused traumas or lasting harms to the animals, if that contradicts their moral or religious convictions, except for the purposes of acquiring particular practical skills.

Section III.
Slaughtering and killing of animals

Art. 159. (1) Slaughter of animals shall be carried out in the quickest manner, after stunning, that shall ensure a full loss of consciousness and sensitivity for the whole period of bleeding.

(2) It shall be prohibited to dismember and handle a carcass of an animal until its full bleeding.

(3) Slaughter shall be permitted of farm animals:

1. that are bred for meat and raw materials production;
2. that are treated for non-contagious diseases, but the medication is of no result or is economically unjustified;
3. for eradication of contagious diseases;
4. for religious rituals of registered religions.

Art. 160. (1) Killing of animals shall be carried out in a manner, that shall not permit causing of any unnecessary pain and suffering.

(2) Killing of animals shall be permitted at:

1. eradication of contagious diseases;

2. pest control;

3. attack on people by an animal and self defense;

4. hunt practicing under the Hunting and Game Protection Act and fishing under the Fisheries and Aquaculture Act.

Section IV.
Transportation of animals

Art. 161. (1) The animals shall be transported under conditions, guaranteeing the health, their physiological and behaviour needs, in specially equipped means of transport.

(2) (amend. – SG 08/11, in force from 25.01.2011) During long transportation of the animals it shall be ensured for them to rest at items, specified by the BFSA.

Art. 162. (1) (amend. – SG 08/11, in force from 25.01.2011) All land transport vehicles, used for long transportation, as well as containers and vessels used for transportation of animals, shall be approved by the BFSA for which a certificate conformed to a specimen shall be issued.

(2) (amend. – SG 08/11, in force from 25.01.2011) The approval certificate shall be issued for a period of 5 years and the information thereof shall be entered by the BFSA in an electronic database in a manner allowing its use by the competent authorities of the Member States.

Art. 163. (amend. – SG 08/11, in force from 25.01.2011) Transportation of animals shall be carried out by carriers who have received a transport license for short or long travelling.

Art. 164. (1) (amend. – SG 08/11, in force from 25.01.2011) Drivers of transport vehicles, in which animals are being transported and persons accompanying animals during transportation could be individuals, who have received a certificate from the director of the RFSD, on which territory the main office of the carrier is situated.

(2) (amend. – SG 08/11, in force from 25.01.2011) The individuals under para 1 shall submit an application form to the director of the RFSD, whereto shall be attached a copy of the course certificate finished on animal protection and welfare during transportation;

(3) (amend. – SG 08/11, in force from 25.01.2011) In a three-days period from the submission of the application form the director of the RFSD shall issue a certificate conformed to a specimen.

Art. 165. (1) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) For receiving of a license for transportation the individuals under art. 163 shall submit to the executive Director of the BFSA an application form conformed to a specimen. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall contain the number and date of issuance of the registration card of the transport vehicle, the certificate of approval

of the transport vehicle, the license to carry out international / domestic freight transport and the certificate of competency under Art. 164, Para. 1 of the driver and companion of the animals. The application shall be accompanied by:

1. (revoked – SG 17/18, in force from 23.02.2018)

2. (revoked – SG 17/18, in force from 23.02.2018)

3. (suppl. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

4. (revoked – SG 17/18, in force from 23.02.2018)

5. plan for urgent actions in cases of a health condition decline of the animals and incidents during transportation;

6. declaration for ensured permanent connection between the carrier and the driver- when the license is issued for long traveling;

7. copy of the document of ownership or of a lease contract for the vehicle;

8. (suppl. – SG 17/18, in force from 23.02.2018) document of paid fee, at the amount specified in the tariff under art. 14, para 2, when the payment is not made electronically.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. and suppl. – SG 17/18, in force from 23.02.2018) In a three-days period from the submission of the application form the executive director of the BFSA by an order shall appoint a commission, that is to carry out an ex-officio check of the declared circumstances and the presented documents under Para. 1, and of the vehicle for compliance with the requirements for the animal protection and welfare during transportation.

(3) (amend. – SG 08/11, in force from 25.01.2011) The commission in a ten-days period shall deliver an opinion to the executive director of the BFSA with a proposal for issuing of a license or a refusal.

(4) (amend. – SG 08/11, in force from 25.01.2011) In a twenty-days period from the submission of the application form the executive director of the BFSA shall issue a certificate for transportation of animals conformed to a specimen or shall refuse motivated its issuing.

(5) (amend. - SG 14/16, in force from 19.02.2016) The license shall be for a period of 5 years and for persons, transporting animals to a determined destination as defined in Art. 6, paragraph 7 of Regulation (EC) № 1/2005 of the Council of 22 December 2004 on the protection of animals during transportation and the operations related to it, and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) № 1255/97, shall be unlimited.

(6) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 4 may be appealed under the Administrative procedure code.

Art. 166. (1) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The BFSA shall maintain on its website a public national electronic register of the issued licenses under art. 165, which shall contain:

1. type, number and date of the issued license;

2. name/address or address of management/main office of the carrier;

3. name/address or address of management/main office of the owner of the vehicle;

4. type, the loading capacity and the registration number of the transporting vehicle;

5. number of the issued approval certificate of the vehicle;

6. number and date of the certificate under art. 164, para 1 of the driver or the person accompanying the animals;

7. the type and the number of animals, that can be transported by the vehicle;

8. date of termination or invalidation of the license;

9. changes of the entered circumstances .

(2) (amend. – SG 08/11, in force from 25.01.2011) The issued license shall be presented at a check of the authorities of the BFSA.

(3) (amend. – SG 08/11, in force from 25.01.2011) The issued license shall be terminated by an order of the executive director of the BFSA:

1. on a request of the carrier;

2. on termination of the activity of the carrier;

3. on change of the ownership or on termination of the lease contract for the vehicle.

(4) (amend. – SG 08/11, in force from 25.01.2011) At systematic or gross breaches of the rules for animal protection and welfare, the executive director of the BFSA shall:

1. temporary suspend the activity of the carrier or the use of the vehicle;

2. invalidate the license;

3. invalidate the approval certificate for the vehicle;

4. temporary prohibit the activity of the driver or the accompanying person;

5. invalidate the certificate under art. 164, para 1 of the driver or the accompanying person.

(5) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; suppl. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The conditions of animal protection and welfare during their transportation shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry, coordinated with the Minister of Transport, Information Technology and Communications.

Art. 167. The drivers of the vehicles, who are transporting animals and the persons, accompanying them, shall be obliged to ensure the quickest possible veterinary medical aid to the animals, that have got sick during the transportation.

Art. 168. The requirements under art. 162 and under art. 166 shall not be applied at transportation:

1. (amend. – SG 84/07) of pets and hunter dogs by their owner with a personal vehicle;

2. of single farm animals for personal needs;

3. up to 65 km;

4. (new – SG 7/13) of race horses in specialized caravans with up to two places.

Art. 169. Prohibited shall be:

1. the transportation of animals in non-registered vehicles and under conditions, causing them pain, injuries and sufferings;

2. during loading, unloading and movement:

a) the animals shall not be hit, pushed and kicked;

b) to press a sensitive body parts of the animal;

c) to squeeze, twist or break the tales of the animals;

d) to be used appliances, that cause pain to the animals;

e) the animals to be moved by mechanical devices, as well as to be lifted or dragged by the head, horns, ears, legs, tail and the fur.

Section V.
Control on observing the requirements on the protection of animals and animal welfare

Art. 170. (1) (amend. – SG 08/11, in force from 25.01.2011) The organizations of protection of the animals and the associations of the animal breeders shall be obliged to assist the BFSA in implementation of the control under art. 7, para 1, item 4.

(2) Representative of an organization of protection of the animals shall have the right to participate at the check, where the signal for a violation of the requirements on protection and welfare of the animals has been forwarded by that organization.

(3) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para 2 the BFSA shall notify the organizations for the time of carrying out the check.

Art. 171. The owners or the managers of zoos and zoo shops and other animal breeding sites and the organizers of activities with the participation of animals shall be obliged to provide for conditions on observing the rules of their protection and welfare.

Section VI.
Pets and dogs for professional, hunting and other purposes (Title amend. – SG 84/07)

Art. 172. (amend. – SG 84/07) The owners of pets shall be obliged:

1. to take measures, that the animals do not soil public places and to clean the place after defecation;

2. to take measures that the animals shall not pose a danger to people or other animals;

3. to take measures of preventing of undesired reproduction of the animals;

4. at their use for reproduction to be considered their physiological, anatomic and behaviour characteristics and not to permit a risk to their health.

Art. 173. The owners of the pet dogs shall be obliged:

1. when taking them out to carry with them the veterinary medical passport and to present it for check to the municipality and veterinary medical authorities;

2. to present the veterinary medical passport when visiting a veterinary; 3. to present the dogs annually for a vaccination against rabies;

4. where breeding them in closed premises shall provide for them an everyday necessary walk;

5. where breeding them permanently tethered in open-air shall provide for them a shelter and a free – movement area.

Art. 174. (1) The owners of the pet dogs, over six–week age, shall present them to a veterinary, who is exercising a veterinary practice for issuing of a passport conformed to a specimen, vaccination and anti-parasitic treatment.

(2) (amend. - SG 14/16, in force from 19.02.2016) At the four – months age or within 7 days period from the acquisition of a dog the owner shall register the dog with a veterinary.

(3) (amend. - SG 14/16, in force from 19.02.2016) When registering the dog, the veterinarian shall put a microchip, corresponding to ISO 11784 standard, and shall enter the data into the Integrated Information System of the Bulgarian Food Safety Agency.

(4) (amend. – SG 08/11, in force from 25.01.2011) The veterinary shall send each month the data of the veterinary medical passport of each registered dog to RFSD and to the respective municipality.

(5) (amend. - SG 14/16, in force from 19.02.2016) The owners of the dogs shall pay the cost of the veterinary medical passport and the placing of the microchip.

Art. 175. (In force from January 1, 2007) (1) For possession of a dog an annual fee shall be paid at an amount specified by the Local Taxes and Fees Act.

(2) Free from fees shall be:

1. (amend. – SG 17/18) the dogs of disabled persons;

2. the service dogs of the budgetary organizations;

3. the dogs, used for experimental purposes;

4. the dogs, used by the Bulgarian Red Cross;

5. the castrated dogs;

6. (amend. - SG 14/16, in force from 19.02.2016) dogs who accompany or guard livestock, bred in a registered livestock site. hunting dogs.

(3) The revenues from the collected fees shall be received in the municipality budget and shall be spent on the measures for reducing the number of the stray dogs.

Art. 176. (1) (amend. – SG 84/07) The owners of the sites, wherein pets are being bred, reared and/or offered for the purpose of trade, of boarding houses, of insulators and shelters for animals shall register them under art. 137 attaching to the application form a certificate of finished training course on animal protection and welfare.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements to the units under para 1 shall be arranged by an ordinance of the Minister of Agriculture and Food.

Art. 177. (1) It shall be prohibited:

1. (amend. – SG 84/07) the carrying out of the following surgery interventions on pets:

a) cutting of the tail;

b) cutting of the ears;

c) cutting-off of the vocal chords;

d) removal of the nails and teeth;

2. (amend. – SG 84/07) breeding and rearing of pets for production of meat and skins;

3. taking out the pet dogs without halter, and the aggressive dogs without muzzle;

4. taking for a walk the pet dogs on open-air kindergarten and places, designated by the municipalities with prohibiting signs.

(2) The interventions under para 1, item 1 shall be permitted as an exception on assessment of a veterinary.

Art. 178. The mayors of municipalities, of the district areas and mayoralties shall organize the control on observing the requirements under art. 172, items 1 and 2, art. 173, item 1 and art. 177, para 1, items 3 and 4.

Section VII.
Euthanasia of animals

Art. 179. (1) Euthanasia of animals shall be carried out with a licensed VMP by a veterinary, who is exercising a veterinary practice.

(2) At an euthanasia the veterinary shall write down in the surgery daily register the reasons of its carrying out and the administered VMITEM

(3) Euthanasia shall be permitted by:

1. incurably sick animals with irreversible pathological changes, causing them pain and sufferings;

2. limitation and eradication of a contagious disease, that poses a hazard to the human or animal health;

3. termination of the experiments with animals, that have led to pathological changes, causing the animals pain and sufferings;

4. animals, the aggressive behaviour of which poses a proven risk to the life and the human or animal health.

Art. 180. (1) The preparation and the carrying out of euthanasia shall be organized in a manner, that reduces to a minimum the stress of the animal.

(2) The euthanasia shall be carried out on a separate premise, which shall not permit to the other animals to watch the process.

(3) The euthanasia shall be carried out with products that are to cause an immediate and full loss of consciousness and pain sensibility, followed by a sure death.

(4) After carrying out of euthanasia the veterinary shall detect the death by reading of a stopped heart activity.

Art. 181. At an euthanasia it shall be prohibited:

1. the independent application of VMP, that are paralyzing the muscles without causing loss of pain sensibility;

2. usage of VMP, that do not result in loss of consciousness.

Section VIII.
Wild animals

Art. 182. (1) Wild animals may be bred outside their natural environment only in zoos, aquariums, terrariums, circuses, farms, volliers and vivariums.

(2) (amend. – SG 08/11, in force from 25.01.2011) The units, where wild animals are bred shall be registered in the respective RFSD under art. 137.

Art. 183. The exotic animals may be bred at home conditions meeting the requirements of animal protection and welfare.

Chapter eight.
BORDER VETERINARY MEDICAL CONTROL

Art. 184. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out border veterinary medical control at import, export and transit of:

1. animals;

2. germinal products;

3. raw materials and foods of animal origin;

4. animal by-products and products, derived there from;

5. specific plant products, feed materials, feed additives, premixes and compound feeding

stuffs;

(2) Subject to a border veterinary medical control shall be also the transport vehicles, wherein transported are the objects under para 1.

Art. 185. (1) The control of the objects under art. 184 shall be carried out through veterinary checks at the Border Inspection Veterinary Points (BIVP).

(2) (amend. – SG 08/11, in force from 25.01.2011) The Border Inspection Veterinary Points shall be approved by the European Commission on a proposal of the executive director of the BFSA, provided that they meet the requirements for:

1. the premises and technical equipment;

2. the personnel, the procedures and the documentation.

(3) The list of the approved BIVP shall be published in State Gazette.

Art. 186. (1) The control of BIVP shall be carried out by official veterinaries.

(2) (amend. – SG 08/11, in force from 25.01.2011) The official veterinary in his activity can be assisted by assistants - veterinary technicians or persons that have graduated training courses, organized by the BFSA.

Art. 187. When implementing their service responsibilities the officials of the Border Inspection Veterinary Control (BIVC) shall wear uniform clothing, identification signs and shall establish their identity by an official card.

Art. 188. (1) The border veterinary medical control of the objects under art. 184, para 1 shall include:

1. documentary check;

2. identity check;

3. physical check;

4. disinfection and insect control of the entering the country transport vehicles.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements to BIVP, the conditions and the order of carrying out of the BIVC shall be arranged by ordinances of the Minister of Agriculture, Foods and Forestry.

Art. 189. (1) (amend. – SG 08/11, in force from 25.01.2011) The breeding animals and those for rearing, imported in the Republic of Bulgaria shall undergo an obligatory quarantine in the quarantine premises registered by the BFSA under art. 137.

(2) Where necessary, during the transport of the animals to the quarantine premises they shall be accompanied by a veterinary, appointed by an order of the director of the respective RFSD.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The conditions and the order of carrying out of quarantine of the animals at importing shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 190. (1) The vehicles entering in the country shall undergo prophylaxis disinfection and insect control at the Border Control Check Point (BCCP) at announced epizootic situation.

(2) (amend. – SG 08/11, in force from 25.01.2011) The disinfection of the vehicles shall be carried out under a scheme, approved by the executive director of the BFSA.

(3) (New - SG 17/18, in force from 23.02.2018) Disinfection and disinsection under Para. 1 of the incoming mobile railway stations shall be carried out at the border checkpoint, following the payment of costs, in service facilities within the meaning of § 1, item 48, letter "a", sub-letter "ee" of the Additional provisions of the Railway Transport Act, owned or managed by a railway infrastructure manager, by a railway undertaking or by other natural or legal persons. The disinfection shall be carried out according to a scheme approved by the Executive Director of the BFSA.

(4) (New - SG 17/18, in force from 23.02.2018) The costs of the service under Para. 3 shall be determined by the operator of the service facility according to the methodology under Art. 35, Para. 3 of the Railway Transport Act, in coordination with the Executive Agency "Railway Administration".

Art. 191. The physical and corporate bodies that are importing, exporting or transiting of the objects under art. 184, para 1:

1. shall transport the consignments to the place for border veterinary medical control and shall present them for veterinary checks;

2. shall transport the consignments in specialized vehicles;

3. shall observe the veterinary medical requirements under art. 56 and art. 61, para 1;

4. shall ensure access of the official veterinaries to the consignments and the accompanying documents;

5. shall execute the orders of the official veterinaries;

6. shall pay fees for importing and transiting at the amount, specified in the tariff under art. 14, para 2.

7. shall observe the imposed bans on importing, exporting and transiting.

8. shall send to BIVP, at least one day before the importing of the consignment, a certificate conformed to a specimen, filled in the respective part.

Art. 192. (In force from October 1 2006) (1) After carrying out the checks under art. 188, para 1, the official veterinary shall permit the importing by filling in the respective part, entering the date, signing and stamping the certificate under art. 191, item 8, after the payment of the fees for carrying out of BIVC, specified in the tariff under art. 14, para 2.

(2) The certificate under para 1 shall accompany the consignments until:

1. they are under customs supervision;

2. (amend. - SG 58/16) they reach the first warehouse or the first establishment – consignee, where the consignments are under customs regime release for free circulation.

(3) Where the consignment is divided into parts, each part shall be accompanied by a separate certificate under para 1.

(4) The Customs authorities at BCCP shall not permit the lifting of the consignment before carrying out of BIVC.

(5) (amend. - SG 58/16) Customs authorities shall authorize the release of goods for the respective customs regime of the consignment according to the certificate under para 1.

Art. 193. (1) Where at the border veterinary checks has been found, that all or some of the animals in the consignment or its accompanying documents do not meet the veterinary medical requirements for import, the official veterinary shall withhold the consignment and after consultations with the importer or the person, responsible for the consignment:

1. shall fix a deadline for clarifying the case, shall accommodate the animals and provide for the necessary care, and at a suspicion shall put them under quarantine;

2. shall reject the consignment of animals, observing the health requirements and those for welfare.

(2) The measures under para 1 shall be imposed by an order.

(3) The official veterinary shall be obliged to administer medical aid to the animals at a necessity.

(4) (amend. – SG 08/11, in force from 25.01.2011) The official veterinary shall write down the reasons for returning of the consignment in the order under para 2, shall put on the original veterinary certificate, that is accompanying it, a seal with an inscription "invalid", shall inform the director of the respective RFSD of the measures taken and shall inform all BIVPs.

(5) A copy of the order and of the original certificate shall be kept at BIVP for a period of 3 years.

(6) The expenditures on withholding of the consignment shall be on the account of the importer.

Art. 194. (Amend. – SG 17/18, in force from 23.02.2018) When the return of the consignment under Art. 193, Para. 1, item 2 is not possible, the requirements of Art. 219a and 219b shall apply.

Art. 195. (Revoked – SG 17/18, in force from 23.02.2018)

Art. 196. (1) When during the border veterinary checks has been detected, that the consignment of the objects under art. 184, para 1, items 2-5 or the accompanying documents do not meet the veterinary medical requirements for import, the official veterinary shall withhold the consignment until the clarifying of the case, and making also a record of findings.

(2) If necessary, the official veterinary may carry out additional checks, and until receiving of the results from them the consignment shall remain under his supervision.

Art. 197. After removing the reasons for withholding of the consignment of the objects under art. 184, para 1, items 2-5, the official veterinary shall permit the import under art. 192.

Art. 198. (1) In case that the reasons of the withholding are not removed, the official veterinary shall not permit the import and after consultations with the importer or his representative, shall write down in the certificate under art. 191, item 8 an order for:

1. rejecting the consignment;

2. an immediate destruction of the consignment.

(2) In the cases under para 1, item 1, the official veterinary shall indicate the reasons for rejecting and shall put on the original veterinary certificate and/or on the other documents, that are accompanying a seal with an inscription "invalid".

(3) In the cases under para 1, item 2 the official veterinary shall direct the consignment for destruction to a plant for processing of animal by-products, after receiving of a written agreement by the importer or of his representative.

(4) A copy of the original certificate and/or the other documents shall be kept at BIVP for a period of 3 years.

Art. 199. (1) Where at the checks under art. 188, para 1, the official veterinary has detected, that the consignment of the objects under art. 184, para 1, items 2-5 poses a hazard to the human and animal health, he shall issue an order for eradication of the consignment, wherein shall determine the place and the way of its destruction.

(2) (amend. – SG 95/09, in force from 01.12.2009, amend. - SG 98/18, in force from 07.01.2019) For the destruction under para 1, the establishment for processing of animal by-products shall issue a confirming document, which shall be sent to BIVP, from where the consignment has been directed for destruction. A copy of the document shall be sent and to the respective territorial directorate of the Customs Agency.

(3) (amend. – SG 08/11, in force from 25.01.2011) The official veterinary shall notify immediately the director of the RFSD, the Head Quarter of the BFSA and the rest of the BIVP of the measures taken under para 1.

(4) (amend. – SG 08/11, in force from 25.01.2011) The Head Quarter of the BFSA immediately shall notify for the measures taken under para 1:

1. the border inspection veterinary points of the Republic of Bulgaria;

2. (in force from January 1, 2007) the border inspection points of the European Union;

3. (in force from January 1, 2007) the European Commission;

4. (in force from January 1, 2007) the country of origin of the consignment;

Art. 200. (1) When the official veterinary has detected, that physical persons are carrying products of animal origin for personal consumption over the quantities, specified in the ordinance under art. 188, para 2, he shall confiscate them.

(2) The products under para 1 shall be destroyed in installation for a waste burning on the territory of BCCP.

Art. 201. (1) (amend. - SG 58/16) The official veterinary shall permit import of consignments of the objects under art. 184, para 1, items 3-5, intended for a free zone or a customs warehouse, if only the person, responsible for the consignments, has in advance sent to BIVP a filled certificate in the respective part as under art. 191, item 8, and a notification, that the consignments:

1. are intended for free circulation on the territory of the Republic of Bulgaria or for another particular end use;

2. meet or do not meet the requirements for import.

(2) When in the notification under para 1 there is no indicated a particular end use, the consignment shall be considered as intended for free circulation.

(3) Consignments under para 1 shall be accompanied by:

1. original veterinary certificate;

2. original veterinary or other documents, identifying the consignment.

(4) Where the consignments under para 1, item 1 meet the requirements for import, the official veterinary shall carry out a documentary check, an identity check and a physical check.

(5) Where the consignments, intended for a particular end use do not meet the requirements for import, the official veterinary shall carry out a documentary check and an identity check.

(6) Where at carrying out of a documentary check in the cases under para 5 there appears a suspicion for a hazard to the human and animal health, the official veterinary shall carry out also a physical check.

(7) Where after carrying out of the checks the official veterinary has detected, that the

requirements are met, he shall permit the import by filling the respective part, signing and sealing the certificate under art. 191, item 8.

(8) (amend. - SG 58/16) Where at the checks under para 4 the official veterinary has detected, that the consignments do not meet the requirements for import, he shall indicate these circumstances in the certificate under art. 191, item 8 and shall permit entering of the consignments in a free zone or a customs warehouse, provided that the consignments are coming from countries for which there are no imposed bans on import and the entity of the customs seals is not damaged.

Art. 202. (amend. - SG 58/16) (1) In the cases under art. 201, para 8, the consignments may leave the free zone or the customs warehouse, provided that one of the following conditions is present:

1. when these are to be forwarded to another country in compliance with the requirements of transit passing;

2. when these are to be transferred to another customs warehouse, the name and the location of which is indicated in the customs document, accompanying the consignment.

(2) Where during the stay in a free zone or a customs warehouse the consignments become unfit for use, relevant to the initially intended, the same are to be transported to a place for destruction.

Art. 203. (amend. – SG 08/11, in force from 25.01.2011) The stores in the free zones, the free or customs warehouses shall be registered in the BFSA under art. 231.

Art. 204. The requirements to the free zones, the free or customs warehouses shall be arranged by the ordinances under art. 188, para 2.

Art. 205. (1) The requirements for import shall not apply to:

1. raw materials and foods of animal origin, which meet at the same time the following conditions :

a) are part of the personal luggage of the travellers and are intended for personal consumption;

b) originate from a country or regions of countries, for which the import is not prohibited;

2. raw materials and foods of animal origin on board of airplanes or ship, that are intended for consumption by the crew and the passengers and are not to be introduced on the territory of the country;

3. (amend. – SG 08/11, in force from 25.01.2011) exhibition or commercial samples permitted in advance by the BFSA;

4. the objects under art. 184, para 1, items 2–5, intended for special examinations;

5. (amend. – SG 08/11, in force from 25.01.2011) permitted in advance by the BFSA raw materials and foods of animal origin, intended for diplomatic representations.

(2) Where the products under para 1, item 2 or waste of them are to be unloaded, these shall be destroyed or transferred directly from one to other vehicle under customs supervision at the same seaport or airport.

(3) (amend. – SG 08/11, in force from 25.01.2011) When the exhibitions and the examinations under para 1, item 3 and 4 are finished, the products unused shall be destroyed under the control of the authorities of the BFSA.

Art. 206. The passing through BCCP raw materials and foods of animal origin, intended for personal consumption, bearing an epizootic risk, shall be confiscated by the official veterinary, after

which shall be destroyed on the territory of the same BCCP.

Art. 207. (1) (Previous text of Art. 207 - SG 17/18, in force from 23.02.2018) Transit passing of animals and germinal products through the territory of the Republic of Bulgaria shall be permitted by the official veterinary, provided that:

1. are coming from a country, where the importing and the transit passing are not prohibited;

2. the checks under art. 188, para 1, items 1-3 are carried out;

3. the consignment is accompanied by original veterinary certificate, issued by the competent veterinary authorities of the country of origin, wherein are indicated the country of destination, other than the Republic of Bulgaria;

4. a written confirmation is received for the acceptance of the consignment by the competent veterinary authority of the country, through which the consignment is to pass after leaving the territory of the Republic of Bulgaria;

5. the fees for carrying out the BIVC are paid, at the amounts determined in the tariff under art. 14, para 2.

(2) (New - SG 17/18, in force from 23.02.2018) Where, during the inspections, the veterinarian establishes violations of the requirements under Para. 1, he shall not allow the consignment to transit and shall return it back.

(3) (New - SG 17/18, in force from 23.02.2018) In the cases under Para. 2 where the return is not possible, by order of the official veterinarian of the Border Veterinary Inspection Post, the animals shall be taken away in favour of the state and shall be intended:

1. for sale via tender - in the cases where the certificate accompanying the consignment indicates that the animals are intended for breeding or for production, whereby with the proceeds shall cover the costs until their sale;

2. for slaughter - where the certificate accompanying the consignment indicates that the animals are intended for slaughter.

(4) (New - SG 17/18, in force from 23.02.2018) In the cases under Para. 3, the requirements of Art. 219a, Para. 3 – 6 shall apply.

Art. 208. (1) Transit passing of the objects under art. 184, para 1 items 3-5 through the territory of the Republic of Bulgaria shall be permitted provided that:

1. these are coming from a country, where the importing and the transit passing are not prohibited;

2. the checks under art. 188, para 1, items 1 и 2 are carried out;

3. the consignments shall be accompanied by original veterinary certificate, original veterinary or other documents, issued by the competent authorities of the country of origin, whereto are attached the legalized translations in Bulgarian language, wherein are indicated the country of destination, other than the Republic of Bulgaria;

4. the veterinary fees for the carried out BIVC are paid, determined in the tariff under art. 14, para 2.

(2) When at carrying out of the documentary check raises a suspicion of a danger to the human and animal health, the official veterinary shall carry out also a physical check.

(3) When at the checks under para 2 the veterinary finds out that the requirements are met he shall permit the transit passing of the consignment.

(4) When at the checks under para 2 the veterinary finds out breaches of the requirements he shall not permit the transit passing and shall return the consignment back.

Art. 209. (1) The official veterinary at the entering BIVP shall notify the BIVP, through which the consignment is to leave the territory of the Republic of Bulgaria, that he has permitted its transit passing.

(2) The official veterinary at the exit BIVP shall notify the official veterinary, permitted the transit passing, whether the consignment has left the territory of the country.

(3) If in a 24-hour period the official veterinary of the entering BIVP is not informed about the exit of the consignment, he shall notify the customs authority of the entering BCCP.

Art. 210. (1) The customs authorities shall not permit transit passing of the objects under art. 184, para 1, before carrying out of BIVC.

(2) Transit passing of objects under para 1 shall be carried out in sealed vehicles or containers.

Art. 211. (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry or an authorized by him person shall issue immediately an order for ban of the import and the passing of the objects under art. 184, para 1 when:

1. official information is received, that on whole territory of a definite country or region/s of it the veterinary authorities have found out the occurrence of a particularly dangerous contagious disease of animals;

2. are found physical or chemical contaminants over the allowed limits, that are posing a hazard to the human and animal health.

(2) The order under para 1 shall not be subject to an appeal.

(3) The ban under para 1 shall be repealed by an order, based on:

1. normative acts of the European Commission;

2. information by the WOAH, based on the requirements of the International zoo-sanitary health code.

(4) The orders under para 1 and 3 shall be published in State Gazette.

Art. 212. (1) Exporting of the objects under art. 184, para 1 shall be permitted provided that at the BIVP, wherefrom the consignment is leaving the country:

1. is presented one of the following documents:

a) (amend. – SG 08/11, in force from 25.01.2011) for animals and germinal products - veterinary medical permission for exporting, issued by the executive director of the BFSA;

b) for raw materials and foods of animal origin, animal products, by-products, obtained there from, specific plantation products, feed raw materials, feed additives, compound feeding stuffs and premixes – written notification by the veterinary, who has issued the veterinary certificate and/or other document, accompanying the consignment;

2. the consignment is accompanied by original veterinary certificate, and for the objects under art. 184, para 1, items 2-5 and/or by other original document;

3. a documentary check has been carried out.

(2) The veterinary certificate at exporting of the objects under art. 184, para 1 is conformed to a specimen of the country of destination, and the text in the certificate is also in Bulgarian language.

(3) (amend. – SG 08/11, in force from 25.01.2011) When the country, to which the consignment is exported, has no approved form, the export shall be carried out with a certificate conformed to a specimen, approved by the executive director of the BFSA.

Art. 213. (1) (amend. – SG 08/11, in force from 25.01.2011) The veterinary medical permission for exporting under art. 212, para 1, item 1, "a" shall be issued after submission of an application form conformed to a specimen to the executive director of the BFSA.

(2) (amend. – SG 08/11, in force from 25.01.2011) In a 10-days period from the submission of the application form, the executive director of the BFSA shall issue a permission for exporting or shall motivate a refusal of its issuing.

(3) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 2 may be appealed under the Administrative procedure code.

Art. 214. Veterinary medical permission for exporting of animals shall not be issued:

1. at a ban for import, imposed by the veterinary authorities of the country for which the export is designated;

2. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) at a ban on export, imposed by an order of the Minister of Agriculture, Foods and Forestry or authorized by him person;

3. when the documents under art. 212, para 1 are not presented.

Art. 215. Veterinary medical permission shall not be required for export of:

1. (amend. – SG 84/07) single pets or decorative animals;

2. animals designated for scientific purposes, exhibitions and donations.

Art. 216. (1) When the official veterinary finds out non-compliance of the consignment with the data in the accompanying documents, an absence of documents and/or breaches of the requirements for animal protection and welfare during transport, he shall withhold the consignment until clarifying the case and shall draw a record of findings conformed to a specimen.

(2) In case that the exporter or his representative does not remove the reasons for the withholding of the consignment, the official veterinary shall issue an order for its returning to the place of loading and shall attach a copy of the record under para 1.

(3) When the reasons for the withholding of the consignment are removed, the official veterinary shall place on the certificate, that is accompanying it, a seal certifying that he has authorized the export of the consignment.

Art. 217. When export of the objects under art. 184, para 1, items 2-5 has been carried out, their returning to the Republic of Bulgaria shall be permitted under the condition that:

1. (amend. – SG 08/11, in force from 25.01.2011) at BIVP a written confirmation is received from the executive director of the BFSA for the accepting them;

2. they are accompanied by the veterinary certificate and/or other documents, with which they have been exported, and the certificate issued by the competent authority of the country, wherefrom the consignment is returned, wherein:

a) it is guaranteed, that the consignment has not undergo manual processing, has not been unloaded and the conditions of the storage and the transportation have been met;

b) are indicated the reasons for turning back of the consignment.

Art. 218. (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall not be responsible for the incurred damage and missed benefits, caused by the withholding of the consignments, when carrying out BIVC.

Art. 219. (1) (amend. – SG 08/11, in force from 25.01.2011) The executive director of the BFSA by an order shall ban the exporting of the objects under art. 184, para 1 in case of a complicated epizootic situation or at occurrence of a hazard to the human and/or animal health.

(2) (Amend. – SG 17/18, in force from 23.02.2018) The order under para 1 and the order for its repeal shall be published on the website of the Bulgarian Food Safety Agency.

(3) The order under para 1 shall not be subject to an appeal.

Art. 219a. (New - SG 17/18, in force from 23.02.2018) (1) Where any third-party recipient refuses to accept a consignment of animals with a country of origin from the European Union in a favorable epizootic environment, the Bulgarian Food Safety Agency shall notify the competent authority of the respective Member State which issued the certificate accompanying the consignment and, subject to the consent of that authority, the official veterinarian of the Border Veterinary Inspection Post shall, following an order, return the consignment. Costs for returning the consignment shall be at the expense of the person responsible for the consignment.

(2) Where the return of the consignment under Para. 1 is not possible due to an unfavorable epizootic situation or because of disagreement of the competent authority of the Member State that issuing the certificate to accept the consignment, where the consignment does not pose a danger to the life and / or health of humans and / or animals, by order of the official veterinarian of the Border Veterinary Inspection Post animals shall be taken away in favour of the state and shall be intended for:

1. sale via auction - in cases where the certificate accompanying the consignment indicates that the animals are intended for breeding or production, with the proceeds covering the costs until their sale;

2. slaughter - where the certificate accompanying the consignment indicates that the animals are intended for slaughter.

(3) In the cases under Para. 2, item 1, the auction shall be conducted under conditions and by an order determined by an ordinance of the Minister of Agriculture, Food and Forestry.

(4) In the cases under Para. 2, item 2, the official veterinarian issuing the order shall immediately inform the Central Office of the BFSA, which shall designate the slaughterhouse. Slaughter shall be organized by the Director of the RFSD, on whose territory the slaughterhouse is located.

(5) (amend. - SG 24/19, in force from 01.01.2020) The raw materials obtained during the slaughter under Para. 2, item 2, when they are fit for human consumption, shall be given to persons authorized to operate a food bank, or to social or integrated health and social services for residential care. Costs of transporting, staying and slaughtering animals, as well as for storage of the products harvested, shall be paid by the persons or the providers of residential care services to which they are provided.

(6) The raw materials obtained during the slaughter under Para. 2, item 2 when they are not fit for human consumption, shall be given away for another disposal or destruction by order of the Director of the respective RFSD, indicating the conditions for realization or destruction. Costs of destruction shall be borne by the person responsible for the consignment.

Art. 219b. (New - SG 17/18, in force from 23.02.2018) (1) Where a third-party recipient refuses to accept a consignment of animals with a country of origin from the European Union and the consignment constitutes a danger to the life and / or the health of the people and / or of the animals, due to the presence of circumstance under Art. 179, Para. 3, the official veterinarian of the Border

Veterinary Inspection Post shall issue an order to euthanize in compliance with animal welfare requirements. Euthanasia and destruction shall be at the expense of the person responsible for the consignment.

(2) The Executive Director of the BFSA shall immediately notify the following parties on the measures taken under Para. 1:

1. the border veterinary inspection posts on the territory of the Republic of Bulgaria;

2. the border inspection posts on the territory of the other Member States of the European Union;

3. the European Commission;

4. the country of origin of the consignment.

Art. 219c. (New - SG 17/18, in force from 23.02.2018) (1) When, during import, export or transit of consignments of animals, violation of the requirements of Regulation (EC) No 1/2005 is established during inspections at the BNIP in the Republic of Bulgaria, the official veterinarian shall with an order impose one of the measures under Art. 23 of the same Regulation, the cost of which is to be borne by the person responsible for the consignment.

(2) Where for the execution of any measure as per Para. 1 it is necessary for the animals to be temporarily staying, the order shall indicate the closest resting point with free standing capacity for the animals, the costs being borne by the person responsible for the consignment.

(3) Where in the cases of Para. 1, a measure under Art. 23, paragraph 2, letter "d" of Regulation (EC) No 1/2005 is imposed, the requirements of Art. 219a and 219b shall apply.

(4) The official veterinarian of BVIP shall issue an injunction for the humane killing or euthanasia of the animals when:

1. the consignment of animals under Para. 1 poses a danger to the health and/or life of humans and/or animals, and/or

2. existence of circumstance under Art. 179, Para. 3 is found, and/or

3. there is no other way to eliminate the violations of animal welfare requirements.

(5) Humane killing or euthanasia shall be carried out in compliance with the animal welfare requirements, and the costs shall be borne by the person responsible for the consignment.

Art. 219d. (New - SG 17/18, in force from 23.02.2018) Where a measure is imposed under Art. 207, Para. 2 and 3, Art. 219a, Para. 1 and 2, Art. 219b, Para. 1 and Art. 219c, Para. 1 and 4 with regard to non-Union goods, the authorities of the BFSA shall notify in writing the customs authorities which to decide to withdraw, destroy or sell in accordance with the provisions of Title V, Chapter 4 "Disposal of Goods" of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 on establishing a Customs Union Code (OJ, L 269/1 of 10 October 2013) and Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 on laying down detailed rules for the application of certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council on laying down Union Customs Code (OJ, L 343/558 of 29 December 2015).

Chapter nine.
STATE VETERINARY-SANITARY CONTROL

Section I.
Conditions and rule of carrying out a stare veterinary-sanitary control

Art. 220. (1) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out state veterinary-sanitary control (SVSC) of:

1. animals, intended for slaughter;

2. raw materials and foods of animal origin;

3. animal by-products;

4. products, obtained from animal by-products.

5. genetically modified organisms as products or food ingredients of animal origin.

(2) The state veterinary-sanitary control on the objects under para 1 shall be aimed at:

1. preventing the occurrence of hazard to the human health, related to consumption of raw materials and foods of animal origin;

2. controlling the type, the composition and the safety of the raw materials and the foods of animal origin, the animal by-products and the products, derived there from;

3. preventing the spreading of contagious diseases on animals.

Art. 221. (amend. - SG 14/16, in force from 19.02.2016) The state veterinary control shall be carried out in respect of:

1. the production, trade and marketing of raw materials and foodstuffs of animal origin;

2. the conditions for transportation and the vehicles which are used to transport the subjects under Art. 220, para. 1;

3. the manufacture of products, derived from animal by-products;

4. the holding of exhibitions for raw materials and foodstuffs of animal origin.

Art. 222. (1) The state veterinary-sanitary control shall be carried out by veterinary under Art. 8, para 1 through:

1. checks and analysis:

a) of the information of the food chain on the basis of the veterinary and/or other documents for compliance of the subjects under Art. 220, para 1 which are accompanying;

b) of the results ante-mortem and post-mortem examinations;

2. check on:

a) compliance with the requirements of protection and welfare;

b) the identification and the health status of the animals, intended for slaughter;

3. inspections:

a) for compliance with the veterinary-sanitary and hygiene requirements during production, transportation, trade and placing on the market of the subjects under Art. 220, para 1, item 2-4;

b) of raw materials and foods of animal origin for presence of VMP residues, hazardous to the human and animal health, growth promoters and the presence of contaminants from the environment;

4. sampling of official samples of raw materials and foods of animal origin, products, obtained from animal by-products from the manufacturing for laboratory testing of the microbiological contamination;

5. carry out expertise of raw materials and foods of animal origin.

(2) Besides the activities under para 1, the official veterinaries shall carry out as well:

1. (amend. – SG 7/13) audits on the implementation of good practices for production and trade with foods of animal origin in the establishments under Art. 7, para 3, item 5 and the procedures based on the self-control system;

2. (amend. – SG 08/11, in force from 25.01.2011) sending of the samples under para 1, item 4 to accredited laboratories of the BFSA.

(3) (amend. – SG 08/11, in force from 25.01.2011) The official veterinaries appointed by the director of regional veterinary services (RFSD) shall determine the frequency of the inspections under para 1, item 3 and para 2 depending on:

1. the type and the quantity of produced and/or stored in the controlled establishment raw materials and foods of animal origin and products, obtained from animal by-products;

2. the risk assessment at all stages of the production and the placing on the market of the manufactured raw materials and foods of animal origin and products, obtained from animal by-products;

3. (amend. – SG 7/13) the guarantees provided by the owner of the controlled establishment or his representative on the implementation of good practices for production and trade with foods of animal origin in the establishments under Art. 7, para 3, item 5 and the procedures, based on the self-control system.

(4) The official veterinaries shall reflect the results of the checks and the inspections under para 1 – in records , and of the audits under para 2, item 1 – in reports.

(5) The veterinary inspectors shall reflect the results of the checks and the inspections under para 1 in records and shall present them to the official veterinaries.

(6) (amend. – SG 08/11, in force from 25.01.2011) On request The Headquarter of BFSA shall inform the management boards of the relevant Branch organizations for the results of the checks under para 1.

Art. 223. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The specific requirements for the execution of official control on raw materials and foods of animal origin shall be regulated by an Ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 224. (1) Where carrying out state veterinary-sanitary control the veterinaries shall have the right:

1. of a free access in the establishments, which they control;

2. of access to the necessary documentation, concerning the origin, type and quantity of the raw materials and the ready product, access to all documents, accompanying the raw materials and the ready product as well as obtaining of copy of the documents, connected with the activity which they control;

3. to require cooperation from the owners and the users of the establishments and their representatives;

4. to undertake immediately even and without the consent of the persons under item 3, the necessary measures for prophylaxis, restraint and liquidation of animal diseases, zoonoses and toxic infections with the people;

5. to take free the necessary quantities of official samples.

(2) The official veterinaries, besides the rights under para 1:

1. shall issue veterinary medical documents conformed to a specimen;

2. shall make arrangements for the destroying of unfit for consumption raw materials and foods of animal origin;

3. shall determine and control the ways for waste disposal, the use of or destroying of conditionally fit raw materials and foods of animal origin;

4. shall prolong or reduce at necessity the expiry period of the raw materials and foods of animal origin;

5. (amend. - SG 14/16, in force from 19.02.2016) shall stop the activity of the establishments, in which said activities are performed, under Art. 221, item 1, 3 and 4 where there is non-payment of the fees, specified in the tariff under Art. 14, para 2.

Art. 225. (1) Where carrying state veterinary-sanitary control (SVSC) the inspectors:

1. shall notify immediately the official veterinary, when suspecting an occurrence of a contagious disease;

2. shall keep documentation, relevant to carrying out their activity;

3. shall keep secret the information, obtained during carrying out their activity;

4. shall put or control the placing of health marking on the carcasses of the slaughtered animals;

5. shall participate in training for qualification increasing.

(2) The official veterinaries, apart from the obligations under para 1, item 2-5:

1. (amend. – SG 08/11, in force from 25.01.2011) shall notify immediately director of the respective RFSD, at a suspicion for occurrence of a contagious disease;

2. shall assist the authorities of the Ministry of Health at occurrence of a hazard to human health;

3. shall place his personal seal where issuing veterinary medical documents;

4. shall approve and control the implementation of the programs for training of the personnel of the establishments, subjected to their control.

Art. 226. (amend. – SG 7/13) The assessment of the designs for construction or reconstruction of the establishments under Art. 7, para 3, item 5 and the establishments under Art. 229, para 1 shall be carried out under Art. 142 of the Spatial Development Act and in compliance with the requirements defined by the Ordinances under Art. 59 and Art. 66, para 2.

Art. 227. (1) The operation of the establishments under Art. 226 shall be authorized under Art. 177 of the Spatial Development Act.

(2) Where the establishment is to undergo a state acceptance by a state accepting commission in its composition shall be included a representative of SVSC.

(3) (amend. – SG 08/11, in force from 25.01.2011) Where the establishments are not to undergo a state acceptance by a state accepting commission their commissioning in operation shall be carried out after delivery of an opinion by the respective RFSD.

Art. 228. Production and trade with raw materials and foods of animal origin, intended for human consumption shall be carried out in establishments, registered under Art. 12 of the Food Act.

Art. 229. (1) (amend. – SG 08/11, in force from 25.01.2011) Production, trade and placing on the market of raw materials and foods of animal origin, not intended for human consumption, and products, obtained from animal by-products, shall be carried out in establishments, registered by the RFSD.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) In order to perform activities under Para. 1, a standard application shall be submitted to the Director of the Regional Directorate for Food Safety, indicating the UIC of the applicant under the Act On The Commercial Register And The Non-Profit Legal Entities Register, or the BULSTAT code, the number and date of issuance of the act for commissioning of the site, issued by the order of the Spatial Development Act, the number and date of an effective administrative act issued by the order of Chapter Six of the Environmental Protection Act and/or by the order of Art. 31 of the Biological Diversity Act. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. a current status document issued by a competent authority of another country, where applicable;

2. copy of a document of right of property and use for the establishment;

3. document of paid fee at an amount, specified in the tariff under Art. 14, para 2, when the payment is not made electronically.

(3) (Amend. – SG 08/11, in force 25.01.2011, suppl. – SG 17/18, in force from 23.02.2018) Within 7 days from the submission of the application form, the director of RFSD shall apitem by an Order a Commission, which shall check ex-officio the declared circumstances and the documents under para 2 and check the establishment for compliance with the submitted documentation and the veterinary medical requirements, determined by the Ordinance under Art. 66, para 2 as well as the technological documentation for production and the self-control system and shall draw up a record conformed to a specimen.

(4) In case of incompleteness and irregularity of documents under para 2 Commission shall notify in writing the applicant and shall fix a period for taking away them.

(5) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) Within 14 days from the submission of the application form or the expiry of the period under para 4, the director of RFSD shall register the establishment and issue certificate for registration or duly substantiated refuse the registration.

(6) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 5 may be appealed under the Administrative procedure code.

Art. 229a. (new - SG 14/16, in force from 19.02.2016) (1) Operators who trade with shipments of animal by-products and/or products, derived from them, without storing them, originating from a Member State, another state - party to the Agreement on the European Economic Area, the Swiss Confederation or from third countries, shall be registered and entered in the register under Art. 232, para. 2.

(2) (Amend. – SG 17/18, in force from 23.02.2018) The operators under para. 1 shall submit to the director of the RFSD at their headquarters, an application for registration form, in which they indicate the UIC under the Act On The Commercial Register And The Non-Profit Legal Entities Register, or the BULSTAT code. The application shall be filed in person, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator.

(3) (Suppl. – SG 17/18, in force from 23.02.2018) With the application shall be submitted a fee payment slip fir the amount, specified by the tariff of Art. 3, para. 4 of the Bulgarian Agency for Food Safety Act, when the payment is not made electronically.

(4) The applicant shall be notified in writing for identified inadequacies and/or inaccuracies in the documents under para. 2 and 3 within 7 days from submitting the application, and a deadline for their correction shall be set.

(5) Where inadequacies and/or inaccuracies are not corrected within the set deadline, the director of the RFSD shall refuse registration in a reasoned answer.

(6) Within 14 days of submission of the application or of removal of inadequacies and/or inaccuracies, the director of the RFSD shall register the operator and shall issue a registration certificate or shall refuse registration in a reasoned answer.

(7) Within three days of the occurrence of a change in the name/business name and/or address/headquarters, operators under par. 1 shall notify the director of the RFSD and shall submit the document, certifying the change, and a document for paid fee, specified by the tariff under Art. 3, para. 4 of the Bulgarian Agency for Food Safety Act.

(8) Within 7 days of receipt of the notification under par. 7, the director of the RFSD shall enter the change in the register under Art. 232, para. 2, and shall issue a certificate for the change made.

(9) The refusal under par. 5 and 6 shall be announced and can be appealed in the order of the

Administrative Procedure Code.

Art. 229b. (new - SG 14/16, in force from 19.02.2016) (1) (amend. - SG 85/17) The operators under Art. 229a, by the 10th day of the month following the respective quarter, are obliged to provide the RFSD, at the operator's headquarters, with information on obtained and/or distributed consignments of animal by-products and/or products, derived from them, originating from a Member State, another state - party to the Agreement on the European Economic Area, the Swiss Confederation or from third countries. The information shall be provided in a form, approved by the Executive Director of the BVU. Information can be submitted electronically in compliance with the requirements of the Regulation (EU) № 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ, L 257/73 of 28 August 2014) and of the Electronic Document and Electronic Trust Services Act.

(2) The Regional Food Safety Directorates shall gather and summarize the information under par. 1.

(3) The Regional Food Safety Directorates, by the 20th day of the month following the respective quarter, shall provide the headquarters of the Bulgarian Food Safety Agency with the summarized information under par. 1.

Art. 230. For the registration of establishments under Art. 229, para 1 where is being executed only storage and/or placing on the market of raw materials and foods of animal origin not intended for human consumption and products obtained from animal by-products, technological documentation for production shall not be required.

Art. 231. (1) (suppl. - SG 14/16, in force from 19.02.2016) The establishments under Art. 229, para 1 shall receive a veterinary registration number and the operators under Art. 229a – a registration number, which shall be entered in the registration certificate.

(2) (suppl. - SG 14/16, in force from 19.02.2016) The registration of establishments and operators under para. 1 shall be unlimited.

Art. 232. (1) (amend. - SG 8/11, in force from 25.01.2011, former text of Art. 232 - SG 14/16, in force from 19.02.2016) The registered establishments under Art. 229, para 1 shall be entered in a register of RFSD, that shall contain:

1. number and date of issuing of the certificate for registration;
2. the veterinary registration number of the establishment;
3. name /name and address/ residence of the owner or user of the establishment;
4. type, subject of activity, capacity and location of the establishment;
5. changes in the circumstances referred to item 3 and 4;
6. number and date of the act for cancellation of registration.

(2) (new - SG 14/16, in force from 19.02.2016) The operators under Art. 229a shall be listed in a register at the RFSD, which shall contain:

1. number and date of issue of the certificate of registration;
2. registration number of the operator;
3. name/company name and/or address/headquarters of the operator;
4. number and date of the act for cancellation of the registration.

Art. 233. (amend. - SG 8/11, in force from 25.01.2011, amend. - SG 14/16, in force from 19.02.2016, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a public national electronic register of the sites under Art. 229, Para. 1 and of the operators under Art. 229a, containing the data of the registers of the RFSD.

Art. 234. (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from

19.02.2016) The regional food safety directorates shall draw up and keep the files of the registered establishments under Art. 229, para 1, and of operators under Art. 229a.

(2) (suppl. - SG 14/16, in force from 19.02.2016) The files shall be kept for a period of at least 3 years from the date of termination of the activity of the establishment, respectively of the operator.

Art. 235. (1) Where introducing new activities, a change in the production technology, the equipment or at a reconstruction of the premises in the establishments under Art. 229, para 1, the owner or the user of the establishment shall submit an application form under Art. 229, para 2 and para 5 within 7 days.

(2) (amend. – SG 08/11, in force from 25.01.2011) Where there is a change of the owner or the user of the establishment, the new owner or user shall submit within 7 days to the director of the RFSD an application form, to which shall attach the document, certifying the change.

(3) In the cases under para 2, new certificate shall be issued without applying the procedure under Art. 229, para 2-5.

Art. 236. (1) (amend. – SG 08/11, in force from 25.01.2011) The certificate for registration of the establishment under Art. 229, para 1 shall be invalidated by an order, issued by the director of the RFSD:

1. at a request of the owner or the user of the establishment;
2. at a change of the function of the establishment;
3. at gross or systematic infringements of the normative requirements
4. at systematic infringements of the hygienic requirements and the system of self-control
5. at non-execution of compulsory administrative measure
6. at systematic impediment of the veterinaries during the execution of their control activity.

(2) (amend. – SG 08/11, in force from 25.01.2011) If the veterinaries ascertain within 3 months from the issuing of the certificate for registration under Art. 229, para 5 that the procedures based on the system of self-control are not applied the director of the RFSD shall invalidate the registration of the establishment.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order under para 1, item 3-6 and para 2 may be appealed under the Administrative procedure code.

Art. 236a. (New - SG 14/16, in force from 19.02.2016) (1) The registration of operators under Art. 229a, para. 1 shall be deleted and the certificate shall be canceled with an order by the Director of RFSD:

1. at the request of the operator;
2. in gross or systematic violations of statutory requirements;
3. failure to implement administrative enforcement;
4. due to systematic obstruction of veterinarians in carrying out their inspection activities.

(2) The order under par. 1, items 2-4 can be appealed under the Administrative Procedure Code.

Art. 237. Exporting to third countries of raw materials and foods of animal origin, animal by-products and products, obtained from them shall be carried out only by the establishments:

1. having received a veterinary registration number;
2. meeting the requirements of the country, for which the consignment is intended.

Art. 238. (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. – SG 17/18, in force from

23.02.2018) For issuing of certificate or other document the exporter shall submit an application form to the director of RFSD, where shall be indicated:

1. the country for which the consignment is intended;

2. the type and the quantity of the raw materials and the foods of animal origin, the animal by-products and the products, derived there from;

3. the veterinary registration number and the name of the establishment, exporting the consignment;

4. BCCP, through which the exporting shall be carried out;

5.additional requirements to the product by the country for which it is exported.

(2) The official veterinary, controlling the establishment or his auxiliary shall be present at the loading of the consignments, intended for exporting.

(3) (amend. – SG 08/11, in force from 25.01.2011) After the loading of the consignment, the veterinary under para 2 shall issue a certificate and/or other document, on which shall place the stamp of the respective RFSD, the stamp of the official veterinary and the stamp with the veterinary registration number of the establishment.

(4) After issuing of the documents under para 3, the official veterinary shall notify the official veterinary of the BIVP, through which the consignment shall leave the country.

Art. 239. The damages, caused by an incomplete or false information under Art. 238, para 1 shall be on the account of the exporter.

Art. 240. (1) Where carrying out an expertise of a batch of raw materials and foods of animal origin or products, obtained from animal by-products, the veterinary:

1. shall check the compliance of the content of the batch with the information in the veterinary and/or other documents, that are accompanying it;

2. shall check the physical condition of the batch;

3. where necessary shall take samples;

4. where necessary shall impose a temporary ban on the batch realization;

(2) The official veterinary shall issue expertise act of the batch, which depending on the results of the actions under para 1 shall contain a provision for:

1. marketing;

2. processing for a guarantee of safety of the obtained end product;

3. destruction.

(3) In the cases under para 2, item 2 and 3, the official veterinary shall indicate in the act also:

1. the way of processing of the batch and the establishment, where this is to be carried out;

2. the establishment of waste disposal for animal by-products or other appropriate way of destruction.

(4) The official veterinary shall hand a copy of the act under para 2 to the owner of the batch or to his representative.

(5) The receiving of the batch in the establishments for waste disposal of animal by-products shall be certified by a document.

(6) Where the destruction has not been carried out in the establishments under para 5 a record shall be drawn, that is to be signed by the official veterinary, a representative of the municipality, on the territory of which is carried out, and the owner of the batch or his representative. A copy of the record shall be given to the representative of the municipality and the owner of the batch or to his representative.

Art. 241. (1) (amend. – SG 08/11, in force from 25.01.2011) For the caused damages of improperly issued expertise act the owner of the batch shall have the right to search for compensation by the BFSA under the common order.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall have the right of counter-claim against the veterinary, having issued the expertise act.

Art. 242. (1) During the expertise of imported raw materials and foods of animal origin, animal by-products and products, obtained from them, the official veterinary shall impose a ban on the consignment realization with an act of prohibition and undertake the actions under Art. 240, para 1, item 1-3.

(2) The official veterinary shall issue an expertise act of the batch which depending on the results under para 1 shall contain a provision:

1. under Art. 240, para 2;

2. for return of the certificate in the issuing country;

3. for the exporting to a third country.

(3) The return under para 2, item 2 shall be admitted keeping the following requirements:

1. (amend. – SG 08/11, in force from 25.01.2011) the owner of the consignments or an authorized person by him shall present in the Headquarters of the BFSA a written confirmation of the acceptance of the consignment by the competent authority, having issued the certificate;

2. the consignment shall be accompanied with the original certificate attaching it and a certificate, conformed to a specimen, issued by the official veterinary who:

a) shall guarantee that the consignment has not endured processing and the conditions for storage and transportation have been kept;

b) shall contain the reasons for the consignment return.

(4) The exporting under para 2, item 3 shall be admitted in condition that:

1. the consignment shall respond to the veterinary medical requirements of the country of import;

2. the consignment shall be accompanied with:

a) a certificate, conformed to a specimen, issued by an official veterinary which shall certify that the requirements of the third country have been kept;

b) copy of the original certificate, attached to it;

3. the official veterinary of the BIVP, through which the consignment shall leave the country shall receive written notification by the veterinary under item 2, letter "a".

(5) Where the owner of the consignment or an authorized by him person declares on paper that he may not carry out the conditions under para 3 and para 4, item 1, the official veterinary shall command a disposal of the consignment in the establishments for waste disposal of animal by-products.

Art. 243. All the expenditures regarding to the transportation and the destruction of the consignment under Art. 242, para 3 and 5 shall be on the account of the owner of the consignment.

Art. 244. The imported raw materials and foods of animal origin, animal by-products and the products obtained from them shall be transported, stored and realized within the terms and at the conditions, determined by the producer.

Art. 245. (1) (amend. – SG 7/13) The transportation of raw materials and foods of animal origin, animal by-products and products, obtained from them, shall be carried out by specialized vehicles, in compliance with the requirements, determined by Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, herein after referred to as "Regulation (EC) No. 852/2004), Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29April 2004 laying down specific hygiene rules for the hygiene of food of animal origin, herein after referred to as "Regulation (EC) No. 853/2004" and Regulation (EC) No. 1069/2009.

(2) During the transportation the raw materials and foods of animal origin, animal by-products and the products, obtained from them, shall be accompanied by veterinary medical and/or other document, wherein shall be entered also the veterinary registration number of the establishment, wherefrom they originate.

Art. 246. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) The owners of means of transport, which shall transport the objects referred to in Art. 245, par. 1, shall submit an application form for registration conformed to a specimen to the director of RFSD. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. a copy of the registration certificate of the vehicle;

2. (amend. – SG 7/13) a copy of license for carrying out international transport of goods and a copy of license for carrying out internal transport of goods, issued by the Ministry of Transport, Information Technology and Communications;

3. contract with the milk processing establishment – for the vehicles, transporting raw milk;

4. a document of paid fee in an amount specified in the tariff under Art. 14, para 2.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within 7 days from the submission of the application form the director of RFSD by an order shall determine a Commission, that is to check the submitted documents and the vehicle for compliance with the requirements, determined by Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and Regulation (EC) No. 1069/2009.

(3) (amend. – SG 08/11, in force from 25.01.2011) The commission shall deliver an opinion to director of RFSD with a proposal for registration or a refusal for registration of the vehicle.

(4) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within 30 days from the submission of the application form the director of RFSD shall enter the vehicle in a register and issue registration certificate or duly substantiated refuse the registration if there are irregularities in the documents submitted or when the vehicle does not meet the requirements, indicated in Regulation (EC)No. 852/2004, Regulation (EC) No. 853/2004 and Regulation (EC) No. 1069/2009.

(5) The registration is termless.

(6) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 4 may be appealed under the Administrative procedure code.

Art. 247. (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) On the website of the Regional Directorate for Food Safety shall be maintained a public national electronic register of the vehicles transporting raw materials and foods of animal origin which shall contain:

1. number and date of the issued certificate;

2. name or address/residence of the owner;

3. type, the loading capacity and the registration number;

4. the type of the raw materials and foods of animal origin, which can be transported by the vehicle.

Art. 248. (amend. – SG 7/13) The persons, carrying out production, transportation, trade and placing on the market of raw materials and foods of animal origin in the establishments under Art. 7, para 3, item 5 and the establishments under Art. 229, para 1:

1. (amend. – SG 08/11, in force from 25.01.2011) shall inform on paper the director of the respective RFSD for the ceasing of their activity and its following resumption;

2.within 3 months from the registration of the establishment they shall implement and maintain procedures, based on the system of self-control for:

a) raw materials and foods of animal origin;

b) products, obtained from the animal-by products;

3. shall mark with an identification marking and label the establishments under Art. 220, para 1, item 2-4;

4. shall keep the veterinary-sanitary and hygienic requirements during the realization of their activity;

5. shall give an opportunity to the veterinaries to free using of premises and equipment, necessary for the realization of their activity;

6. shall inform in good time the official veterinaries for changes of their activity in their establishments;

7. shall cooperate with the veterinaries during the realization of their activity;

8. during performing disinfection, disinsection and deratisation shall use preparations, approved by the Ministry of Health;

9. shall keep the requirements for storage of animal-by products from the production process and shall give them for destruction;

10. shall always ensure access of veterinaries to:

a) the places in which animals, intended for slaughter, raw materials and foods of animal origin and products, obtained from animal –by products can be found;

b) the vehicles by which the objects under letter "a" shall be transported;

11. in case of request shall present to the veterinaries the necessary documents;

12. shall inform the veterinaries for an arising danger for the health of people and the animals;

13. shall keep the issued directions and the imposed bans by the veterinaries.

Art. 249. (1) The system of self-control of raw materials and foods of animal origin, not intended for the consumption of people shall contain:

1. the technological documentation with a description of the manufactured products and of their purpose;

2. a description of the sequence of the stages of the production process;

3. analysis of danger and risk assessment during all the stages of the production process;

4. critical control items of the production process;

5. critical limits for each critical control item;

6. monitoring rules and control of the indicators in critical control items;

7. a description of the corrective actions at deviation of monitored indicators in critical control items;

8. requirements for control of hygienic and quality indicators of the raw materials and foods;

9. requirements for keeping the documentation which shall contain the data under item 1-8.

(2) The owner or the user of the establishment shall determine specialists who are responsible

for the system and shall periodically summarize and analyze the results.

(3) The system of self-control of raw materials and foods of animal origin, intended for human consumption shall meet the requirements under Art. 18, para 2 of the Food Act.

Art. 250. (1) An urgent or sanitary slaughter of animals shall be carried out under the control of a veterinary:

1. in slaughterhouses – after finishing the regular slaughter;

2. outside the slaughterhouses referred to item 1, where the transportation of the animals thereto is not possible.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, amend. – SG 58/17, in force from 18.07.2017) Under a complicated epizootic situation the Minister of Agriculture, Foods and Forestry may conclude a contract for carrying out of a sanitary slaughter in slaughterhouses, proposed by the executive director of the BFSA.

Art. 251. (amend. – SG 7/13) The following shall be prohibited:

1. the consumption and the placing on the market of raw materials and foods of animal origin, obtained at an urgent or sanitary slaughter, where no veterinary-sanitary control has been carried out;

2. sending back of foodstuffs of animal origin by wholesale and retail points of trade to production facilities, except for in the cases referred to in Art. 19 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of the food law, establishing the European food safety authority and laying out procedures in matters of food safety, herein after referred to as "Regulation (EC) No. 178/2002".

Section II.
Compulsory administrative measures, imposed during exercising of state veterinary-sanitary control

Art. 252. At a suspicion for deviation from the requirements of safety on raw materials and foods of animal origin or products, obtained from animal by-products, the official veterinaries:

1. shall impose a written temporary ban and leave under a responsible keeping the raw materials and foods of animal origin and the products, obtained from animal by-products in a warehouse of the owner or their consignee;

2. shall carry out an expertise under Art. 240.

Art. 253. (1) Depending on the type and extent of the breaches, indicated in the record or the report referred to Art. 222, para 4, shall be taken some of the following measures:

1. giving of binding instructions for removal the breaches;

2. ban of transportation, trade and placing on the market of raw materials and foods of animal origin and the products, obtained from animal by-products;

3. directing for processing or destruction of raw materials and foods of animal origin and products, obtained from animal by-products;

4. ceasing of a part or the whole activity at the establishments under Art. 221;

(2) The measures under para 1 shall be enforced by the official veterinaries with:

1. a prescription – under item 1;

2. an act of ban - under item 2;

3. an order – under item 3 и 4;

(3) A copy of the acts under para 2 shall be handed to the owner or the user of the establishment or to his representative.

(4) (amend. - SG 30/06, in force from 12.07.2006; amend. – SG 08/11, in force from 25.01.2011) The individual administrative acts under para 2 may be appealed before the director of RFSD under the Administrative procedure code.

(5) The appealing of the acts under para 2 shall not stop their execution.

(6) (amend. – SG 08/11, in force from 25.01.2011) Where imposing the measure under para 1, item 4 the official veterinaries shall place designation signs of the BFSA, by which shall certify the partial or full termination of the activity of the establishment.

Art. 254. (1) Where the owner of the establishment had removed the breaches before the expiry of the prescribed period indicated in the prescription, he shall in writing inform the veterinary, who had issued it for carrying out an inspection of the establishment.

(2) Within 3 days after the expiry of the period for removal of the breaches, indicated in the prescription, the official veterinary, who had issued it, shall carry out an inspection at the establishment and in case that the breaches have been removed, shall reflect this in the prescription, putting down a date, signature and stamp.

(3) Where the breaches have not been removed, after expiry of the indicated in the prescription period, the official veterinary within 3 days shall issue an order for stopping that part or the whole activity at the establishment.

Art. 255. After removing of the breaches, indicated in the order under Art. 254, para 2 the owner of the establishment shall submit an application form to the official veterinary, having issued the order for executing the check in the establishment. Where the breaches have been removed, the veterinary within 3 days shall repeal his order putting down on the backside of the act a date, signature and stamp.

Art. 256. The measure under Art. 253, para 1 shall be imposed independently or simultaneously by imposing of an administrative penalty.

Art. 257. (1) The official veterinaries by an order under Art. 253, para 2, item 3 shall direct for destruction raw materials and foods of animal origin, animal by-products and products, obtained from them, where:

1. they find out, that they are unfit for consumption or dangerous to the human and/or animal health;

2. they find out, that these are of unknown origin;

3. they find out, that these are imported in violating the requirements of Art. 61;

4. an official information is received, that these are dangerous to the human and/or animal health;

5. (new - SG 31/06, in force from 01.05.2006) they find out these are produced in sites which are stopped from operation according to the order of this Act or of the Foodstuffs Act or in sites not registered according to the order of the Foodstuffs Act;

6. (new – SG 7/13, suppl. - SG 14/16, in force from 19.02.2016) raw materials and foodstuffs are produced from animals, bred in facilities, which are not registered under Art. 51 or with the

provision of Art. 137.

(2) In the cases under para 1 the official veterinary shall draw a record, wherein shall describe the type, the quantity, the number and other characteristics of the establishments, subjected to a destruction.

(3) The record is an indispensable part of the order under para 1.

Art. 258. The losses and missed benefits from the imposed ban for non-following the veterinary medical requirements shall be charged to owners of the establishments, subject to control.

Chapter ten.
DISPOSAL, STORAGE, TRANSPORTATION AND DESTRUCTION OF ANIMAL BY-PRODUCTS (IN FORCE FROM 1.01.2006Г.)

Art. 259. (in force from 1.01.2006г.) (1) (amend. – SG 08/11, in force from 25.01.2011) Disposal of animal by-products and of products, obtained from them shall be executed in establishments, registered in RFSD.

(2) (amend. – SG 08/11, in force from 25.01.2011) Storage of animal by-products and of products, obtained from them shall be executed in establishments, registered in RFSD.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) Regardless of the cases under para 1 disposal of animal by-products and products, obtained from them as well as specific risk materials shall be executed under the conditions and a procedure which exclude the risk for the people and the environment, determined by an Ordinance by the Minister of Agriculture, Foods and Forestry.

Art. 259a. (New - SG 14/16, in force from 19.02.2016) (1) Disposal of animal by-products and of products, derived from them, can be carried out if necessary in incinerators and co-incinerators, registered in the RFSD.

(2) Installations under par. 1 may be stationary or mobile and shall meet the conditions, set out in Annex III, Chapter II, Section I of Regulation (EU) № 142/2011 of the Commission of 25 February 2011 implementing Regulation (EC) № 1069/2009 of the European Parliament and of the Council laying down health rules concerning animal by-products and derivatives, not intended for human consumption, and implementing Council Directive 97/78/EC with regards to certain samples and items exempt from veterinary border checks under said Directive (OB, L 54/1 of 26 February, 2011), hereinafter referred to as "Regulation (EU) № 142/2011".

(3) Mobile installations shall be registered in the RFSD, on which territory the seat of their owner or operator is located.

(4) In the mobile installations can be disposed animal by-products and products, derived from them, throughout the country of the whole country in compliance with the requirements of Regulation (EC) № 1069/2009.

(5) The owners or operators of mobile installations shall notify in writing the director of the RFSD, on which territory they shall operate, 24 hours prior to disposal of animal by-products and of products, derived from them on that territory.

Art. 260. (1) (In force from 1.01.2006, former text of Art. 260 - SG 14/16, in force from 19.02.2016) The assessment of the projects for the establishment or reconstruction of establishments in which the disposal of animal by-products and the introduction into exploitation shall be carried out

under Art. 142 of the Spatial Development Act and in compliance with the veterinary-medical requirements, indicated by the Ordinance under Art. 66, para 2.

(2) (New - SG 14/16, in force from 19.02.2016) The requirements under par. 1 shall not apply to installations of Art. 259a.

Art. 261. (In force from 1.01.2006г.) (1) The utilization of the establishments under Art. 259, para 1 and 2 shall be permitted in compliance with Art. 177 of the Spatial Development Act.

(2) (amend. – SG 08/11, in force from 25.01.2011) Where the establishment is to undergo a state acceptance by a state accepting commission a representative from the RFSD shall be included in it.

(3) (amend. – SG 08/11, in force from 25.01.2011) Where the establishments are not to undergo a state acceptance by a state accepting commission their introduction to exploitation shall be carried out after presenting of an opinion of the respective RFSD.

Art. 262. (In force from 1.01.2006) (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016, amend. – SG 17/18, in force from 23.02.2018) A trader who shall carry out the disposal of animal by-products or the storage of such products shall submit an application form, conformed to a specimen, indicating the activity of the establishment to the director of the respective RFSD a template application for registration of an object under Art. 259, Para. 1 or 2 and of an installation under Art. 259a, Para. 1. The application shall be filed personally, by proxy, by electronic means under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall indicate the activity in the site, the UIC of the merchant under the Commercial Register Act and the register of the non-profit legal entities, and shall be accompanied by:

1. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

2. (suppl. - SG 14/16, in force from 19.02.2016) copy of the act for introduction of exploitation of the establishment, issued under the Spatial Development Act. This document shall not be attached to the registration of an installation under Art. 259a, para. 1;

3. copy of the document of right of property or right of use of the establishment

4. (suppl. – SG 17/18, in force from 23.02.2018) a document of paid fee at the amount, specified in the tariff under Art. 14, para 2, when the payment is not made electronically.

(2) (amend. – SG 08/11, in force from 25.01.2011) Within 7 days from the filing of the application form the director of RFSD shall appoint by an order a Commission, that shall carry out checking of the documents under para 1 and execute conformity check of the establishment with the presented documentation and the veterinary-medical requirements as well as the technological documentation for disposal, respectively storage of animal by-products as well as the self–control system and prepare a record, conformed to a specimen concerning the results of the check.

(3) In the presence of incompleteness and irregularity of the documents under para 1 the Commission shall inform in writing the applicant and determine a term for the removal of them.

(4) (amend. – SG 08/11, in force from 25.01.2011) Within 30 days from the submission of the application form or from the expiry of the term under para 3, the director of RFSD shall enter the establishment for disposal, respectively storage of animal by-products in register and issue a registration certificate or duly substantiated refuse a registration when the establishment does not meet veterinary-medical requirements, determined by the Ordinance under Art. 66, para 2.

(5) (amend. - SG 30/06, in force from 12.07.2006) The refusal under para 4 may be appealed under the Administrative procedure code.

Art. 263. (In force from 1.01.2006г.) (1) (amend. - SG 14/16, in force from 19.02.2016) The registration of establishments under Art. 259, para. 1 and 2 and of the installations under Art. 259a para. 1 shall be indefinite.

(2) (suppl. - SG 14/16, in force from 19.02.2016) The registered establishments and installations shall receive veterinary registration numbers to be entered in the register and in the certificate of registration.

Art. 264. (In force from 1.01.2006, suppl. SG 14/16, in force from 19.02.2016, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the establishments and installations for the disposal of animal by-products and for the storage of animal by-products which shall contain:

1. number and date of issue of the registration certificate;
2. veterinary registration number of the establishment;
3. trader's data;
4. type, activity, capacity and location of the establishment;
5. changes of the entered circumstances under para 3 and 4;
6. number and date of the order for deletion of the registration.

Art. 265. (In force from 1.01.2006) (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) For each registered establishment under Art. 259, para 1 and 2 and installation under Art. 259a, para. 1, in the RFSD shall be prepared a dossier in which the application form and the documents under Art. 262 and 266 as well as the acts of the accomplished checks and imposed penalties shall be stored.

(2) The dossiers shall be stored for a period of 3 years from the date of termination of the activity of the establishment.

Art. 266. (In force from 1.01.2006) (1) At a change in the technology of the production, the equipment and/or a reconstruction of the building under Art. 259, para 1 and 2 the entered in the register trader within 7 days shall submit an application form under Art. 262.

(2) (amend. – SG 08/11, in force from 25.01.2011) At a change of the entered in the register trader the new owner or user of the establishment shall submit an application form within 7 days to the director of RFSD, attaching to it the document, certifying the change.

(3) In the cases of para 2 a registration certificate shall be issued without applying the procedure under Art. 262.

Art. 267. (In force from 1.01.2006) (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) The registration of the establishment under Art. 259, para 1 and 2 and of an installation under Art. 259a para. 1, shall be deleted and the certificate invalidated by a duly substantiated order, issued by the director of RFSD at:

1. request of the entered in the register trader;
2. change of the purpose of the establishment;
3. gross and systematic penalties of the normative requirements;
4. systematic penalties of the hygienic requirements and the self-control system;
5. non-execution of a compulsory administrative measure.

(2) (amend. – SG 08/11, in force from 25.01.2011) Within 3 days from the setting in of a circumstance under para 1, item 1 and 2 the entered in the register trader shall submit an application form to the director of RFSD.

(3) (amend. – SG 08/11, in force from 25.01.2011) Within 3 days from the submission of the application form under para 2 the director of RFSD by an order shall delete the registration of the establishment and shall mark it in the register.

(4) (amend. - SG 30/06, in force from 12.07.2006; amend. – SG 08/11, in force from 25.01.2011) The order of the director of RFSD for the deletion of registration in the cases of para 1, item 3, 4 and 5 may be appealed under the Administrative procedure code.

Art. 268. (In force from 1.01.2006г.) At establishment of penalty of the normative requirements respectively Art. 253 or 254, para 3 shall be applied.

Art. 269. (In force from 1.01.2006; amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) The Bulgarian Food Safety Agency shall inform the Member States and the European Commission regarding the establishments and installations, entered in the register under Art. 264, as well as regarding the establishments and installations, which registration is deleted.

Art. 270. (In force from 1.01.2006г.) (1) The persons, carrying out activity in establishments under Art. 259, para 1 and 2:

1. shall implement a self-control system;

2. shall appoint specialists who are responsible for the self-control system and periodically summarize and analyze the results;

3. shall take samples of each batch of the end product for determining of compliance with the indicators, which must be met by the products, indicated in the Ordinance under Art. 66, para 2;

4. shall implement a system of traceability of the movement of each batch of the end product.

(2) Where the results of the sample examinations do not comply with the indicators, set out in the Ordinance under Art. 66, para 2, the person under para 1:

1. immediately shall notify the official veterinary of the type of non-compliance;

2. shall find out the reason of the non-compliance;

3. shall reprocess the batch or destroy it under the control of the veterinary referred to item 1;

4. shall increase the number of the samples taken for testing;

5. shall check the documentation of the received animal by-products, wherefrom the batch has been manufactured;

6. shall take measures for cleaning and disinfection of the establishment.

Art. 270a. (New - SG 14/16, in force from 19.02.2016) The owners or operators of installations under Art. 259a, para. 1 shall:

1. introduce a system of self-control;

2. identify experts to be responsible for the system of self-control and shall periodically summarize and analyze the results.

Art. 271. (In force from 1.01.2006; amend. – SG 7/13) (1) The Director of the respective RFSD shall permit the usage of animal by-products in cases referred to in Regulation (EC) No. 1069/2009.

(2) (Amend. – SG 17/18, in force from 23.02.2018) Natural persons and legal entities, wishing to use animal by-products shall submit to the Director of the RFSD an application in a standard form, with attached payment slip of a fee, determined by the tariff under Art. 14, par. 2, when the payment is not made electronically. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed

postal operator.

(3) The RFSD Director by an order shall appoint a commission to inspect the facility for compliance with the requirements of Regulation (EC) No. 1069/2009.

(4) In case of identified inconformity with the requirements of Regulation (EC) No. 1069/2009 the commission shall issue written directions to the applicant for their elimination and shall allocate a time period thereof.

(5) Upon elimination of inconformity, the applicant shall notify in writing the RFSD Director and the commission under par. 3 shall re-inspect the facility.

(6) The commission shall submit to the Director of the RFSD an opinion with a proposal on permitting the use of animal by-products or a refusal of their use.

(7) Within 30 days from the submission of the application, respectively from the elimination of the blanks, the RFSD Director shall issue a permit in a standard form for the use of animal by-products , indicating the terms and conditions of their use and storage or justified refusal to issue a permit.

(8) The refusal under par. 7 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure.

(9) The RFSD shall maintain a list of issued permits for use of animal by-products, containing:

1. name (name and address) and main office of the person carrying out the activity;
2. location of the facility, where the activity is being carried out;
3. number and date of the issued permit;
4. purpose of use, category and type of the permitted for use animal by-products;
5. number and date of the order for termination or withdrawal of the issued permit.

(10) The Central Administration of BFSA shall maintain a list of the issued permits for use of animal by-products, containing the information from the RFSD lists. The list shall be published on the Internet site of BFSA.

Art. 271a. (new – SG 7/13) The persons having obtained a permit for use of animal by-products, shall maintain a record book, where to register the type, quantity, origin and date of delivery of the products to the site.

Art. 271b. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) Each consignment of animal by-products, which are used in accordance with Art. 271, shall be accompanied by a commercial document in accordance with Regulation (EU) № 142/2011. A copy of the document shall be kept in the establishment of origin, as well as in the destination establishment, for at least two years from the date of issuance.

Art. 271c. (new – SG 7/13) (1) In case of violation of the requirements, related to use of animal by-products under Art. 271, the provisions of Art. 253 and Art. 254, par. 3 shall apply.

(2) By an order of the Director of the respective RFSD the permit for use of animal by-products under Art. 271:

1. shall be withdrawn – in cases referred to in Art. 236, par. 1, items 3, 4, 5 and 6;
2. shall be terminated – in cases referred to in Art. 236, par. 1, item 1 and 2.

(3) The order for withdrawal of the permit under par. 2 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure.

Art. 272. (In force from 1.01.2006, suppl. - SG 14/16, in force from 19.02.2016) Individuals and judicial persons as a result of the activity of which are obtained animal by-products, shall be obliged to keep them in isolated premises, containers or in equipped sites till their delivery for rendering or

storage to the establishments under Art. 259, para 1 and 2, and installations under Art. 259a, para. 1.

Art. 273. (In force from 1.01.2006) (1) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016, amend. – SG 58/17, in force from 18.07.2017) The Minister of Agriculture, Foods and Forestry, on a proposal of the Executive director of the BFSA by an order shall determine the regions of servicing of the registered establishments for storage and rendering of animal by-products.

(2) (suppl. - SG 14/16, in force from 19.02.2016) The persons, carrying out the activities in the establishments under Art. 259, para 1 are obliged to organize the collecting of the animal by-products from their designated areas and from sites under Art. 259, para. 2.

(3) (new - SG 14/16, in force from 19.02.2016) The persons operating in the sites under Art. 259, para. 2, are obliged to organize the collection and storage of animal by-products from their designated areas and shall submit them for disposal at establishments under Art. 259, para. 1.

Art. 274. (In force from 1.01.2006, revoked - SG 14/16, in force from 19.02.2016)

Art. 275. (In force from 1.01.2006; amend. – SG 7/13) (1) (suppl. - SG 14/16, in force from 19.02.2016) Natural persons and legal entities, the activity of which results in production of animal by-products, shall be obliged to deliver them to sites under 259, par. 1 or 2, and installations under Art. 259a, para. 1, except for the cases under Ordinance No. 22 of 2006 for the terms and conditions and the procedure of safe disposal of animal by-products and of derivatives thereof and of specific hazardous materials beyond the facilities, registered in the RVMS.

(2) (suppl. - SG 14/16, in force from 19.02.2016) The persons under par. 1 shall pay the owners, respectively the operators of the sites under Art. 259, par. 1 and 2 and of installations under Art. 259a, par. 1, the cost of collection, transportation, safe disposal and storage of the animal by-products at prices agreed between them.

(3) (suppl. - SG 14/16, in force from 19.02.2016) The owners, respectively the operators of facilities for safe disposal of animal by-products shall be obliged to deliver the produced from the safe disposal products for destruction or utilization according to Regulation (EC) No. 1069/2009. The cost of destruction or utilization shall be agreed upon by and between the owner of the safe disposal facility and the owner of the facility for products destruction or utilization.

(4) (amend. - SG 14/16, in force from 19.02.2016) At the expense of the state budget shall be the costs for:

1. collection, transportation, storage and disposal of dead animals from livestock sites, registered under this Act;

2. collection, transportation, storage and disposal of dead animals and of animal by-products, derived from the slaughter of animals in facilities for personal needs only;

3. collection, transportation, storage and disposal of animals under Art. 141, para. 1, as well as of germ products, raw materials and foodstuffs of animal origin, animal by-products and derivatives thereof under Art. 141, par. 2, except for the cases under Art. 142, par. 1, the expenses for which shall be at the expense of the animals owners.

(5) (amend. - SG 14/16, in force from 19.02.2016) The costs to perform the services under para. 4, items 1 and 3 shall be provided in the form of state aid through the State Fund "Agriculture".

Chapter eleven.
VETERINARY MEDICAL PRODUCTS

Section I.
Use of veterinary medical products (VMP)

Art. 276. (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) (1) In the Republic of Bulgaria shall be imported, traded, stored and used VMP, licensed for use subject to the provisions of this Chapter or according to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, herein after referred to as "Regulation (EC) No. 276/2004".

(2) The requirements under par. 1 shall apply also to medicinal premixes, produced in industrial conditions or by a method, including an industrial process.

(3) Where in consideration of the properties of a particular product there is a doubt whether this is a VMP or not, because it falls under the definition of § 1, item 9 of the Supplementary provisions, but falls within the scope of definition of products, provided in another regulatory acts, the requirements of this Chapter shall apply to this product.

(4) The requirements of this Chapter

Use of veterinary medical products in the country shall be carried out after issuing of a license by the BFSA. Shall apply also to active substances, used as an initial raw materials for production of VMP and particular substances in the content of VMP with anabolic, anti-infection, anti-parasitic, anti-inflammatory, hormonal or psychotropic effect.

(5) Where upon issuing of a license for use of VMP any changes occur, related to the species of animals, for which the product is meant, the concentration, pharmaceutical form, method of administration or any other changes, the provision of Art. 314 shall apply.

(6) The license holder for VMP use shall be held responsible for the offering of VMP on the market, including n cases where they have nominated their representative.

Art. 277. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Executive director of the BFSA shall issue a license of use of VMP, intended for productive animals, if its active substance/s meet the requirements for maximum acceptable limits of residue substances of VMP, determined by the Regulation (EC) No. 37/2010.

(2) (amend. – SG 7/13) An application form for the issuing of a license of use of VMP, intended for one or more types of productive animals which pharmacologically active substances for these animals are not included in Table 1 "Permitted substances" of theAnnex of Regulation (EC) No. 37/2010 and for which there is no submitted application form for the determining of the maximum acceptable limits of residue substances of VMP in raw materials and foods of animal origin.

(3) An application form for the issuing of a license of use of VMP under para 2 may be submitted not earlier than 6 months from the filing of an application to the European Medicines Agency which shall contain proofs of established maximum acceptable limits of residue substances of VMP in raw materials and foods of animal origin.

(4) (amend. – SG 08/11, in force from 25.01.2011; amend. and suppl. – SG 7/13) in case of amendment of the Annex of Regulation (EC) No. 37/2010 the Executive director of the BFSA shall issue an order by which shall amend or terminate the license of use of VMP respectively within 60 days of the amendment.

(5) (suppl. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) By an exception a license of use of VMP regarding to definite equidae animals, kept for breeding purposes and not intended for human consumption according to Regulation (EC) No. 2015/262 shall be issued under the following conditions:

1. (amend. – SG 7/13) their pharmacologically active substances are not included in Table 1 "Permitted substances" of Annex I of Regulation (EC) No. 37/2010;

2. (amend. – SG 7/13) do not contain active substances, included in Table 2 "Forbidden substances" of the Annex of Regulation (EC) No. 37/2010;

3. are not intended for cure of the illnesses of equidae animals, indicated in the short characteristics of another licensed of use of VMITEM

(6) (amend. – SG 7/13) An application form for the issuing of a license of use of VMP under para 5 may be submitted without meeting the requirements of Regulation (EC) No. 37/2010 in case that a documentation that proves the quality, safety and efficiency of VMP is presented.

Art. 278. (amend. – SG 7/13) License of use of VMP shall be issued by the Managing Director oaf BFSA to an individual or a legal entity, based in the territory of a Member State.

Art. 279. (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) For issuing of a license of use of VMP the persons under Art. 278 shall submit an application form, conformed to a specimen to the Executive director of the BFSA, indicating the UIC under the Act On The Commercial Register And The Non-Profit Legal Entities Register, or the BULSTAT code. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) a certificate of valid registration, issued by a competent body of another state, where applicable;

2. registration dossier of VMP which shall contain:

a) (suppl. – SG 7/13) part one – administrative data, short characteristics of the product, prototype of its primary and exterior packing and information leaflet and expert's reports to the documentation referred to letters "b"–"d";

b) part two - physical-chemical, pharmaceutical, microbiological and biological documentation;

c) part three – data on safety and residue quantities;

d) part four - ante clinical and clinical documentation

3. samples of VMP, standard substances for medicinal VMP, reference strains, toxins and sera of immunological VMP, sufficient for carrying out of 3 examinations;

4. (amend. – SG 7/13) copy of manufacturing license or a contract with a licensed manufacturer of VMP and/or active substances, where the person referred to Art. 278 is not a manufacturer, or a contract with a licensed wholesaler in VMP and/or active substances, in cases where the person referred to in Art. 278 is not a wholesaler and VMP or active substances are manufactured in a Member State;

5. (suppl. – SG 7/13) data on the qualified person under Art. 295 – name, address and professional qualifications and declaration by the qualified person under Art. 353, that the active substances included in the composition of the VMP are manufactured subject to compliance with the good manufacturing practice requirements;

6. (new – SG 7/13) copy of Good manufacturing practice certificate;

7. (prev. item 6 – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) a document of paid fee at the amount, specified in the tariff under Art. 14, para 2 when the payment is not made electronically.

Art. 279a. (new – SG 7/13) The documents under Art. 279, item 2 shall be submitted on a hard copy or on an electronic storage device, except for the brief product description, its primary and exterior packing and the information leaflet which shall be submitted on an electronic storage device.

Art. 280. (1) (amend. – SG 7/13) The applicant is not obliged to present results of examinations on safety and maximum acceptable limits of residue substances of VMP or results of ante clinical and

clinical examinations when he has presented proofs that VMP, indicated in the application form is generic to a reference VMP which is licensed or has been licensed in a Member State for minimum eight years.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. and suppl. – SG 7/13) The applicant shall indicate in his application form in which Member State the reference VMP has obtained a license. The Executive director of the BFSA shall require from the competent authority of the Member State to submit within one month a confirmation that the reference VMP possesses or has possessed a license of use in this State, full composition of the reference VMP and if necessary – any other complementary documentation.

(3) (amend. – SG 08/11, in force from 25.01.2011) The procedure under para 2 shall be applied in the cases where a competent authority of the Member State requires a confirmation in writing by the BFSA.

(4) (amend. – SG 7/13) A license of use of a generic VMP prior to expiration of 10 years from the date of initial issue of the license of use of the reference VMP, and for VMP intended for fish and bees or other animal species, determined by the European Commission, this time period may be extended up to 13 years by a decision of the European Commission.

(5) The different salt, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance of VMP shall be considered as an identical active substance besides if they do not differentiate substantially regarding to safety and efficiency. At substantial differences to the application form shall be presented proofs of the safety and the efficiency of the separate salts, esters or derivatives of the active substance, included in the composition of the licensed of use VMITEM

(6) (amend. – SG 7/13) The different per oral pharmaceutical forms with an immediate action shall be considered as one and the same pharmaceutical form. The applicant shall not present the results of examinations of bioavailability if he has proven that VMP is generic to a reference VMP.

(7) (amend. – SG 7/13) The applicant shall present data, pre-clinical and clinical tests in cases, where a biological VMP, similar to the reference biological VMP complies with the definition of a generic VMP due to a difference regarding the input raw materials or the manufacturing processes of the biological VMP and these of the reference VBP. The type and quantity of additional information to be presented by the applicant must meet the respective criteria according to the ordinance referred to in Art. 284. The results of other tests and trials, indicated in the file of the reference product, shall not be presented.

(8) (amend. and suppl. – SG 7/13) At VMP intended for productive animals with new active substance which has not been included in the composition of a licensed of use VMP in a Member State till 30 April 2004, the 10-year time limit under para 4 shall be prolonged with one year for each extension of the scope of the license of use regarding to other types of productive animals, if the extension has been done till the 5-th year of the issuing of the initial license. This term cannot be longer than 13 years for VMP intended for four or more species of productive animals.

(9) (amend. – SG 7/13) The prolongation of the time limit under para 8 shall be admitted only if the owner of the license of use of the reference VMP initially has applied for determination of maximum acceptable limits of residue quantities of VMP for the types of animals for which it is intended.

(10) (amend. – SG 7/13) The applicant shall present personal data of safety examinations, maximum acceptable limits of residue quantities of VMP, of ante clinic and clinic examinations, where the VMP is not generic or where bio equivalence cannot be proven by examination of bioavailability or at a change of an active substance respectively of the active substances, therapeutical indicators, the activity, pharmaceutical form or the mode of application.

(11) Where VMP contains active substances which shall be included in the composition of a licensed of use VMP, but they are not used in combination for therapeutical purposes, analyses methods, the results of safety examinations and the residue quantities of VMP, of ante clinic and clinic examinations shall be represented, regarding to this combination.

(12) The owner of a license of use of VMP may permit use of the documentation of pharmaceutical examinations, safety examinations and residue quantities of VMP, ante clinic and clinic examinations, included in the dossier of VMP at the submission from other person of an application form of issuing of a license of use of VMP which has the same quantity and quality composition of the active substances and one and the same pharmaceutical form.

(13) At complicated epizootic circumstances the applicant is not obliged to present in the registration dossier the results of the field tests with immunological VMP beyond animals for which the product is intended if these tests could not be carried out due to justified reasons.

(14) (amend. – SG 7/13) Carrying out of required examinations and tests, related to the product, for compliance with the requirements of par. 1 – 10, shall not be considered violation of patent rights or of the extra protection certificate.

Art. 281. (1) (amend. – SG 7/13) The applicant shall not be obliged to present the results of the safety examinations and the residue quantities of VMP or the results of ante clinic and clinic examinations where he could prove that the active substances of VMP have an approved at least ten-year use in a Member State, they have recognized efficiency and acceptable safety level and provided that the legislation related to industrial and commercial property protection is not infringed. In this case the applicant may present appropriate data for scientific publications.

(2) (suppl. – SG 7/13) In the cases under para 1 as a proof may be used in the part of safety and residue quantities of VMP and the published in the European drugs agency report for established maximum acceptable limits of residue quantities of VMP in compliance with Regulation (EC) No. 37/2010.

(3) (suppl. – SG 7/13) Where the applicant uses scientific publications for a definite type of productive animals to obtain a license of use of VMP and for another type of productive animals he presents results of personal examinations regarding to residue quantities of VMP according to Regulation (EC) No. 37/2010 and the results of clinic examinations of VMP for this type.

(4) The results under para 3 may not be used from third parties before the expiry of 3 years from the submission of the license of use.

Art. 281a. (new – SG 7/13) (1) For licensing of homeopathic VMP, intended for productive animals special simplified procedure shall apply, where:

1. they are applied in a way, described in a monograph of European pharmacopeia, and where it is not available – in other pharmacopeias of Member States;

2. on the label, packing of VMP or any other information related to the product there is no specific therapeutic indication;

3. they are distributed in a sufficient degree, which shall guarantee product safety, and the homeopathic VMP does not contain more than one ten-thousandth share of the mother tincture.

(2) The requirements for issuing of a license under Art. 279 shall apply to VMP under par. 1, except for the requirements of Art. 291, par. 1 – 4, and also the requirements for provision of evidences of therapeutic effect.

(3) The requirements of Regulation (EC) No. 37/2010 shall apply to homeopathic VMP intended for productive animals.

Art. 282. (1) (amend. – SG 7/13) Simplified procedure shall apply for issuing of a license for use of a series of homeopathic VMP, obtained from one and the same homeopathic reserve respectively homeopathic reserves, whereby an application form under Art. 279 shall be submitted.

(2) (amend. – SG 7/13) For substantiation of the quality of a homeopathic VMP and the batch homogeneity, the documents referred to in Art. 279, items 1, 3 – 6 shall be attached to the application, and also the registration file, containing:

1. (amend. – SG 7/13) scientific or other name of homeopathic reserve respectively homeopathic reserves, indicated in pharmacopeia, methods of application, pharmaceutical forms and extent of dilution;

2. a description of an origin and the mode of control of homeopathic reserve respectively homeopathic reserves, bibliographic reference regarding to the homeopathic nature and the containing biological substances homeopathic VMP – also a description of the measures of not admitting of pollution with pathogens;

3. a description of the production and control for every pharmaceutical form, the mode of dilution and increasing of the action;

4. (amend. – SG 7/13) a copy of a production license or a contract with a licensed manufacturer of the respective homeopathic VMP;

5. copy of licensing documents of use, issued for the same VMP in another Member State, if there is such a State;

6. one or more scale models of the outer and the initial package of the VMP which shall be licensed;

7. data for VMP stability;

8. the defined grounded time limit of withdrawal.

(3) (amend. – SG 7/13) Application of homeopathic VMP shall be allowed also in the cases referred to in Art. 322.

(4) (amend. – SG 7/13) Application of homeopathic VMP shall be allowed also in the cases referred to in Art. 323, where their active substances are included in Table 1 “Permitted substances” of the Appendix of Regulation (EC) No. 37/10.

(5) (new – SG 7/13) The provisions of Section V, Section VI and Section VII of this Chapter shall apply to homeopathic VMP .

Art. 282a. (new – SG 7/13) The provisions of Art. 281a and 282 shall not apply to immunologic homeopathic VMP.

Art. 282b. (new – SG 7/13) Homeopathic VMP, except for these, referred to in Art. 281a, apr. 1 shall be licensed for use subject to compliance with the provisions of Art. 279, Art. 280, par. 11 – 13.

Art. 283. (amend. – SG 08/11, in force from 25.01.2011; revoked – SG 7/13).

Art. 284. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The requirements to the data which the documentation of the issuing of license of use of VMP shall be regulated by an Ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 285. (1) (amend. – SG 08/11, in force from 25.01.2011) At the BFSA an expert assessment of the dossier and the qualities of VMP shall be prepared.

(2) (amend. – SG 08/11, in force from 25.01.2011) At the assessment of the dossier the BFSA

shall:

1. (amend. – SG 7/13) shall carry out conformity check of the applied documentation with the requirements, indicated in the Ordinance under Art. 284;

2. shall explore the end product and at necessity the middle product or the raw materials of VMP for the confirmation of analyses methods, used by the manufacturer and described in the dossier;

3. may require from the applicant additional written information where establishes inaccuracy and/or incompleteness of the dossier;

4. may require from the applicant to present substances in the necessary quantities for the confirmation of the analyses method for finding out of residue substances of VMITEM

(3) (new – SG 7/13) For carrying out the analyses for the preparation of an assessment under para 1 the applicant shall pay a fee in an amount, specified in the tariff under Art. 14, para 2.

(4) (amend. – SG 8/11, in force from 25.01.2011, revoked, prev. par. 3, suppl. – SG 7/13) In cases referred to in par. 2, items 3 and 4 BFSA shall notify the applicant in writing. The term under art. 288, par. 1 shall stop elapsing from the date of the notification until confirmation of the analytical method and/or provision of the requested information or substance but not later than within 180 days.

(5) (new – SG 7/13) In cases of par. 4, where the applicant fails to submit the requested information and/or substances within a period of 180 days after the date of receipt of the written notification, the Managing Director of BFSA by an order shall terminate the procedure of issuing of a license and shall notify the applicant thereof in writing.

(6) (new – SG 7/13) The order under par. 5 shall be communicated and maybe appealed according to the provisions of the Code of Administrative Procedure. The appealing shall not suspend the execution.

(7) (new – SG 7/13) In cases of par. 5 an application for issuance of a license for use of VMP may be submitted according to the provision of Art. 279.

(8) (New – SG 17/18, in force from 23.02.2018) Where the tests under Para. 2, item 2 can not be performed in a laboratory of the BFSA, within 45 days from the filing of the application under Art. 279, the BFSA's Executive Director shall notify the applicant in writing and send the test samples to an official laboratory for the control of veterinary medical products (VMP) within the territory of the European Union.

(9) (New – SG 17/18, in force from 23.02.2018) The costs of sending the samples and carrying out the tests under Para. 8 shall be at the expense of the applicant.

Art. 286. (1) (amend. – SG 08/11, in force from 25.01.2011) Specialized commissions with the statute of permanently acting consultative authorities shall be established to the Executive director of the BFSA, as follows:

1. Commission on medicinal VMP (CMVMP);

2. Commission on immunological VMP (CIVMP).

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. and suppl. – SG 82/12) The Executive director of the BFSA by an order shall apitem the membership of the commissions and shall approve the rules of work of these. This order shall establish the remuneration of commission members, unless the law provides otherwise.

(3) The members of the specialized commissions:

1. shall be obliged to keep secret the data of the dossier of the VMP proposed for licensing for use at least for 5 years after termination of his membership in the commission;

2. shall not use the documents data for their or third persons benefit;

(4) (amend. – SG 08/11, in force from 25.01.2011) For the circumstances under para 3, the members of the commissions shall sign a declaration conformed to a specimen, that shall be submitted to the Executive director of the BFSA. The Executive director shall keep the declaration for a period of 5

years from the date of the termination of the membership in the commissions.

Art. 287. (1) The respective commission, on the basis of the documentation presented under Art. 279 и Art. 282, para 2 and the expert assessment under Art. 285, para 1, shall draw up a position on the application for issuing a license for use of VMITEM

(2) Where drawing up a position the commission:

1. shall require from the applicant additional written information, where discrepancies and/or incompleteness are found in the dossier ;

2. shall propose, if necessary, the carrying out of additional laboratory and/or clinical examinations.

Art. 288. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Within 210 days after the submission of the application under Art. 279 the Executive director of the BFSA, based on the position of the respective specialized commission, shall issue a license for use of VMP conformed to a specimen or shall justify the refusal for not issuing a license.

(2) (amend. – SG 08/11, in force from 25.01.2011; revoked – SG 7/13).

(3) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA shall refuse issuing a license for use of VMP under para 1, when:

1. the registration dossier does not correspond to the requirements;

2. (suppl. – SG 7/13) the ratio advantage/risk during the use of VMP is not favourable under the terms and conditions of use, under which the license is issued;

3. (new – SG 7/13) the ratio advantage/risk during the use of VMP, intended, intended for zoo-technical use, is unfavourable for animals' health, the human approach to them and consumers' safety;

4. (prev. item 3 – SG 7/13) the VMP does not possess the diagnostic, prophylactic or medical effect for the animal species for which it is intended, or the presented proof by the applicant is not sufficient;

5. (prev. item 4 – SG 7/13) the quantitative and qualitative composition of the VMP do not correspond to the indicated in the dossier;

6. (prev. item 5, amend. – SG 7/13) the specific withdrawal time, proposed by the applicant is insufficient to guarantee, that the foodstuffs, produced from the treated animals, do not contain residues of VMP, which could be potentially dangerous for consumer's health or no enough proofs of this term have been provided;

7. (prev. item 6 – SG 7/13) the proposed label on the packaging and the leaflet offered by the applicant do not comply with the requirements.

8. (prev. item 7, suppl. – SG 7/13) the use of the VMP is forbidden by an administrative or a regulatory act.

(4) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Executive director of the BFSA may refuse issuing of a license of use for the products under para 1 and where amendments of the European Union acts are scheduled, related to imposition of restricting measures and this is required for humans and animals health protection.

(5) (amend. - SG 30/06, in force from 12.07.2006) The refusal under paras 3 and 4 may be appealed under the Administrative procedure code.

Art. 288a. (new – SG 7/13) (1) Under exceptional circumstances and upon consultation with the applicant the Managing Director of BFSA shall issue a license for use of BMP, provided that the

applicant applies specific procedures for VMP safety, for notification of BFSA of any accident, related to its use, and for undertaking of relevant measures. Such license shall be issued only in case of existing objective reasons which can be verified.

(2) The terms and conditions under par. 1 shall be recorded in the license and in the register under Art. 290.

(3) Annually BFSA shall assess the compliance with the terms and conditions, under which the license has been issued. Where the assessment is negative, the Managing Director of BFSA by an order shall terminate the license.

(4) The order under par. 3 shall be communicated and may be appealed following the provisions of the Code of Administrative procedure. The appeal shall not suspend the execution.

Art. 289. (in force from January 1, 2007) (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. – SG 7/13) The Executive director of the BFSA does not process an application for issuing a license for use of VMP when ascertained that such a license has been applied for in another member state and he notifies the applicant that in this case a procedure for mutual recognition of licenses for use of VMP or a decentralized procedure is being applied.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. and suppl. – SG 7/13) The Executive director of the BFSA does not process an application for issuing a license for use of VMP when notified that such a license has been issued in another member state, except for the cases where the application has been submitted subject to compliance with the procedure for mutual recognition of licenses for use of VMP or a decentralized procedure.

Art. 290. (1) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the issued licenses for use of VMP under Art. 288, para 1 containing:

1. the number and date of issue of the license;

2. the name of VMP, pharmaceutical form, quantity of the active substance and quantity of VMP in one package ;

3. name/name, address/main office and address of management of the holder of the license;

4. code under ATC;

5. expiry date of VMP;

6. administering regime of VMP;

7. withdraw period;

8. number and date of the position of the respective specialized commission for issuing of license for use of VMP;

9. number and date of issue of the order of suspension of the license of use for VMP;

10. remarks on entered circumstances .

(2) (revoked – SG 7/13).

Art. 291. (1) (amend. – SG 08/11, in force from 25.01.2011) An approved short characteristic of the VMP shall be attached to the license by the Executive director of the BFSA when the license is issued.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall fill in the register under Art. 290 the issued license for use along with a short characteristic of the VMITEM

(3) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) After issuing a license for use the Bulgarian Food Safety Agency shall prepare an

assessment report of the dossier according to the results from the pharmacological tests, safety and residues tests of the product, pre-clinical and clinical tests and submits it to the Executive director of the BFSA. The report shall be modified with information crucial for the quality, safety and efficiency of the VMITEM

(4) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; amend. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The report under para 3 shall be published on the Internet site of the Ministry of Agriculture, Foods and Forestry without the confidential information contained therein.

Art. 292. (1) The license for use of VMP under Art. 288, para 1 is issued for a period of 5 years.

(2) (revoked – SG 7/13).

(3) The license under para 1 can be renewed after its expiry according to a second assessment of the ratio advantage/risk.

(4) (amend. and suppl. – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) For renewing the license its holder, at least 6 months before expiry of the term under para 1, shall submit a consolidated list of all submitted documents, related to the quality, safety and efficiency of the VMP, possible changes after the issue of the license, up to date report for safety for the term of validity of the license, which includes an assessment of the ratio advantage/risk from the use of VMP and a document for a paid fee, determined in the tariff under Art. 14, par 2, when the payment is not made electronically. The Managing Director of BFSA may at any time to require from the applicant to submit the documents itemized in the list.

(5) (amend. – SG 08/11, in force from 25.01.2011) The renewed license shall not be limited unless the Executive director of the BFSA decides to renew it for a 5 year period due to reasons connected to pharmacological vigilance.

(6) The license for use of VMP shall be suspended when the VMP is not on the market 3 years after the issue of the license.

(7) The license for use of VMP shall be suspended when the VMP is not market for 3 consecutive years.

(8) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA may exclusively by an order allow the use of VMP under paras 6 and 7 when this is necessary for the protection of human and animal health.

(9) (suppl. – SG 7/13) By expiry of the license period of use of VMP under Art. 288, para 1, the trade and use of VMP shall be prolonged till the exhaustion of the available quantities, supplied prior to expiration of the term of validity of the license, but not for more than one year.

Art. 293. (1) (suppl. – SG 7/13) The holder of license for use of VMP shall be obliged to introduce innovations and changes in accordance with the achievements of the science and technical progress, in order to update the manufacturing methods and the methods of analysis required for the production and control of VMP following general scientific methods.

(2) (new – SG 7/13) The changes referred to in par. 1 shall be approved by the Managing Director of BFSA.

(3) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 2 – SG 7/13) In the cases under para 1 the Executive director of the BFSA may require from the applicant or the holder of a license for use to submit substances in the necessary quantities for the purpose of control for the presence of residues of VMITEM

(4) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 3 – SG 7/13) Upon request from the Executive director of the BFSA the holder of the license for use of VMP shall render technical and

practical assistance for facilitation of the analytical method for detection of residual quantities of VMP in the national referent laboratory.

Art. 294. (1) The license holder for use of VMP immediately:

1. (amend. – SG 08/11, in force from 25.01.2011) submits to the Executive director of the BFSA any new information that can alter data or documents under Art. 279 and 280;

2. (amend. – SG 08/11, in force from 25.01.2011) notifies the Executive director of the BFSA for any ban or restriction imposed by the competent authorities of another country, in which a license for use of VMP has been issued, as well as any other new information that can impact the assessment of the ratio advantage/risk in the use of VMITEM

(2) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA may at any time inquire from the license holder for use of VMP to submit data that proves the ratio advantage/risk remains positive.

Art. 295. (1) (suppl. – SG 7/13) The holder of license for use of VMP shall sign a contract with a qualified person, who shall be in charge of the pharmaceutical awareness system and is based in the territory of a European Union Member State, and:

1. (amend. – SG 7/13) shall develop and maintain a system of collection and processing of the obtained information about any possible adverse reactions, having occurred as a result of application of VMP and shall report to the manufacturer, including to their representatives;

2. (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) shall be responsible for the regular reports on safety, to be sent to the BFSA;

3. (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) shall declare, that the supplied additional information upon BSFA request, necessary for the assessment of the ration advantage/risk in case of application of VMP for the volume of sales of VMP and the prescription for them are complete and true;

4. (amend. – SG 7/13) shall be responsible for the information delivered to the BFSA, relevant to the evaluation of the ratio advantage/risk of the usage of VMP, including information about research, related to market supervision upon issuance of the license for use;

(2) (revoked – SG 7/13).

(3) (revoked – SG 7/13).

(4) (revoked – SG 7/13).

Art. 296. (1) The holder of a license for use of VMP:

1. (amend. – SG 7/13) shall keep documentation about all suspected adverse reactions, related to the use of VMP, found out in Member States or in third countries; under extraordinary circumstances these reactions shall be communicated electronically in a form of a report;

2. (amend. and suppl. – SG 7/13) shall document all suspected serious adverse reactions and adverse reactions in people, relevant to the use of VMP, of which he/she has obtained information or which are suspected that they might occur;

3. (amend. – SG 7/13) shall send a report for the information under item 1 and item 2 to the competent authority of the member state on which territory the adverse reaction had been found not later than 15 days of the date of the receiving of such information;

4. (amend. – SG 7/13) shall guarantee that the information received from another country for all suspected serious unexpected adverse reactions, adverse reactions in humans, and also any suspected transmission of an infectious agent, having occurred in the territory of a third country after the use of

VMP shall be immediately reported and not later than 15 days after receiving the information to the European Drug Agency and to the competent bodies of the Member States, in the territory of which the VMP is licensed for use;

5. (amend. – SG 7/13) shall guarantee that the information about all suspected serious adverse reactions and adverse reactions in humans after the use of high-technology VMP, licensed in the European Union or VMP which are subject to a procedure of mutual recognition or a decentralized procedure, is provided to the competent authority of the referent Member State;

6. presents an up to date report on safety every 6 months after the issue of the license for use of VMP, or immediately on inquiry, based on the reports under ps.3 – 5 that includes a scientific assessment on the ratio advantage/risk from the use of VMP;

7. (amend. – SG 08/11, in force from 25.01.2011) may not distribute information in connection to pharmacological vigilance about the licensed VMP without notifying the BFSA

8. shall maintain a system of blocking and withdrawal from the market of VMITEM

(2) (amend. – SG 08/11, in force from 25.01.2011) The holder of license for use of VMP shall keep the documentation referred to in para 1, item 1 - 3 and 6 at least 5 years and shall present it to the BFSA upon request.

(3) (new – SG 7/13) For submission of the information under par. 1, items 3 – 5 the license holder for the use of VMP must comply with the provisions of the ordinance referred to in Art. 382, par. 6.

Art. 297. (1) (amend. – SG 08/11, in force from 25.01.2011) After the issue of the license for use of VMP the holder notifies the Executive director of the BFSA for the date on which the VMP has been put on the market.

(2) (amend. – SG 08/11, in force from 25.01.2011) The holder of a license for use notifies the Executive director of the BFSA if he temporarily or permanently stops the licensed VMP from putting on the market.

(3) Under exceptional circumstances the notification under para 2 shall be done at least 2 months after the temporary or permanent discontinuation from putting on the market of the licensed VMITEM

(4) (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13) Upon request of the Executive director of the BFSA concerning pharmacological vigilance the holder of a license for use of VMP submits to him data on the volume of sales of the VMP and also the information regarding the number of issued prescriptions.

(5) (amend. – SG 08/11, in force from 25.01.2011) The BFSA officers that have access to the information under para 4 are obliged to keep it confidential and in no way by using it to favour themselves or third persons.

Art. 298. (1) (amend. – SG 7/13) The license holder for use of immunological VMP shall:

1. (amend. – SG 08/11, in force from 25.01.2011) keep representatives samples of each batch of VMP until the end of its expiry and to present them to the BFSA upon request;

2. (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) prior to launching of VMP on the market present for testing and control upon request of BFSA samples of every batch of bulk product and/or the end VM product sufficient for three examinations and accompanied by the documents referred to in item 3 – where this is required for animals and humans health protection;

3. (new – SG 7/13) present upon request by BFSA copies of all documents for VMP batches control, signed by a qualified person, subject to compliance with Art. 353a, par. 1, by which to certify

that the reference tests, carried out with VMP and/or with the active substances and intermediate products of the production process comply with the terms and conditions under which the license for use has been issued.

(2) (amend. – SG 41/10, in force from 01.06.2010; revoked – SG 7/13).

(3) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13).

(4) (new – SG 102/09; revoked – SG 7/13).

Art. 298a. (new – SG 7/13) (1) The Managing Director of BFSA shall inform the competent authorities of the Member States where an immunological VMP is licensed for use, and the European drug quality administration of their intention to control a particular batch or batches of the product.

(2) Where a competent authority of a Member State has informed BFSA of their intention to control a particular batch of batches of an immunological VMP, licensed for use in the Republic of Bulgaria, BFSA shall not carry out control over this batch or batches.

Art. 298b. (new – SG 7/13) (1) Upon assessment of the documents referred to in Art. 298, par. 1, item 3 BFSA shall carry out again all tests of the presented samples according to the methods, indicated in the product file.

(2) Where the Member States where the product is licensed for use, and where necessary in the European drug quality administration, agree, only part of the tests of par. 1 may be carried out.

(3) For immunological VMP, licensed according to Regulation (EC) No. 728/2004, the tests may be reduced upon European drug agency consent.

(4) In cases referred to in par. 1 and 2, where the tests have been carried out by a competent body of a Member State, BFSA shall acknowledge the results of these tests.

(5) The tests under par. 1 shall be carried out within 60 days after receiving of the samples of a batch of immunological VMP, except for the cases, where BFSA has informed the European commission, that a longer period of time is required for their implementation.

(6) The Managing Director of BFSA shall inform within the time referred to in par. 5 the competent body of the Member States in which the product is licensed for use, the European drug quality administration, the license for use holder, and where necessary – the production license holder, about the test results.

(7) Where BFSA finds out that VMP does not comply with the documents referred to in Art. 298, par. 1, item 3 or to the license for use of VMP, the Managing Director of BFSA shall undertake the measures under Art. 317 regarding the license for use holder, and where necessary – regarding the production license holder, and shall inform the competent authorities of the Member States, where the product is licensed for use.

Art. 299. (amend. – SG 7/13) Issuance of a license for use of VMP shall not relieve the manufacturer of the product and the license holder from liability in case of non-compliance with the provisions, provided in this Chapter.

Art. 300. (amend. – SG 7/13) (1) (Suppl. – SG 17/18, in force from 23.02.2018) For small variations of type IA and type IB and for big variations of type II in the scope of a license for use of VMP, laid down in Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use

and veterinary medicinal products (OJ, L 334/7 of 12 December 2008), herein after referred to as "Regulation (EC) No. 1234/2008", the license holder shall submit an application in a standard form to the Managing Director of BFSA, to which they shall attach documents, related to the variations, and also a receipt of a paid fee in an amount, determined by the tariff under Art. 14, par. 2, when the payment is not made electronically. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator.

(2) The related between them variations shall be indicated in the application under par. 1 subject to compliance with the provisions of Art. 7 of Regulation (EO) No. 1234/2008.

(3) Assessment of documents, attached to the application for variations of type IA and type IB following the provisions of Art. 8 and 9 of Regulation (EC) No. 1234/2008 shall be carried out in BFSA.

(4) Based on the assessment under par. 2 the Managing Director within 30 days after the submission of the application shall approve the variation or shall reject the approval with justification.

(5) Where the approved variations require amendment of the content of the license for use of VMP, the Managing Director of BFSA shall issue a supplement to the license and shall register the amendments into the register under Art.290. The amendments of the license for use shall be displayed in the brief description, on the label and the product application leaflet, where necessary.

(6) Where the approved variations do not require amendment of the content of the license for use of VMP, the Managing Director of BFSA shall notify in writing the applicant of their approval and shall attach the documents, related to the amendment in the VMP file.

(7) Assessment of documents attached to the application for variation of type II shall be carried out in BFSA following the provisions of Art. 285 and 287.

(8) The Managing Director of BFSA based on the opinion of the commission under Art. 287 shall approve the variations of type II or shall refuse their approval with justification.

(9) The Managing Director of BFSA shall approve the variations of type II, as follows:

1. within 6o days after the submission of the application, which may be extended to up to 90 days – for the variation referred to in Part 1 of Annex V of Regulation (EC) No. 1234/2008;

2. within 90 days after the submission of the application – for the variations, referred to in Part 2 of Annex V to Regulation (EC) No. 1234/2008;

3. within 60 days – for all other variations.

(10) The Managing Director of BFSA shall:

1. issue a supplement to the license for use of VMP, where the approved variations require amendment of the content of the license, and shall register the amendments in the register under Art. 290; the variations in the license for use shall be displayed in the brief description, on the label and in the product application leaflet, where relevant;

2. notify in writing the applicant of the approval of variations, where the approved variations do not require amendment of the content of the license, and shall attach the documents, related to the variation, in VMP file.

(11) The refusal under par. 4 and 8 shall be communicated and may be appealed according to the provisions of the Code of Administrative Procedure.

Art. 301. (1) (amend. – SG 08/11, in force from 25.01.2011) At small changes of type IA the holder of license for use shall submit to the Executive director of the BFSA an application, whereto shall be attached:

1. the documentation, relevant to the changes;

2. a document for paid fee at an amount, specified by the tariff under Art. 14, para 2.

(2) (amend. – SG 7/13) The requirements to the documentation shall be determined in the ordinances under Art. 284.

Art. 302. (1) For each change of type IA the holder of license of use for VMP shall submit a separate application.

(2) (amend. – SG 08/11, in force from 25.01.2011) Where the holder of the license of use for VMP is to submit to the Executive director of the BFSA several applications for changes of type IA, he shall indicate in each application data on the type of the changes, for which the rest of the applications have been submitted.

(3) Where the applied change of type IA results in following, interconnected changes of the same type, the license holder of use for VMP shall submit one general application, wherein shall indicate the connection between the basic and the related to it changes.

(4) When the change of type IA results in changes in the short characteristics of the product in the label and/or the leaflet, these changes shall be considered as a part of the applied for change of type IA and for these shall not be submitted a separate application.

Art. 303. (amend. – SG 08/11, in force from 25.01.2011) Where the requirements under Art. 301 and Art. 302 are met, in a 14-days period from the submission of the application, the changes shall be approved by the Executive director of the BFSA.

Art. 304. (1) (amend. – SG 08/11, in force from 25.01.2011) For small changes of type IB the holder of the license for use of VMP shall submit an application to the Executive director of the BFSA, whereto shall attach:

1. documents relevant to the change;

2. a document for paid fee at the amount, specified in the tariff under Art. 14, para 2.

(2) (amend. – SG 7/13) The requirements to the documentation shall be determined in the ordinance under Art. 284.

Art. 305. (1) For each change under Art. 304 the holder of license of use for VMP shall submit a separate application.

(2) (amend. – SG 08/11, in force from 25.01.2011) Where the holder of license of use of VMP shall submit to the Executive director of the BFSA at one and the same time several applications of small changes of type IB, he shall indicate in each application data on the type of the changes, for which the rest of the applications have been submitted.

(3) When the requested by the applicant change of type IB in the license of use for VMP is to result in consequent changes of type IA or type IB, the holder of license of use for VMP shall submit one general application, wherein is to be indicated the relation between the basic and the relevant to it changes of type I.

(4) When the changes require a change in the short characteristics of the product, in the label and/or the leaflet, those changes are to accepted as a part of the applied for change of type IB and for those shall not be submitted a separate application.

Art. 306. (1) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) In a period of up to 30 days from the date of submission of the application for variation of type IB the Institute for control of the Bulgarian Food Safety Agency shall review the documentation and shall submit a position to the Executive director of the BFSA on the

requested changes.

(2) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) Where discrepancies and incompleteness are detected in the documentation, the Institute for control of BFSA shall notify the holder of the license for use.

(3) The holder of license for use, in a period of 30 days from the date of receiving of the notification, shall change or complement the documentation. In this case the period under para 1 shall stop running.

(4) Where in the period referred to in para 3, the holder of license of use of VMP do not present the required documentation, the application shall not be proceeded.

(5) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA, on the basis of the position referred to in para 1, shall approve the changes.

Art. 307. (amend. – SG 08/11, in force from 25.01.2011) For changes of type II in the dossier of the VMP the holder of license for use shall submit to the Executive director of the BFSA an application, whereto shall be attached:

1. the parts of the dossier, that contain the changes ;
2. additional or new expert reports, relevant to the change;
3. a document for a paid fee at an amount, specified in the tariff under Art. 14, para 2.

Art. 308. (1) For each change of type II a separate application shall be submitted.

(2) (amend. – SG 08/11, in force from 25.01.2011) When the holder of a license for use of VMP submits to the Executive director of the BFSA several applications for changes of type II, in each of these shall be indicated data of the type of the changes, for which the rest of the applications have been submitted.

(3) Where the requested change of type II is to result in consequent, interconnected changes of the same type, the holder of license of use of VMP shall submit one general application, wherein shall indicate the connection between the basic and the relevant to it changes.

(4) Where the change of type II is to result in a change of the short characteristics of the product, on the label and/or the leaflet, these changes shall be accepted as a part of the applied for change type II and for those shall not be submitted a separate application.

Art. 309. (1) (amend. – SG 08/11, in force from 25.01.2011) In a period of up to 90 days from the date of the submission of the application under Art. 307 the Bulgarian Food Safety Agency shall draw up an expert assessment on the change applied for, based on which the respective commission under Art. 286 shall submit a position to the Executive director of the BFSA.

(2) The period under para 1 may be:

1. reduced under urgent cases, where these refer to the requirements on safety of VMP;
2. prolonged by 90 days at a change, by which shall be changed or supplemented the therapy indications;
3. prolonged with 90 days in the cases, where the short characteristics of the product is to change or to add new species of non-production animal, for which VMP has been intended.

(3) In the period referred to in para 1 the commission under para 1 can require additional information from the applicant. In that case the period shall stop running till its supply.

(4) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA, based on the position of the commission under para 1 shall approve the changes and shall enter these in the register under Art. 290.

Art. 310. (amend. – SG 08/11, in force from 25.01.2011) Where the changes impose a change in the content of the license of use of VMP, the Executive director of the BFSA shall issue a supplement to it and shall enter the changes in the register under Art. 290.

Art. 311. (1) (amend. – SG 08/11, in force from 25.01.2011) Where the holder of the license detects a risk for human or animal health at using of VMP, he shall take urgent limiting measures and immediately shall notify in writing the BFSA.

(2) (amend. – SG 08/11, in force from 25.01.2011) The BFSA shall express its position on the measures, in the period of one working day from the notification.

(3) (amend. – SG 08/11, in force from 25.01.2011) Where the BFSA shall do not give a position in the period under para 2, it shall be considered that the measures have been approved.

Art. 312. (1) (amend. – SG 08/11, in force from 25.01.2011) Where the BFSA find out, that there is a risk for human or animal health from using VMP, the holder of the license have to take limiting measures immediately.

(2) The measures under para 1 shall be agreed in advance under Art. 311, para 2 and 3.

Art. 313. (amend. – SG 08/11, in force from 25.01.2011) In the cases under Art. 311 and Art. 312 the holder of license for use of VMP shall submit to the Executive director of the BFSA an application for change under Art. 307 not later than 15 days from the date of the undertaking of the measures.

Art. 314. (amend. – SG 7/13) (1) (Suppl. – SG 17/18, in force from 23.02.2018) The license holder shall submit an application in a standard form for amendments in the scope of the license for use of VMP to the Managing Director of BFSA. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator.

(2) The documents referred to in Art. 279, item 2 related to amendment of the scope of the license for use and a receipt of a paid fee in an amount, determined in the tariff under Art. 14, par. 2, shall be attached to the application under par. 1.

(3) Depending on the amendments of the scope of the license the applicant shall submit samples and/or products under Art. 279, item 3.

(4) Assessment of the documents attached to the application referred to in par. 1 shall be carried out following the provisions of Art. 285 and 287.

(5) The Managing Director of BFSA shall issue a new license for use or a supplement to the existing license subject to compliance with the provision of Art. 288 depending on the amendments of the scope of the license for use.

Art. 315. (amend. – SG 7/13) (1) The holder of license for use may transfer his/her rights on the license to another person, meeting the provisions of Art. 278.

(2) (Amend. – SG 17/18, in force from 23.02.2018) In cases under par. 1 the person wishing to acquire the rights under the license for use, shall submit to the Managing Director of BFSA an

application in a template. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. written agreement, concluded by and between the license holder and the transferee;

2. information about the qualified person under Art. 295 – name, address and professional qualification;

3. other documents, related to the change, if relevant;

4. (suppl. – SG 17/18, in force from 23.02.2018) a receipt of a paid fee in an amount, determined by the tariff of Art. 14, par. 2, when the payment is not made electronically.

(3) In case of identified blanks in the documents under par. 2 BFSA shall notify in writing the applicant within 30 days after the submission of the application to submit the required further information. The term under par. 5 shall stop elapsing from the date of notification to the time of submission of the requested information.

(4) When within the term of par. 3 the applicant fails to submit the information, the procedure of transfer of rights on the license for use of VMP shall be terminated by an order of the Managing Director of BFSA.

(5) Within 30 days after the date of submission of the application under par. 2 the Managing Director of BFSA shall issue to the acquirer a license for use and shall register the change in the register under Art. 290, par. 1 or refuse to issue it with justification. The license shall remain valid until the expiration of the time of validity of the license, issued to the former holder.

(6) The refusal under par. 5 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure.

(7) The new holder of license for use shall undertake in full all rights and obligations of the former license holder.

(8) The term for which the license for use of VMP has been issued shall remain unchanged upon transfer of rights.

Art. 316. (1) (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13) The Executive director of the BFSA by an order shall suspend the license for use of VMP and shall instruct its holder to block and to withdraw the VMP from the market, when it is ascertained that:

1. assessment of the ratio advantage/risk of the licensed VMP is not favourable;

2. VMP does not have the stated in the dossier therapy effect on the species of animals, for which it is intended;

3. the quantity and the quality composition of VMP is different from that described in the dossier;

4. (amend. – SG 7/13) the withdrawal period indicated in the license is unsuitable;

5. (revoked – SG 7/13);

6. the information in the register documentation is not real;

7. (amend. – SG 7/13) the control tests under Art. 353a, par. 1 have not been carried out;

8. (amend. – SG 7/13) . the requirements under Art. 293, paras 1 and 4 have not been respected;

9. (new – SG 7/13) the holder of license for use has failed to submit the reports referred to in Art. 296, par. 1, item 6;

10. (new – SG 7/13) the terms and conditions set out in the license for use, are not complied with;

11. (new – SG 7/13) the requirements of the ordinance referred to in Art. 361, par. 2 are not complied with.

(2) (amend. – SG 7/13) The Managing Director of BFSA by an order shall terminate the license for use of VMP:

1. upon holder's written request;

2. where a ban for use of VMP has been imposed after issuing the license;

3. where an active substance of VMP, intended only for productive animals, is excluded from Table 1 "Permitted substances" of the Annex to Regulation (EC) No. 37/2010;

4. where an active substance of VMP is included in Table 2 "Forbidden substances" of the Annex to Regulation (EC) No. 37/2010;

5. upon termination of trader's activity.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order under para 1 may be appealed under the Administrative procedure code. The appeal shall not stop the implementation.

(4) (new – SG 7/13) The orders under par. 1 and 2 shall be published on the Internet site of BFSA.

Art. 316a. (new – SG 7/13) (1) The Managing Director of BFSA by an order may suspend the validity of the license for use of VMP up to verification of the circumstances under Art. 316, par. 1, item 2 – 4, 10 and 11.

(2) Where it is ascertained, that the circumstances under par. 1 are not existing and the holder of the license for use has undertaken actions for correction of incompliances under Art. 316, par. 1, item 2 – 4, 10 and 11, the Managing Director of BFSA shall cancel the order for suspension of license validity.

(3) The order referred to in par. 1 shall be communicated and may be appealed according to the provisions of the Code of Administrative Procedure. The appealing shall not suspend the execution.

Art. 317. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Executive director of the BFSA by order shall ban the use and trade of a definite batch of VMP, where there is present one of the reasons under Art. 316, para 1, item 1 – 4, 6, 10 and 11, without suspending of the license, and shall order to the holder of license for use of VMP the withdrawal of the batch from the market.

(2) (amend. - SG 30/06, in force from 12.07.2006) The order under para 1 may be appealed under the Administrative procedure code. The appeal shall not stop the implementation of the order.

Art. 318. (1) (amend. – SG 7/13) The owner of a VMP or an authorized by him person, shall reject and destroy it according to the provisions of the Law for waste management, where the product:

1. is prohibited for use and trade under Art. 317;

2. is with an expired validity period;

3. there is a deviation in the quality parameters as a result of inappropriate storage or transportation;

4. is manufactured by a person, who does not hold a license for manufacturing of VMP;

5. is being traded or kept by a person who does not hold a license for trading in VMP;

6. is not licensed for use;

7. is imported by a person, who does not hold a license issued according to the provision of Art. 356.

(2) The persons referred to in para 1 shall make a record of discarding and eradication of VMP, which shall contain the type, the quantity, the batch number, the reasons for rejecting and the way of destruction.

(3) The expenditures on destruction of rejected VMP shall be at the expense of their owner.

Art. 319. (1) (amend. – SG 08/11, in force from 25.01.2011; prev. Art. 319 – SG 7/13) The Executive director of the BFSA may prohibit manufacturing, trade, import and use of immunological VMP in the country, should it be ascertained that:

1. (amend. - SG 14/16, in force from 19.02.2016) their application on animals impede the implementation of measures from the program for prevention, supervision, control and eradication of animal diseases and zoonoses or in detecting of absence of contamination on animals, feed raw materials, feed additives, compound feeding stuffs or raw materials and foods, obtained from treated animals;

2. the disease, against which VMP creates an immunity, is not registered in the country.

(2) (new – SG 7/13) The Managing Director of BFSA shall notify in writing the European Commission of an imposed ban under par. 1.

Art. 320. (amend. – SG 7/13) In a complicated epizootic situation the Executive director of the BFSA by an order may permit temporarily the use of a not licensed for use immunology VMP where there is no suitable licensed VMP, upon advising the European Commission of the terms and conditions under which the product will be used.

Art. 320a. (new – SG 7/13) (1) Where an animal is being imported or exported to a third country and regarding this animal prevention measure has to be undertaken, the Managing Director of BFSA may permit to apply immunology VMP to this animal, which is not licensed for use in the Republic of Bulgaira, but is permitted for use according to the laws of the third country.

(2) In cases referred to in par. 1 BFSA shall carry out control over the import and use of immunology VMP.

Art. 321. (amend. – SG 7/13) When medical situation requires so, the Managing Director of BFSA by an order may permit the use of VMP, licensed for use in another Member State which shall be used subject to compliance with the provisions of this Chapter.

Art. 322. (amend. – SG 7/13) (1) When in the Republic of Bulgaria there is no a licensed VMP, suitable to relieve suffering of non-productive animals, as an exception the veterinarian may apply at his/her own responsibility therapy with:

1. VMP, licensed according to the provisions of this Chapter or according to Regulation (EC) No. 726/2004 for another specie or for the same animal species, but with other therapy indications;

2. medicinal product, licensed for humanitarian purposes in the Republic of Bulgaria or according to Regulation (EC) No. 726/2004 or

3. VMP licensed for use under the laws of another Member State for the same or for a different animal species for the same of another medical condition – where a product under item 1 is not available;

4. VMP, prepared in a pharmacy by a legally capable person from a prescription of a veterinary, where a VMP under item 2 and 3 is not available.

(2) For therapy of solid-footed animals the requirements of par. 1 shall apply, provided that the products, produced from the animals, are not meant for human consumption.

(3) Substances required for therapy of solid-footed animals, for which the withdrawal period should not be less than 6 months, are listed in the Annex to Commission Regulation (EC) No.

1950/2006 of 13 December 2006 establishing in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae.

Art. 323. (amend. – SG 7/13) (1) Where in the Republic of Bulgaria there is no VMP, suitable to relieve suffering of productive animals in a particular animal breeding site, the veterinarian may apply at his/her own responsibility therapy with:

1. VMP, licensed according to the provisions of this Chapter or according to Regulation (EC) No. 726/2004 for another specie or for the same animal species, but with other therapy indications;

2. medicinal product, licensed for humanitarian purposes in the Republic of Bulgaria or according to Regulation (EC) No. 726/2004 or

3. VMP licensed for use under the laws of another Member State for the same or for a different animal species for the same of another medical condition – where a product under item 1 is not available;

4. VMP, prepared in a pharmacy by a legally capable person from a prescription of a veterinary, where a VMP under item 2 and 3 is not available.

(2) The provisions of par. 1 shall apply if pharmacological active substances that are contained in VMP, included in Table 1 "Permitted substances" of the Annex to Regulation (EC) No. 37/2010 and the veterinary, who is carrying out the treatment has determined a relevant withdraw period.

Art. 324. (1) Where withdraw periods are not indicated for the VMP, intended for productive animals, the following minimum periods shall be observed:

1. for eggs and milk - 7 days;

2. for poultry meat and meat from mammals, fats and offal - 28 days;

3. for fish products - 500 degree days.

(2) Food products for human consumption may be derived from test animals when a withdraw period is determined for the VMP the animals have been treated with.

(3) (new – SG 7/13) For homeopathic VMP intended for productive animals, active substances of which are included in Table 1 of the Annex to Regulation (EC) No. 37/2010, the withdrawal time under par. 1 shall be zero days.

Art. 325. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The veterinary, who is administering treatment with VMP under Art. 323, shall keep the documentation for at least 5 years from the date of application of VMP and shall present it to the authorities of the BFSA for verification.

(2) In the documentation shall be written the date of the check of the animals, the data of the owner, the number, the species and the identification number of the treated animals, the diagnosis, the prescribed VMP, the course of the treatment and the determined withdraw periods.

Art. 326. No license shall be required for use of VMP when:

1. the VMP is prepared in a pharmacy from magisterial or pharmacopoeia prescription;

2. manufacturing of VMP with exporting purposes;

3. samples of VMP are necessary for the procedure of issue of a license for use.

4. veterinaries from member states, who carry out veterinary services on the territory of the Republic of Bulgaria may have single packages of VMP when the following conditions are met:

a) the VMP is licensed in the member state, in which the veterinary exercises his practice;

b) the VMP is carried in its original package;

c) the veterinary does not give the VMP to the owner or the keeper of the animals;

d) the veterinary is keeping detailed records about the animals he has been treating, the diagnosis, the applied VMP, dosage, length of treatment and the withdraw period. These records shall be kept for 7 years;

e) the quantity of VMP does not exceed the daily needs determined by the good veterinary practice;

5. (amend. – SG 84/07) the VMP are intended for aquarium fish, cage birds, pet doves, terrarium animals, small rodents and rabbits - pets should VMP do not contain substance, which use is subject to veterinary control and measures for preventing their use on other animals have been taken;

6. (new – SG 7/13) VMP are intended for clinical tests for the development of new VMP.

Art. 327. (1) There shall be advertised only licensed for the country VMITEM

(2) (amend. – SG 08/11, in force from 25.01.2011) The advertisement shall be coordinated with the BFSA.

Art. 328. (1). The advertisement of VMP may be directed to:

1. unlimited groups of persons;

2. veterinary medical specialists;

3. sponsoring of scientific congresses.

(2) The advertisement must present reliable therapeutically indications of VMITEM

(3) The content of the advertisement must correspond to the data of the approved short characteristics of the product at the issue of the license for use of VMITEM

(4) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The persons, wishing to advertise VMP, shall submit to the Executive director of the BFSA an application conformed to a specimen. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. a draft of the advertisement;

2. an agreement of the holder of license for use, where the application shall be submitted by another person;

3. (amend. – SG 17/18, in force from 23.02.2018) document for a paid fee at an amount, specified in the tariff under Art. 14, para 2, when the payment is not made electronically.

(5) In the cases under para 1, item 2 the applicant shall present to the documentation under para 4 information on the literature source of the quotations, tables and other materials used.

(6) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) In a period of 15 days of the presentation of the documents under para 4 and 5 the Executive director of the BFSA shall or shall not approve the advertisement.

(7) (amend. – SG 08/11, in force from 25.01.2011) Where at a documentary check under para 4 и 5 discrepancies and/or incompleteness are detected, the Executive director of the BFSA shall notify the applicant in writing for correction of these.

(8) The period under para 6 shall stop running till the elimination of the discrepancies and/or incompleteness.

Art. 329. It shall be prohibited:

1. the advertising of therapy effects and indications of VMP, different from the approved at the issue of the license of use;

2. advertisement with a misleading text and/or picture;

3. advertisement of VMP according to Art. 328, para 1, for which a prescription is required.

Art. 329a. (new – SG 7/13) (1) Bulgarian Food Safety Agency shall issue to the holder for use certificates according to the certification scheme of the World Health Organization.

(2) (Suppl. – SG 17/18, in force from 23.02.2018) For issuing of Certificate under par. 1 the holder of license for use shall submit to the Managing Director of BFSA an application in a standard form, to which a receipt of a paid fee in an amount, determined by the tariff under Art. 14, par. 2 shall be attached, when the payment is not made electronically. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator.

(3) The Managing Director of BFSA shall issue the certificate within 14 days after the submission of the application under par. 2.

Section II.
Procedure for mutual recognition of a license for use of veterinary medicinal products and decentralized procedure (In force from 01.01.2007; title amend. – SG 7/13)

Art. 330. (In force from 01.01.2007; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) (1) When in a member state a license for use of VMP is issued and an application is submitted for issuing of a license for use of the same VMP in several Member States, including in the Republic of Bulgaria, the procedure of mutual recognition of the license shall be applied.

(2) Where in a Member State no license for use of VMP is issued and an application is submitted for issuance of a license for use of the same VMP in several Member States, including in the Republic of Bulgaria, decentralized procedure of issuance of the license for use shall be applied.

Art. 331. (In force from 01.01.2007) (1) A coordination group shall be established for consideration of every aspect in connection with the issuing of licenses for use of VMP in Bulgaria and in one or more member states. The Secretariat of the coordination group shall be determined by the European pharmaceutical agency.

(2) The coordination group shall consist of delegates – one per a member state and he shall be nominated by the competent authority of the respective member state for a 3 years period. Members of the group can be assisted by experts.

(3) The coordination group shall adopt rules for its work, which will enter into force after a positive opinion of the European Commission. The rules shall be public.

Art. 332. (In force from 01.01.2007; amend. – SG 7/13) (1) For recognition of issuing of a license for use of VMP in more than one Member State, the person under Art. 278 shall submit an application with attached identical file to the Managing Director of BFSA and to preferred by him/her Member States, herein after referred to as “interested”. The file shall contain administrative information and research and technical documentation under Art. 279, and also information about the compliance with the provision of Art. 280, par. 9 in cases, where relevant.

(2) In the application the person under Art. 278 shall indicate the interested Member States and

a Member State as a reference state, the competent body of which shall issue a report or update the report on assessment of the file of VMP. Where required, the report shall contain an assessment of the initially determined maximum allowable values of residual quantities of VMP under Art. 280, par. 9 and of the results under Art. 281, par. 3.

(3) Where prior to submission of the application under par. 1 a license for use of VMP has been issued in a Member State, the holder of the license for use shall request from the reference Member State to update the report on assessment of the file of the VMP licensed for use.

(4) The reference Member State shall update the report on assessment of the VMP file within 90 days from the acceptance of a valid application. The report together with the approved brief characteristic, the label and the application leaflet of the product shall be sent to the interested Member States and to the applicant.

(5) Where prior to submission of the application under par. 1 a license for use of VMP has not been issued in a Member State, the applicant shall nominate a reference Member State to issue a draft-report on assessment of the file and drafts of brief characteristic, label and application leaflet of the VMP within 120 days after the acceptance of a valid application and shall send it to the interested Member States and to the applicant.

(6) Within 90 days after the receipt of the documents under para 4 and 5, interested Member States shall approve them and shall inform the referent state. The referent Member State shall document the approval, finalize the procedure and inform the applicant.

(7) Within 30 days after the finalization of the procedure under par. 3 or 5 the Executive director of the BFSA shall issue respectively a decision for recognition of the license for use of VMP or a license for use of VMP and shall enter then in the register under Art. 290.

(8) When the referent Member State is the Republic of Bulgaria it has the obligations under paras 4 – 6.

Art. 333. (In force from 01.01.2007) (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) When in the term under Art. 332, para 6 the Executive director of the BFSA does not approve the documents under Art. 332, paras 4 and 5 due to possible serious risk for humans or animals health, he shall prepare a detailed report to the referent country, other interested parties and the applicant, in which he shall indicate the reasons for disapproval. The reasons for disapproval are immediately presented to the coordination group.

(2) (amend. – SG 7/13) The coordination group shall give an opportunity to the applicant to present an position relevant to the disapproval under para 1. Should in 60 days from the receipt of the report under para 1 the coordination group reaches an agreement the referent country shall enter the agreement, conclude the procedure and inform the applicant. In this case Art. 332, para 7 is applied.

(3) (amend. and suppl. – SG 7/13) When as reasons for disapproval of the documents under Art. 332, paras 4 and 5 are indicated the circumstances under Art. 319, par. 1, the Republic of Bulgaria shall cease to be an interested party in the procedure.

(4) Should in 60 days the coordination group does not reach an agreement it shall immediately inform the European Medicines Agency and submit a detailed description of the issues on which an agreement had not been reached and the reasons for that. Copy of the information sent to the European Medicines Agency shall be sent to the applicant.

(5) Following the receipt of the information under para 4 the applicant shall immediately send a copy of the dossier under Art. 332, para 1 to the European Medicines Agency.

(6) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para 4, when the Executive director of the BFSA has approved the report for assessment of the dossier, the short characteristic, label and leaflet of the VMP upon request he issues a license for use before the conclusion of the procedure.

Art. 334. (In force from 01.01.2007; amend. – SG 7/13) When in two or more member states, under procedures for issuing a license for use of one and the same VMP different decisions have been made in connection to issuance, discontinuation or suspension of the license – a member state, the European Commission or the holder of the license may remit the question to the Committee on VMP at the European Medicines Agency.

Art. 335. (In force from 01.01.2007) (1) (amend. – SG 7/13) Short harmonized characteristics of VMP licensed for use under a centralized procedure, shall be drawn up according to the following procedure:

1. the member states shall send to the coordination group a list of the licensed by them VMP, for which they have prepared a short characteristic;

2. on the basis of the received lists under para 1 the coordination group after reaching an agreement shall draw up a general list of VMP and send it to the European Commission;

(2) The decision of the Committee for VMP at the European Medicines Agency shall be applied for VMP under Art. 334.

(3) The Committee for VMP jointly with the European Medicines Agency shall approve the final list of VMP after considering the positions of the interested parties.

Art. 336. (In force from 01.01.2007) (1) In case of breach of EU interests the member states, the applicant, the holder of a license for use of VMP or the European Commission may lodge a complaint in the Committee for VMP at the European Medicines Agency before a decision for issuance, discontinuation or suspension of a license for use of VMP or changes in the terms of operation of issued licenses for use of VMP that are imposed by the information derived from the system of pharmacological vigilance is taken.

(2) The complaint under para 1 shall include detailed arguments and attached to it shall be all the documents concerning the appealed question.

(3) When the complaint concerns more than one VMP or a therapeutic group the holder of a license for use of VMP shall inform all member states, in which a license for use of this particular VMP has been issued.

(4) In 15 days after the receipt of the decision of the Committee for VMP the applicant may appeal it in front of the European Medicines Agency. In this case, in 60 days upon receipt of the decision he shall send detailed arguments attached to his complaint to the European Medicines Agency.

(5) The decision of the European Medicines Agency is final.

Art. 337. (In force from 01.01.2007) (1) When the Republic of Bulgaria or another member state consider that the changes in the term of operation of a license for use of VMP issued under the rules of this section or its discontinuation or suspension is necessary for the protection of human and animal health or the environment they shall immediately inform the European Medicines Agency.

(2) When urgent action is needed to protect human and animal health or the environment the Republic of Bulgaria or another member state may discontinue the use of the respective VMP on their territory prior to the decision of the European Medicines Agency and shall inform on this the European Commission and the other member states in one working day.

Art. 337a. (new – SG 7/13) The terms and provisions and the procedure of amendment of licensed for use of VMP issued under a procedure of mutual recognition and decentralized procedure, shall be regulated by Regulation (EC) No.1234/2008.

Art. 338. (In force from 01.01.2007; amend. – SG 7/13) Every application for amendment of a license for use of VMP, issued under a procedure of mutual recognition and decentralized procedure, shall be submitted to the Member States, in which the product has been licensed for use.

Art. 339. (In force from 01.01.2007; suppl. – SG 7/13) Recognition of a license for use of VMP according to this section may be refused in the cases under Art. 319, par. 1.

Section III.
Central procedure for issuance of license for use of veterinary medicinal products

Art. 340. (revoked – SG 7/13)

Art. 341. (revoked – SG 7/13)

Art. 342. (In force from 01.01.2007; revoked – SG 7/13)

Section IV.
Manufacturing, importing and exporting of veterinary medicinal products

Art. 343. (1) (amend. – SG 08/11, in force from 25.01.2011) Manufacturing of VMP in the country shall be carried out by physical and corporate bodies, registered under the Commerce Act and having a manufacturing license, issued by the Executive director of the BFSA.

(2) (amend. – SG 7/13) Manufacturing license of VMP shall be issued for full and partial manufacturing and different processes, such as partition and packaging.

(3) In the cases referred to in para 2 a manufacturing license shall not be required should the processes of partition, mixing or packaging are carried out according to a magisterial or pharmacopoeia prescription at a veterinary medical pharmacy.

(4) (amend. – SG 7/13) Export of VMP shall be carried only by persons that have manufactured the VMP and hold a license for manufacture of VMP.

(5) (In force from 01.01.2007; amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA shall send to the European Medicines Agency a copy of the license for manufacture of VMP to be entered in the data base of the EU.

(6) (new – SG 7/13) Where VMP are imported to the Republic of Bulgaria and are intended for another Member State, they shall be accompanied by a copy of the manufacturing license of VMP.

Art. 343a. (new – SG 7/13) Production of active substances, used as input raw materials, shall include full or partial production, partition, packing, re-packing or re-labeling prior to inclusion of the substance in the content of VMP.

Art. 344. (amend. – SG 7/13) To obtain a manufacturing license of VMP and/or active substances, the persons under Art. 343 shall:

1. indicate in the application the types of VMP and/or active substances and their pharmaceutical forms, which will be produced or imported, and also the place of production and/or control;

2. dispose of suitable premises, technical equipment and facilities for control of VMP and/or active substances under item 1;

3. dispose at any time of at least one qualified person under Art. 353.

Art. 345. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) For issue of manufacturing license of VMP the persons under Art. 343, par. 1 shall submit to the Executive director of the BFSA an application in a standard form indicating the UIC by BULSTAT, number and date of issuance of an act for putting into operation of the sites under Art. 344, item 2, issued by the order of the Spatial Development Act. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. documents regarding the types of VMP and the pharmaceutical forms which are to be manufactured in;

2. documents concerning the capacity and experience of the managers of production, control and providing for the quality and the qualified person under Art. 353;

3. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

4. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

5. (amend. – SG 7/13) a list of the VMP or active substances, wherein shall be indicated:

a) types and pharmaceutical forms;

b) description of the manufacturing process and the methods of analysis;

c) name of the active substances or the strain of micro organisms, contained in the composition of the VMP;

d) the administration method of the VMP.

6. (new – SG 7/13) plans of manufacturing, control and storage premises;

7. (prev. item 6 – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) a document for a paid fee at an amount, specified in the tariff under Art. 14, para 2, when the payment is not made electronically.

(2) In the manufacture of VMP that contain narcotic substances, the requirements of the Control on Drugs and Precursors Act shall be applied.

(3) Where some of the manufacturing stages or the control examinations in the production process are carried out under contract in other establishment on the territory of the country or outside it, the person referred to in para 1:

1. shall indicate the location of the establishment;

2. shall present a copy of the contract, wherein are to be arranged:

a) the obligations of each of the parties regarding the compliance with the requirements of the good production practices in the production of VMP;

b) the obligations of the qualified person under Art. 353.

Art. 346. (1) (amend. – SG 36/08, amend. – SG 58/17, in force from 18.07.2017) The requirements for good production practices in the manufacture of VMP shall be arranged by an

ordinance of the Minister of Agriculture, Foods and Forestry.

(2) In the manufacture of active substances used as raw materials the requirements for good production practices under para 1 shall be applied.

Art. 347. (1) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA shall determine a commission that shall:

1. assess the documentation presented under Art. 345, para 1;

2. (suppl. – SG 7/13) carry out on-the-spot checks for finding out compliance of the documentation referred to in item 1 with the conditions of production, control and storage of the raw materials and the VMP and with the Good Manufacturing Practice (GMP) requirements;

3. shall check the compliance of the production conditions, control and storage of the raw materials and the VMP with the requirements for good production practices.

(2) The commission under para 1 shall notify the applicant in writing and shall give him instructions, should it detect:

1. (suppl. – SG 7/13) incompliance of the presented documentation with the production, control and storage conditions of VMP and/or active substances and GMP requirements.

(3) (suppl. – SH 7/13) In the cases under para 2 the period for a manufacturing license issue shall stop running till the implementation of the instructions, but not more than 180 days.

(4) (amend. – SG 08/11, in force from 25.01.2011) The commission under para 1 shall prepare a position to the Executive director of the BFSA.

(5) (new – SG 7/13) In cases under par. 3 where the applicant fails to fulfill the instructions within 180 days from the day of receipt of a written notification, the Managing Director of BFSA by an order shall terminate the procedure of issuance of a license and shall notify the applicant in writing thereof.

(6) (new – SG 7/13) The order referred to in par. 5 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure. The appeal shall not suspend the execution.

(7) (new – SG 7/13) In cases referred to in par. 5 an application for issuance of a manufacturing license under the provision of Art. 354 may be issued.

Art. 348. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. and suppl. – SG 7/13) The Executive director of the BFSA in a period of 90 days upon the submission of the application under Art. 345, based on the position of the commission shall issue a manufacturing license of VMP or of active substances or by a justified order shall refuse to issue a license.

(2) (amend. - SG 30/06, in force from 12.07.2006; suppl. – SG 7/13) The refusal under para 1 shall be communicated and may be appealed under the Administrative procedure code.

(3) (suppl. – SG 7/13) The license for manufacture of VMP or of active substances shall not be limited in time.

Art. 348a. (new – SG 7/13) (1) The Managing Director of BFSA may issue a license for manufacturing of VMP or of active substances provided that the applicant will follow the instructions of BFSA, issued during the procedure of issuing of a license.

(2) In cases of par. 1 where the instructions are not fulfilled within the indicated term therein, the Managing Director of BFSA shall withdraw the license by an order.

(3) The order under par. 2 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure.

Art. 349. The manufacturing license shall contain the data under Art. 350, para 1, item 1-6 and shall relate only to the indicated in it VMP, their pharmaceutical forms and the premises of production, control and storage.

Art. 350. (1) (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the manufacturing licenses issued for VMP and/or active substances. The register shall contain:

1. number and date of issue of the license;

2. name, seat and address of management of the manufacturer;

3. location of the premises of production, control and storage of VMP;

4. (amend. and suppl. – SG 7/13) the types of VMP, their pharmaceutical forms and active substances;

5. data of the production manager and the quality control manager;

6. data of the qualified person under Art. 353;

7. reason and date of issue of the order for suspension of the manufacturing license;

8. remarks on the entered circumstances .

(2) Where the VMP and their substances have an anabolic, anti-infectious, anti-parasite, anti-inflammatory, hormonal, narcotic or psychotropic effect it shall be noted in the register.

Art. 351. (1) (suppl. – SG 7/13) The holder of the manufacturing license of VMP or of active substances shall submit an application conformed to a specimen at any change of the entered in the register circumstances under Art. 350, para 1, item 2 - 6.

(2) (Suppl. – SG 17/18, in force from 23.02.2018) To the application shall be attached documents, relevant to the change and a document for a paid fee at an amount, specified in the tariff under Art. 14, para 2, when the payment is not made electronically.

(3) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the BFSA shall appoint a commission that shall carry the actions under Art. 347.

(4) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Executive director of the BFSA, in a period of 30 days upon submission of the application, shall issue an addition to the manufacturing license for VMP on the basis of the position of the commission referred to in para 3. The period for issuing an addition may be extended up to 90 days in case of change of the circumstance under Art. 350, para 1, item 3 and 4.

Art. 352. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Executive director of the BFSA by an order shall amend the production license, by excluding from its scope some kinds of products or shall withdraw the license for all products, where some of the provisions of Art. 344 have not been complied with or the prescriptions of BFSA bodies have not been followed.

(2) (new – SG 7/13) Depending on the type and severity of violation of the manufacturing or import requirements, the Managing Director of BFSA by an order may:

1. suspend the production or import of VMP and/or active substances;

2. terminate the validity of the manufacturing license for particular kinds of products or of all products;

3. withdraw the license referred to in item 2.

(3) (prev. par. 2 – SG 7/13) The license for manufacturing VMP is discontinued:

1. upon written request by its holder;

2. upon termination of the activity, for which it has been issued;

3. upon erasure of the registration of the trader;

4. upon death of the physical person – one-man business.

(4) (amend. - SG 30/06; prev. par. 3, suppl. – SG 7/13) The order under para 1 and 2 shall be communicated and may be appealed under the Administrative procedure code. The appeal shall not stop the implementation.

Art. 352a. (new – SG 7/13) Where the Managing Director of BFSA has issued an order for amendment of the scope of the manufacturing license, he/she shall re-issue the license and shall register the amendment into the register referred to in Art. 350, par. 1.

Art. 353. (1) The license holder for manufacturing shall conclude a contract of employment with at least one qualified person.

(2) (amend. – SG 7/13) The qualified person under para 1 must:

1. hold a document of acquired qualification from education in a higher school or a course, equivalent to this education, recognized pursuant to the Law for recognition of professional qualifications or the Ordinance for the state requirements for recognition of acquired higher education and accomplished periods of education in foreign higher schools (prom. SG 69/00; amend. – SG 25 and 79/09; SG 59/10 and SG 102/11);

2. have minimum two years of practical experience with a licensed pharmaceutical manufacturer, related to quality analysis of medicinal products, quantitative analysis of active substances and other tests, required for products quality assurance.

(3) (new – SG 7/13) The duration of the practical experience referred to in par. 2, item 2 may be reduced by one year where the course of study in a higher school takes minimum 5 years, or by a year and a half where the course of study takes minimum 6 years.

(4) (revoked, new – SG 7/13) The education in a higher school and the course under par. 2, item 1 must have a duration of minimum 4 years and to include theory and practice in one of the following majors: pharmacy, medicine, veterinarian medicine, chemistry, pharmaceutical chemistry and technology, biology or bio-technology.

(5) (revoked, new – SG 7/13) Minimum period of education in a higher school may be with a duration of three and a half years, where it is followed by a theoretical and practical course with a duration of minimum one year, whereby the practical training takes minimum 6 months and takes place in a pharmacy. The course must be accomplished by a University-level test.

(6) (revoked, new – SG 7/13) Where in a Member State higher schools provide education with a duration of more than three and more than 4 years, or courses under par. 2, item 1 with the same duration are carried out, the document of acquired qualification , issued by a higher school with more than three year course of study or upon accomplishment of a course with the same period of education, it shall be deemed, that it meets the requirement for duration of education under par. 4 and the documents for acquired qualification, issued upon accomplishment of higher schools, or of courses with more than three and more than 4 years shall recoginized as equivalent to each other documents.

(7) (new – SG 7/13) Education and the course referred to in par. 2, item 1 must include theoretical and practical training in the following key academic subjects: experimental physics, general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry, including medicinal products analysis, general and applied bio-chemistry (medical), physiology, microbiology, pharmacology, pharmaceutical technology, toxicology and pharmacognosy.

(8) (prev. par. 3, amend. – SG 7/13) When the license holder for manufacturing of VMP complies with the requirements under para 2 - 7, he/she can carry out the obligations of the qualified person.

Art. 353a. (new – SG 7/13) (1) The qualified person referred to in Art. 353, par. 1 shall:

1.issue a certificate of release of the batch, by which he/she guarantees that each batch of VMP is produced and controlled in compliance with the requirements of this Section and the terms and conditions of the license for use of the product;

2. issue a certificate of release of an imported batch of VMP, including where the batch is manufactured in a Member State, by which he/she shall guarantee that prior to launching of the batch on the market in a Member State, comprehensive quality analysis, quantitative analysis of active substances as a minimum has been carried out, and also all tests or control, required for VMP quality assurance subject to compliance with the license for use requirements.

(2) Carrying out of analyses, tests and control under par. 1, item 2 is not required for launching on the market of a batch of VMP accompanied by a certificate of their release, issued by a qualified person, based in an European Union Member State.

(3) The qualified person shall not carry out the analyses, tests and control under par. 1, item 2 in case of import of VMP from a third country, having concluded a contract with the European Union, guaranteeing that the GMP requirements are applied in this country, which as a minimum are equivalent to those applied in the European Union, and that the analyses, tests and control for product quality assurance have been made.

(4) The qualified person shall maintain a record book, containing records, guaranteeing that each batch of VMP has been manufactured and controlled subject to compliance with the provisions of this Section and in compliance with the license for use of VMP.

(5) The record book under par. 4 shall be kept for minimum 5 years after the last entry and upon request shall be presented to BFSA authorities.

(6) In case of instituted administrative penal or punitive proceedings for violations, perpetrated by a qualified person, the Managing Director of BFSA shall notify in writing the manufacturing license holder, that the latter should suspend the qualified person from the office until the finalization of the proceedings institute against him/her.

Art. 354. (1) The license holder for manufacturing of VMP:

1. shall dispose of staff according to the requirements of the ordinance under Art. 346;

2. (amend. – SG 7/13) shall keep available only VMP, for which a manufacturing license;

3. (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG) shall notify in advance the control bodies of the BFSA for each change of the conditions, under which the manufacturing license has been issued and shall provide access at any time to the site for manufacturing and control;

4. (amend. – SG 08/11, in force from 25.01.2011) shall notify immediately the control bodies of the BFSA in a case of change of the qualified person under Art. 353;

5. shall ensure for the qualified person under Art. 353 the necessary conditions for carrying out his obligations;

6. (suppl. – SG 7/13) shall observe the requirements of the good manufacturing practice of VMP and/or active substances and use as input raw materials only active substances, manufactured subject to compliance with the good manufacturing practice requirements;

7. (amend. – SG 7/13) shall maintain documentation about all supplied by him/her VMP and/or active substances, including supplied samples, containing:

a) delivery date;

b) name of VMP and/or active substances;

c) delivered quantity;

d) name and address of consignee;

e) VMP and/or active substances batch number.

(2) (amend. – SG 7/13) The documentation referred to in par. 1, item 7 shall be kept for minimum three years after the last record and upon request shall be provided to BFSA authorities.

(3) The license holder for manufacturing of VMP shall develop and maintain a system of blocking and withdrawal from the market of VMP, which do not meet the quality requirements.

(4) The license holder for manufacturing shall be obliged to block and withdraw VMP from the wholesale establishments, in the cases under Art. 311, para 1 and Art. 317, para 1.

Art. 355. (1) (prev. Art. 355 – SG 7/13) The import of licensed for use VMP in the Republic of Bulgaria shall be implemented only by persons, who have been authorised by the manufacturer and comply with the conditions under Art. 343.

(2) (new – SG 713/) In cases referred to in par. 1 the persons must have an available copy of a GMP certificate, issued to a manufacturer of VMP by a competent body of a Member State or another state – a party to the Agreement on the European Economic Area, and in case of import of VMP from a third country, having concluded an agreement with the European Union, guaranteeing that the GMP requirements are being applied in the same country, which are as a minimum equivalent to these in the European Union – a copy of a GMP certificate, issued by the third country competent body.

Art. 356. (1) (amend. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) In order to obtain a license for manufacturing VMP the persons under Art. 355 shall submit an application conformed to a specimen indicating the number and date of issuance of the act for putting into operation of the storage facilities of VMPs in the Republic of Bulgaria, issued by the order of the Spatial Development Act. The application shall be filed personally, by proxy, electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. the documents referred to in Art. 345, par. 1, items 1, 3 and 5 – 7;

2. documents of qualification and work experience of:

a) the managers of the production, the control and quality assurance in the country of production;

b) and of the qualified person, who is responsible for the quality of the imported in Republic Bulgaria VMP;

3. (revoked – SG 17/18, in force from 23.02.2018)

(2) A license for manufacturing of VMP shall be issued to the persons under para 1 according to the provisions of Art. 347 and Art. 348 and shall be entered in the register under Art. 350.

(3) (new – SG 7/13) In cases referred to in par. 2 no on-site inspection is required f the VMP production site in a third country, having concluded an agreement with the European Union, guaranteeing that in the same country GMP requirements are being applied, which as a minimum are equivalent of these in the Eropean Union.

(4) (prev. par. 3, amend. and suppl. – SG 7/13) The license shall be amended, suspended, withdrawn or terminated in conformity with the provisions of Art. 352.

Art. 357. (revoked – SG 7/13).

Art. 358. When importing veterinary medicinal products the persons, as referred to in Art. 355 shall resent to the customs authorities copies of the license for production and the license for use of veterinary medicinal products.

Art. 359. (1) (amend. – SG 7/13) The manufacturers of veterinary medicinal products shall deliver veterinary medicinal products only to wholesale traders, who have received a license in accordance with Art. 365, para 8.

(2) (amend. – SG 7/13) The persons, referred to in Art. 355 have the right to sell veterinary medicinal products to wholesale traders.

(3) (revoked – SG 7/13).

Art. 360. (1) (amend. – SG 7/13) The importers of VMP must:

1. comply with the requirements of Art. 354, par. 1, items 1, 4 and 5;

2. keep on stock only VMP for which they hold a license for use;

3. notify in advance the BFSA control authorities of any circumstances under which the manufacturing license has been issued, and to provide access to production, storage and control facilities;

4. comply with GMP requirements;

5. keep documentation, containing:

a) the date of buying and selling;

b) the name of the veterinary medicinal products;

c) the number and the expiry date of the batch of veterinary medicinal products;

d) the quantities of veterinary medicinal products purchased and sold;

e) the name and the address of the supplier and the buyer.

(2) (suppl. – SG 7/813) The documentation referred to in par. 1, item 5 shall be stored for a minimum of three years since the last entry, and shall be presented to the controlling organs upon request.

(3) The persons, as referred to in para 1 shall once a year carry out a full revision of the quantities of veterinary medicinal products delivered (bought), sold and available in store. All inconsistencies established shall be listed.

Art. 361. (1) The packaging of the end veterinary medicinal products shall consist of a primary and/or a secondary (outer) packing.

(2) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The requirements on the packaging and the leaflet for use of veterinary medicinal products shall be arranged with an ordinance of the Minister of Agriculture, Foods and Forestry.

(3) (amend. – SG 08/11, in force from 25.01.2011; revoked – SG 7/13).

Art. 362. (suppl. – SG 7/13) The transportation of veterinary medicinal products and active substances shall be carried out in accordance with the rules, specified by the manufacturer.

Section V.

Wholesale trade with veterinary medicinal products

Art. 363. (1) (amend. – SG 08/11, in force from 25.01.2011) Wholesale in veterinary medicinal products can be carried out by natural or legal persons, registered, as referred to in the Commerce Act, and which have obtained a license from the Executive director of the Bulgarian Food Safety Agency.

(2) The manager of an establishment for wholesale in veterinary medicinal products shall be only a veterinary doctor.

(3) (suppl. – SG 7/13) The manufacturers of veterinary medicinal products and/or active substances may sell to wholesale traders with veterinary medicinal products and/or active substances only products, manufactured by themselves, for which no license for wholesale shall be required.

(4) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; suppl. – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The requirements to the establishments for wholesale trade with veterinary medicinal products and/or active substances shall be determined in an Ordinance of the Minister of Agriculture, Foods and Forestry.

(5) (new – SG 7/13) Wholesale of active substances, intended to production of VMP may carry out persons, holding a license under par. 1.

Art. 364. (1) (Amend. – SG 17/18, in force from 23.02.2018) For the purposes of issuing a license, the person referred to in Art. 363, Para. 1 shall submit an application form. The application shall be submitted in person, or by proxy, or electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall indicate the Unified Identification Number according to the Commercial Register Act and The Register Of The Non-Profit Legal Entities, the number and date of issuance of the act for putting into operation of the wholesale site with VMPs issued by the order of the Spatial Development Act, the number and the date of issue of the diploma of the manager of the wholesale establishment with VMP, and to it shall be attached:

1. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)
2. (revoked – SG 17/18, in force from 23.02.2018)
3. (revoked – SG 17/18, in force from 23.02.2018)
4. a copy of the document for the right of ownership or the right to use the establishment;
5. (suppl. – SG 17/18, in force from 23.02.2018) document of the fee paid in the amount specified in the tariff, as referred to in Art. 14, Para. 2, when the payment is not made electronically.

(2) In case of wholesale trade with veterinary medicinal products which contain narcotic substances, the requirements of the Control on Drugs and Precursors Act shall apply.

(3) In case of wholesale trade with veterinary medicinal products and substances which have an anabolic, anti-infectious, anti-parasitic, anti-inflammatory or hormonal action, the requirements of the ordinance, as referred to in Art. 363, para 1 shall apply.

Art. 365. (1) (amend. – SG 08/11, in force from 25.01.2011) The executive director of the BFSA shall issue an order to appoint a commission, which shall review the documents, as referred to in Art. 364, para 1 and shall carry out an on-the-spot check.

(2) Where discrepancies (missing elements) are detected in the presented documents, or non-compliance between the condition (state) of the establishment and the requirements, which have been set in the ordinance, as referred to in Art. 363, para 4, the commission shall inform the applicant in writing and shall give instructions for their elimination.

(3) (suppl. – SG 7/13) In the cases, referred to in para 2 the term for issuing a license stops to run for the time it takes to eliminate the discrepancies, but not longer than 180 days.

(4) (amend. – SG 08/11, in force from 25.01.2011) The commission, as referred to in para 1 shall draw up an opinion and present it to the executive director of the BFSA.

(5) (new – SG 7/13) Where the applicant fails to correct the blanks within 180 days from the date of receipt of written notification, the Managing Director of BFSA by an order shall terminate the procedure of issuing of a license and shall notify the applicant in writing thereof.

(6) (new – SG 7/13) The order referred to in par. 5 shall be communicated and may be appealed according to the provisions of the Code of Administrative Procedure. The appealing shall not suspend the execition.

(7) (new – SG 7/13) in cases referred to in par. 5 an application for issuing of a license in compliance with the provisions of Art. 364 may be filed.

(8) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 5 – SG 7/13) Within three months after the application has been placed, the executive director of the BFSA, on the basis of the opinion of the commission, shall issue a license for wholesale trade with veterinary medicinal products, or shall issue a motivated order to refuse the issuing of a license.

(9) (new – SG 7/13) The license under par. 8 shall not expire.

(10) (amend. - SG 30/06, in force from 12.07.2006; prev. par. 6, amend. – SG 7/13) The refusal, as referred to in para 8 shall be communicated and may be appealed following the procedure laid down in the Administrative procedure code.

Art. 366. (1) The license for wholesale trade with veterinary medicinal products shall contain the data, as referred to in para 2, item 1 to item 5 and, as referred to in Art. 364, para 2 and para 3.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the licenses issued for wholesale trade with veterinary medicinal products, which register shall contain:

1. the number and the date, on which the license was issued;

2. the name, headquarters and address of management of the person, who was granted the license;

3. the location of the establishment for wholesale trade;

4. the name of the manager of the establishment for wholesale trade;

5. (suppl. – SG 7/13) a list of the pharmacological groups and/or active substances, which are being traded with;

6. the number and the date, on which the order of suspension of the license was issued;

7. remarks on the circumstances entered.

(3) The circumstances, as referred to in Art. 364, para 2 and para 3 shall be indicated in the register.

Art. 367. (1) (amend. – SG 08/11, in force from 25.01.2011) The license for wholesale trade with veterinary medicinal products shall be taken away with an order of the Executive director of the BFSA in the case of:

1. a violation of the conditions, as referred to in which it has been issued;

2. (amend. – SG 08/11, in force from 25.01.2011) a non-implementation of the prescriptions of the control bodies of the BFSA.

(2) The license for wholesale trade with veterinary medicinal products shall be terminated:

1. at the written request of its holder;

2. when the activity has ceased, for which the license was issued;

3. when the registration of the trader has been deleted (terminated);

4. in case of death of the natural person who is a sole proprietor.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order, as referred to in para 1 may be appealed, as referred to in the Administrative procedure code. The appeal shall not stop its implementation.

Art. 368. (1) The holder of a license for wholesale trade with veterinary medicinal products shall submit an application conformed to a specimen, in the case of:

1. whenever a new establishment for wholesale trade has been opened;

2. whenever there have been changes in:

(a) the entered circumstances in the register , as referred to in Art. 366, para 1, item 2, item 4 and item 5;

(b) the location or the conditions of the premises of the establishment, in which the activity has been carried out.

(2) (suppl. – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) To the application shall be attached the documents, related to the change and a receipt of a paid fee in an amount, determined by the tariff under Art. 14, para. 2, when the payment is not made electronically.

(3) (amend. – SG 08/11, in force from 25.01.2011) In the cases referred to in para 1, item 2, letter (a), the executive director of the BFSA shall within fourteen days from the date, on which the application was submitted, enter the changes into the register, as referred to in Art. 366, para 2.

(4) In the cases referred to in para 1, item 1 and para 1, item 2, letter (b), the commission, as referred to in Art. 365 shall carry out an on-the-spot check of the establishment and in the case of irregularities found, shall give instructions for their removal (elimination).

(5) (amend. – SG 08/11, in force from 25.01.2011) In the cases referred to in para 1, item 1 and para 1, item 2, letter (b), the executive director of the BFSA shall within three months from the date, on which the application was submitted, approve the changes and enter them into the register. The period shall stop running for the time needed for the implementation of the instructions referred to in para 4.

(6) (amend. – SG 08/11, in force from 25.01.2011) In the cases referred to in para 1 the Executive director of the BFSA shall issue a new license.

Art. 369. (amend. – SG 7/13) (1) The wholesale traders with veterinary medicinal products have the right to supply veterinary medicinal products to other wholesale and retails traders of VMP, to veterinary medical establishments, referred to in Art. 26, para 1, items 1 and 2 as well as to owner persons upon presentation of a prescription, issued by a registered veterinary doctor.

(2) The wholesale traders with veterinary medicinal products may supply active substances for production of VMP only to other wholesalers of VMP and to VMP manufacturers.

(3) Financial document shall be issued for the supply referred to in par. 1 and 2 or a delivery and acceptance certificate shall be signed, indicating the type, quantity, batch number and expiry date of the VMP and/or the active substance and delivery date.

(4) It is forbidden to carry out wholesale trade with VMP the information on the packing of which and in the leaflet for use are not in compliance with the requirements of the ordinance referred to in Art. 361, par. 2.

Art. 369a. (new – SG 7/13) Where a wholesaler does not hold a licensee for use of a particular VMP, but intends to deliver this VMP from another Member State for commercial purposes, he/she must notify in writing the holder of the license for use of the product and the Managing Director of BFSA of this intention of his/her.

Art. 370. (1) The holder of a license for wholesale trade with veterinary medicinal products shall develop and maintain a system of blocking and recall from the market of veterinary medicinal products, which do not meet the quality requirements.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The holder of a license for wholesale trade with veterinary medicinal products shall develop and apply an action plan in case of emergency for withdrawal of the product from the market upon an order of the Managing Director of BFSA and in case of joint withdrawal of the product with a manufacturing license or of a license for use of VMP.

(3) (amend. – SG 7/13) The holder of a license for wholesale trade with veterinary medicinal products shall be obliged to block and recall veterinary medicinal products from the veterinary medical pharmacies, clinics, surgery and consulting rooms, in the cases , as referred to in Art. 316, para 1, Art. 317, para 1 and Art. 318, para 1, items 1-4, 6 and 7.

Art. 371. (1) The wholesale traders with veterinary medicinal products shall keep documentation, which shall contain:

1. the date of buying and selling of veterinary medicinal products;
2. the name of the veterinary medicinal products;
3. the number and the term of validity of the batch of veterinary medicinal products;
4. the quantities of veterinary medicinal products bought and sold;
5. the name and the address of the supplier and the buyer.

(2) The documentation shall be stored for a minimum of three years since the last entry, and shall be presented to the controlling organs upon request.

(3) The persons, as referred to in para 1 shall once a year carry out a full revision of the quantities of veterinary medicinal products delivered (bought), sold and available in store. All inconsistencies established shall be listed.

Section VI.
Retail trade with veterinary medical products

Art. 372. (1) Retail trade of veterinary medicinal products shall be carried out only in veterinary medical pharmacies.

(2) At the veterinary medical pharmacy the following shall be carried out:

1. (amend. – SG 84/07) keeping (storage) and selling of veterinary medicinal products, instruments, devices and appliances for veterinary medical and animal breeding purposes, as well as pet foods and decorative animal foods in their original packages;
2. preparation and release of veterinary medicinal, as referred to in a magistral or a pharmacopoeia prescription.

Art. 373. (1) (amend. – SG 08/11, in force from 25.01.2011) Retail trade of veterinary medicinal products shall be carried out by natural or legal persons, registered, as referred to in the Commerce Act, after having received a license by the Executive director of the BFSA.

(2) The manager of the veterinary medical pharmacy and the persons, selling veterinary medicinal products have to be veterinary doctors.

(3) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in

force from 18.07.2017) The requirements to the veterinary medical pharmacies shall be arranged with an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 374. (1) It is necessary that a prescription is required when selling the following veterinary medicinal products:

1. veterinary medicinal products for which the requirements of the Control on Drugs and Precursors Act are applicable;

2. veterinary medicinal products, at the administration of which measures are to be taken for the purposes of avoiding a risk for:

a) the animals, for which they are intended;

b) the persons, administering the veterinary medicinal products on the animals;

c) the consumers of raw materials and foods, obtained from animals, treated with veterinary medicinal products;

d) the environment.

3. veterinary medicinal products, intended for the prophylactics or treatment of diseases, which require an advance diagnosis or the administering of which may impede or have an adverse effect to the subsequent diagnostic procedures or therapeutical activities;

4. (revoked – SG 7/13);

5. veterinary medicinal products, intended for productive animals;

6. veterinary medicinal products, which have a strong and poisonous action;

7. (new – SG 7/13) with a new active substance, including within less than 5 years ago in the content of a VMP licensed for use.

(2) The prescription, as referred to in para 1 shall be issued only by the practicing (regional) veterinary doctor, as referred to in Art. 25, para 1.

(3) (new – SG 7/13) The quantity of VMP prescribed in the prescription must be the minimum required for the respective therapy.

(4) (prev. par. 3 – SG 7/13) The prescription shall be issued in two identical copies – one intended for the purchase of veterinary medicinal products from the pharmacy, and the second one – for the owner of the animals, for whose therapy they are intended.

(5) (prev. par. 4, amend. – SG 7/13) The manager of the pharmacy and the owner of the animals, as referred to in para 4 shall keep the prescriptions referred to in para 1 for a period of 5 years from the date of their preparation.

Art. 375. (1) (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13, amend. – SG 17/18, in force from 23.02.2018) For the purposes of issuing a license for retail trade with VMP, the persons under Art. 373, Para. 1 shall submit a standard application to the BFSA's Executive Director. The application shall be submitted in person, or by proxy, or electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall indicate the UIC under the Commercial Register Act and the Register of Non-Profit Legal Entities, the number and date of issue of the act for putting into operation of the veterinary pharmacy, issued by the order of the Spatial Development Act, the number and date of issuance of the diploma of the persons under Art. 373, Para. 2, and shall be accompanied by:

1. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

2. (amend. – SG 7/13, revoked – SG 17/18, in force from 23.02.2018)

3. (revoked – SG 17/18, in force from 23.02.2018)

4. (suppl. – SG 17/18, in force from 23.02.2018) a document certifying that a fee has been paid at an amount, specified by the tariff, as referred to in Art. 14, para 2, when the payment is not made

electronically.

(2) In case of retail trade with veterinary medicinal products which have an anabolic, anti-infectious, anti-parasitic, anti-inflammatory or hormonal action, the requirements of the ordinance, as referred to in Art. 363, para 4 shall apply.

(3) In case of wholesale trade with veterinary medicinal products which contain narcotic substances, the requirements of the Control on Drugs and Precursors Act shall be applied.

Art. 376. (1) (amend. – SG 08/11, in force from 25.01.2011) The Executive director of the Bulgarian Food Safety Agency, or a person which has been authorized by him, shall appoint the commission, which shall check the submitted documentation and the establishment.

(2) (suppl. – SG 7/13) Where discrepancies (missing elements) are detected in the presented documents, or non-compliance between the condition (state) of the establishment and the requirements, which have been set in the ordinance, as referred to in Art. 363, para 3, the commission shall inform the applicant in writing and shall give instructions for their elimination. In these cases the term for issuing a license stops to run for the time it takes to eliminate the missing elements and/or the discrepancies, but for not more than 180 days.

(3) (amend. – SG 08/11, in force from 25.01.2011) The commission shall draw up an opinion and present it to the executive director of the Bulgarian Food Safety Agency.

(4) (new – SG 7/13) Where the applicant fails to correct the faults within 180 days from the date of receipt of the written notification, the Managing Director of BFSA by an order shall terminate the procedure of issuance of a license and shall notify the applicant in writing thereof.

(5) (new – SG 7/13) The order under par. 4 shall be communicated and may be appealed following the provision of the Code of Administrative procedure. The appealing shall not suspend the implementation.

(6) (new – SG 7/13) In cases referred to in par. 4 an application for issuing of a license according to the provision of Art. 375 may be submitted.

(7) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 4 – SG 7/13) Within one month after the application has been placed, the executive director of the Bulgarian Food Safety Agency, on the basis of the opinion of the commission, shall issue a license for retail trade with veterinary medicinal products, or shall issue a motivated order to refuse the issuing of a license

(8) (new – SG 7/13) The license under par. 7 shall not expire.

(9) (amend. - SG 30/06, in force from 12.07.2006; prev. par. 5, amend. – SG 7/13) The refusal, as referred to in para 7 shall be communicated and may be appealed (attacked in court) following the procedure laid down in the Administrative procedure code.

Art. 377. (1) The license for retail trade with veterinary medicinal products shall contain the data, as referred to in para 2, item 1 to item 4, and, as referred to in Art. 375, para 2 and para 3.

(2) (amend. – SG 08/11, in force from 25.01.2011, amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the issued licenses for retail trade with veterinary medicinal products, which shall contain:

1. number and date, on which the license was issued;
2. name, headquarters and address of the management of the person, who was granted a license;
3. address/ location of the pharmacy;
4. data on the manager of the pharmacy;
5. number and date, on which the order of suspension of the license was issued;
6. remarks on the circumstances entered.

(3) The circumstances, as referred to in Art. 375, para 2 and para 3 shall be entered into the register.

Art. 378. (1) (amend. – SG 08/11, in force from 25.01.2011) The license for retail trade with veterinary medicinal products shall be suspended by an order of the Executive director of the veterinary medicinal products in the case of repeated or serious breaches of the requirements, determined in the ordinance, as referred to in Art. 373, para 3.

(2) The license for retail trade with veterinary medicinal products shall be terminated:

1. at the written request of its holder;

2. when the activity has ceased, for which the license was issued;

3. in case of death of the natural person who is a sole proprietor.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order, as referred to in para 1 shall be appealed, as referred to in the Administrative procedure code.

Art. 379. (1) The holder of the license for retail trade with veterinary medicinal products shall submit an application conformed to a specimen, at a change of :

1. whenever a new establishment for retail trade has been opened;

2. whenever there have been changes in:

(a) the entered circumstances in the register , as referred to in Art. 377, para 1, item 2 to item 4;

(b) the conditions of the establishment, in which the activity has been carried out.

(2) (suppl. – SG 7/13, suppl. – SG 17/18, in force from 23.02.2018) The application shall be accompanied by the documents, related to the change and by a receipt of a paid fee in an amount, determined by the tariff referred to in Art. 14, para. 2, when the payment is not made electronically.

(3) In the case of a change in the location of the pharmacy or the conditions in the premises, the commission, as referred to in Art. 376 shall carry out an on-the-spot check of the establishment and in the case of irregularities found, shall give instructions for their removal (elimination).

(4) (amend. – SG 08/11, in force from 25.01.2011) In the cases referred to in para 1, item 1 and in the cases of a change in the circumstances, as referred to in Art. 377, para 2, item 3, the executive director of the Bulgarian Food Safety Agency shall within one month from the date, on which the application was submitted, re-issue the license and enter the changes into the register, as referred to in Art. 377. The period shall stop running for the time needed for the implementation of the instructions referred to in para 3.

(5) (new – SG 7/13) In cases referred to in par. 3 and 4, where the applicant fails to fulfill the commission’s instructions within 120 days, the requirements of Art. 376, par. 4 – 6 shall apply.

(6) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 5 – SG 7/13) In the cases of a change in the circumstances, as referred to in 377, para 1, item 2 and item 4, the Executive director of the Bulgarian Food Safety Agency shall within 14 days after the application was submitted, enter the changes into the register and issue a new license.

Art. 380. (1) The holder of the license for retail trade with veterinary medicinal products shall keep a daily register, which shall contain:

1. the date of buying and selling of veterinary medicinal products, including quantities;

2. the name of the veterinary medicinal products;

3. the number and the term of validity of the batch of veterinary medicinal products;

4. the name and the address of the supplier and the buyer;

5. the name and the address of the veterinary doctor, who has issued the prescription.

(2) The documentation shall be stored for a minimum of five years since the last entry, and shall be presented to the controlling organs upon request.

(3) The holder of a license for trade with veterinary medicinal products is obliged to carry out at least once a year a full revision to determine the consistency between the veterinary medicinal products available in store and the quantities, which have been detailed in the documents, and for all inconsistencies a record shall be drafted.

Art. 381. (amend. – SG 7/13) It is forbidden to carry out retail trade with veterinary medicinal products, the data of which indicated on the packing and the application leaflet are not in compliance with the requirements of the ordinance referred to in Art. 361, par. 2.

Section VII.
System of pharmacological alert

Art. 382. (1) (In force as from the 1st of January 2007; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Bulgarian Food Safety Agency shall establish and maintain a pharmacological alert system.

(2) (amend. – SG 08/11, in force from 25.01.2011; revoked – SG 7/13).

(3) The system is intended for the collection and assessment of information as a result of the use of veterinary medicinal products, related to:

1. any adverse reactions in animals and/or humans;
2. (amend. – SG 7/13) an absence of the expected efficiency;
3. (amend. – SG 7/13) an withdrawal period;
4. (amend. – SG 7/13) the use of veterinary medicinal products, which are non-compliant with the data on the packing and in the product application leaflet;
5. ecological problems.

(4) The system shall contain data, incoming from:

1. the holders of licenses for use of veterinary medicinal products;
2. the veterinary doctors;
3. the owners of productive animals;
4. the manufacturers of veterinary medicinal products;
5. the traders with veterinary medicinal products;
6. (revoked – SG 7/13).

(5) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) The Bulgarian Food Safety Agency shall provide by entering into the data base under Art. 57, paragraph 1, item "d" of Regulation (EC) No. 726/2004 the collected information to other competent bodies of the Member States and to the European Drug Agency. The information must be available to all Member States.

(6) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) The conditions and the procedure for the submission of information on the pharmacological alert shall be arranged by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 383. (1) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Upon assessment of the data from the pharmacological alert, the Managing Director of BFSA by an order may:

1. withdraw the license for use;

2. suspend the validity of the license for use;

3. make amendments of the license for use, related to limitation of the indications for administration, adjustment of the dose, addition of indications, addition of new preventive measures.

(2) (new – SG 7/13) In cases referred to in par. 1, the Managing Director of BFSA shall notify immediately the holder of the license for use of VMP, the competent bodies of the remaining Member States and the European Drug Agency of the undertaken measures.

(3) (amend. – SG 08/11, in force from 25.01.2011; prev. par. 2, amend. – SG 7/13) In the case of an immediate necessity for the preservation of the health of people or animals, the executive director of the Bulgarian Food Safety Agency may suspend the validity of the license for use of veterinary medicinal products, in which case he shall inform the European Agency for Medicines, the European Commission and the competent bodies of the remaining Member States not later than the next working day.

Art. 384. (revoked – SG 7/13).

Section VIII.
State veterinary medical control over veterinary medicinal products

Art. 385. (1) (amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13) The Bulgarian Food Safety Agency shall carry out control on the manufacturing, the wholesale and retail trade, the import, the advertisement and the use of veterinary medicinal products, and also on the manufacturing and wholesale of active substances.

(2) (amend. – SG 08/11, in force from 25.01.2011) The Bulgarian Food Safety Agency shall carry out on-the-spot checks also at the request of the competent authority of the interested member state, the European Commission and the European Agency for Medicines.

Art. 386. (1) (suppl. – SG 7/13) The control, as referred to in Art. 385, para 1 shall be carried out by inspectors and experts.

(2) (amend. – SG 7/13) The employees under par. 1 shall carry out periodical and unexpected checks and, where relevant, shall send samples of veterinary medicinal products and active substances for laboratory tests or to an accredited laboratory in the European Union.

(3) (new – SG 7/13) The inspection of the manufacturing conditions of active substances for compliance with the GMP requirements may be carried out also upon request of the active substances manufacturer.

Art. 387. (amend. – SG 7/13) The control shall be carried out through:

1. laboratory testing of samples of VMP and active substances;

2. revision of documents and the conditions of manufacturing, import, storage and control of VMP;

3. revision of documents and the conditions of manufacturing, import, storage and control of active substances;

4. revision of documents and the conditions of wholesale and retail trade of VMP;

5. revision of documents and the premises of the holders of licenses for use of VMP.

Art. 388. (1) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) Inspectors and experts from BFSA:

1. (amend. and suppl. – SG 7/13) shall check at any time the establishments for manufacturing, storage, control, sale and administration of VMP, and also the documents and the premises of the holders of a license for use of VMP;

2. shall demand and examine all documents, relevant to manufacturing and quality of veterinary medicinal products;

3. shall issue written prescriptions for the removal of detected breaches/inconsistencies;

4. (suppl. – SG 7/13) shall put under ban veterinary medicinal products and active substances in case of suspected deviation of the quality parameters until the results of the laboratory tests have been received, and also in case of violations of the provisions of this Chapter;

5. (suppl. – SG 7/13) shall take samples for laboratory analysis of the raw materials and of end products;

6. shall give a conclusion for the compliance of the establishments, as referred to in item 1 with the requirements;

7. (revoked – SG 7/13);

8. (amend. – SG 7/13) shall inspect the activities of the persons, as referred to in Art. 344, item 3;

9. (suppl. – SG 7/13) shall check the compliance with the requirements on the good manufacturing practices at the manufacturing of veterinary medicinal products in the Republic of Bulgaria, and also for compliance with the requirements for production processes validation and for assurance of repeatability of the batches of immunology VMP;;

10. shall check the observance of the requirements on the good manufacturing practices at the manufacturing of veterinary medicinal products in other countries:

a) when part of the production of the persons, as referred to in Art. 343, para 1 has been carried out outside the territory of the Republic of Bulgaria;

b) (suppl. – SG 7/13) in the cases , as referred to in Art. 355, par. 1.

(2) (amend. – SG 08/11, in force from 25.01.2011; amend. – SG 7/13) In the course of carrying out of inspections under par. 1 the holders of licenses for production, use and trade in VMP and registered veterinarians shall be obliged to provide assistance and access to the sites under par. 1, item 1 and to the documentation, related to their activity.

(3) (new – SG 7/13) The employees of RFSD, appointed to carry out control of VMP, shall inspect the sites for selling, storage and application of VMP, shall issue a conclusion on the compliance of the facilities for wholesale and retail trade in VMP with the provisions of this Chapter and shall carry out the activities under par. 1, item 3 – 5.

(4) (prev. par. 3, amend. – SG 7/13) For the results of the inspections, as referred to in para 1, item 1, 2, 6, 8, 9 and 10 a detailed report shall be drawn up, and a copy thereof shall be submitted to the inspected persons.

(5) (new – SG 7/13) In the course of inspections under par. 1 the inspectors and the experts of BFSA may open packages with VMP or active substances, to copy documents and take photographs in the controlled sites.

(6) (new – SG 7/13) The employees under par. 1 shall not have the right to disclose information made available in the course of inspections.

Art. 388a. (new – SG 7/13) (1) The Managing Director of BFSA shall issue a GMP certificate within 90 days after the inspection of a site for production of VMP and the inspections under Art. 388, par. 1, item 9 and 10, where they show that the GMP requirements are complied with.

(2) The certificate under par. 1 shall have a three-year validity.

(3) Where the inspection under par. 1 is carried out upon request of the European Drug Quality Directorate, the Managing Director of BFSA shall issue a certificate of compliance with the monograph.

(4) Bulgarian Food Safety Agency shall make record into the European Union date base (EudraGMP) the information of the issued GMP certificates or information about the identified inconformity with GMP requirements.

Art. 389. (1) (amend. – SG 08/11, in force from 25.01.2011) Where detecting breaches, in accordance with the kind and the seriousness of the breaches, the Bulgarian Food Safety Agency shall:

1. (amend. – SG 08/11, in force from 25.01.2011) issue instructions for their elimination;

2. stop temporarily the activity of a part or the whole establishment, until the breaches/ inconsistencies have been eliminated;

3. (new – SG 7/13) instruct for rejection and destruction of VMP in cases referred to in Art. 318, par. 1.

(2) The measures, as referred to in para 1 shall be applied:

1. as referred to in item 1 – with instructions from the inspectors of the Bulgarian Food Safety Agency;

2. (amend. - SG 30/06, in force from 12.07.2006; amend. – SG 08/11, in force from 25.01.2011) as referred to in item 2 – with an order of the Executive director of the Bulgarian Food Safety Agency, which may be appealed in court following the procedure, laid down in the Administrative procedure code. The appeal does not stop the application;

3. (new – SG 7/13) under item 3 – by an instruction of the inspector, having identified the violation.

Art. 390. The samples for laboratory analysis of veterinary medicinal products shall be taken in the presence of the owner of the veterinary medicinal products or his representative, of which a record shall be drawn.

Art. 391. (1) For the purposes of laboratory examinations three samples shall be taken from the veterinary medicinal products, from intact whole packages, each of them sufficient for carrying out of the three analyses. After taking the samples, they are to be sealed or stamped (packaged).

(2) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011; suppl. – SG 7/13) One of the samples shall be tested in a laboratory of the Bulgarian Food Safety Agency, and the remaining two shall be stored respectively by the owner of veterinary medicinal products and in the Bulgarian Food Safety Agency until the expiry of the their validity period and shall serve as a proof, in case a dispute arises.

Art. 392. (1) (amend. – SG 41/10, in force from 01.06.2010; amend. – SG 08/11, in force from 25.01.2011) Where there has been an appeal as regards the results of the testing in the Bulgarian Food Safety Agency, the interested party has the right within 7 working days of receiving of the results to require a second testing of the product.

(2) The second testing shall be carried in a reference laboratory, the results of which shall be final.

(3) The expenditures on the testing referred to in para 2 shall be at the expense of party, which has required it.

Art. 393. (amend. – SG 7/13) Laboratory examinations of veterinary medicinal products shall be carried out according to the methods, indicated in the European pharmacopoeia and/or according to other officially recognized methods of assessment of the end product, included in the dossier, as referred to in Art. 279, para 1, item 3.

Art. 394. The requirements, as referred to in this Section shall not apply to:
1. medicated feeding stuffs;
2. veterinary medicinal products, which have been manufactured from radioactive isotopes;
3. feed additives;
4. veterinary medicinal products, designated for scientific studies;
5. (new – SG 7/13) inactivated immunologic VMP, produced from pathogenic micro-organisms and antigens, obtained from and animal or animals from a particular animal breeding site, and which are applied on an animal or animals from the same site.

Chapter twelve.
SAFETY OF FEEDSTUFFS RAW MATERIALS, FEED ADDITIVES, PRE-MIXES AND COMBINED AND MEDICATED FEEDING STUFFS (REVOKED - SG 97/12)

Section I.
Control on the safety of feeding stuffs (revoked - SG 97/12)

Art. 395. (revoked - SG 97/12)

Art. 396. (revoked - SG 97/12)

Art. 397. (revoked – SG 100/08)

Art. 398. (amend. - SG 55/06; revoked – SG 100/08)

Art. 399. (revoked - SG 55/06)

Art. 400. (revoked - SG 97/12)

Art. 401. (In force as from the 1st of January 2007; revoked - SG 97/12)

Art. 402. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010; revoked - SG 97/12)

Section II.

Medicated feeding stuffs (revoked - SG 97/12)

Art. 403. (revoked - SG 97/12)

Art. 404. (revoked - SG 97/12)

Art. 405. (revoked - SG 97/12)

Art. 406. (revoked - SG 97/12)

Art. 407. (amend. – SG 36/08 ; amend. – SG 41/10, in force from 01.06.2010; revoked - SG 97/12)

Art. 408. (revoked - SG 97/12)

Section III.
National monitoring program (revoked - SG 97/12)

Art. 409. (amend. – SG 08/11, in force from 25.01.2011; revoked - SG 97/12)

Art. 410. (In force as from January 1 2007; revoked - SG 97/12)

Chapter twelve "a".
IN-VITRO DIAGNOSTIC VETERINARY MEDICINAL AIDS (NEW - SG 7/13)

Art. 410a. (new - SG 7/13) (1) (amend. - SG 14/16, in force from 19.02.2016) In-vitro diagnostic veterinary medicinal aids may be used for the fulfillment of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses upon issuance by BFSA of a certificate of registration of a diagnostic aid.

(2) Import of in-vitro diagnostic veterinary medicinal aids from third countries may be carried out only by a person authorized by the manufacturer, registered as a trader according to the provisions of the Commercial law or under the laws of an European Union Member State or of another state which is a party to the Agreement on the European Economic Area or of the Confederation of Switzerland.

Art. 410b. (new – SG 7/13) (1) (Amend. – SG 17/18, in force from 23.02.2018) For issuance of a certificate of registration of an in-vitro diagnostic veterinary medicinal aid the manufacturer, respectively the person under Art. 410a, par. 2, shall submit an application in a standard form to the Managing Director of BFSA indicating the UIC under the Commercial Register Act and the Register of Non-Profit Legal Entities. The application shall be submitted in person, or by proxy, or electronically under the conditions and by the order of Art. 5 and 22 of the Electronic Governance Act, or through a licensed postal operator. The application shall be accompanied by:

1. (amend. – SG 17/18, in force from 23.02.2018) a certificate of valid registration, issued by the competent body of another state, if applicable;

2. original copy of a power of attorney or a power of attorney certified by a notary public – where the application is submitted by a proxy;

3. original copy or a power of attorney certified by a notary public – in cases referred to in Art. 410a, par. 2;

4. a copy of a document, issued by an accredited laboratory in a Member State, for compliance of the aid with the manufacturer's technical specification;

5. manufacturer's information, containing general technological and/or analytical specifications, production processes and quality control;

6. description of analytical and diagnostic parameters of the diagnostic aid;

7. manufacturer's declaration stating that the production of the diagnostic aid is in compliance with the requirements of the ordinance under Art. 410c;

8. operation manual in Bulgarian language;

9. a copy of a registration document, issued in another state, if available;

10. three samples for testing of the in-vitro diagnostic veterinary medicinal aid;

11. other documents and information, referred to in the ordinance under Art. 410c;

12. (suppl. – SG 17/18, in force from 23.02.2018) a receipt of a paid fee in an amount, determined by the tariff under Art. 14, par. 2, when the payment is not made electronically.

(2) Where the documents under par. 1, items 1 – 7 and 9 are in a foreign language, they must be accompanied by a legalized translation into Bulgarian language.

Art. 410c. (new – SG 7/13, amend. – SG 58/17, in force from 18.07.2017) The requirements to the information, contained in the documentation for issuance of a registration certificate, the packaging, application leaflet and production of an in-vitro diagnostic veterinary medicinal aid and the procedure of conducting of sensibility test shall be determined by an ordinance of the Minister of Agriculture, Foods and Forestry.

Art. 410d. (new – SG 7/13) (1) Within 60 days after the submission of the application, BFSA shall carry out revision of the documentation and shall test the sensitivity of the in-vitro diagnostic veterinary medicinal aid.

(2) In case of identified blanks in the submitted documents the Managing Director of BFSA shall notify the applicant to correct them. In this case the term referred to in par. 1 shall stop elapsing.

(3) The Managing Director of BFSA within 7 days after the receipt of the results of inspection and testing under par. 1 shall issue a certificate of registration or shall refuse to issue it with justification and shall notify the applicant thereof.

(4) The certificate under par. 3 shall not expire.

(5) Sensitivity test under par. 1 shall be done in a laboratory of BFSA.

Art. 410e. (new – SG 7/13) The Managing Director of BFSA shall refuse to issue a registration certificate, where:

1. the quantitative and qualitative content of the in-vitro diagnostic veterinary medicinal aid is different from the one indicated in the presented by the applicant documentation;

2. the in-vitro diagnostic veterinary medicinal aid does not have the required sensitivity, specificity, reproducibility and precision;

3. the information on the packaging and/or the application leaflet does not meet the

requirements of the ordinance referred to in Art. 410c.

(2) The refusal under par. 1 shall be communicated and may be appealed following the provisions of the Code of Administrative Procedure.

(3) (Amend. – SG 17/18, in force from 23.02.2018) The Bulgarian Food Safety Agency shall maintain on its website a national public electronic register of the in-vitro diagnostic veterinary medicinal aids having obtained a registration certificate containing:

1. the name of the diagnostic aid;

2. number and date of issue of the registration certificate;

3. diseases to be diagnosed, for which the diagnostic aid is intended;

4. name, main office and address of registration of the manufacturer and of the person under Art. 401a, par. 2, having obtained the certificate.

(4) In case of change of registered particulars under par. 3, item 4 and Art. 410b, par. 1, items 5m 6 and 8 the registration certificate holder within three days after the occurrence of the change shall notify in writing the Managing Director of BFSA and shall attach the documents, related thereof, for entering into the register.

(5) In case of change of registered particulars under par. 3, item 3 an application shall be submitted according to the provision of Art. 410b.

(6) In case of change of particulars a supplement to the registration certificate shall be issued.

(7) In case of withdrawal of a diagnostic aid from the market, the registration certificate holder shall notify BFSA.

Art. 410f. (new – SG 7/13) (1) The Managing Director of BFSA by an order shall delete the registration of an in-vitro diagnostic veterinary medicinal aid, where:

1. the diagnostic aid does not have the diagnostic effect, sensitivity and/or the specificity, indicated in the documentation;

2. the diagnostic aid does not meet the declared in the registration documentation qualitative and quantitative content;

3. there is an imposed prohibition for application of the diagnostic aid after issuing of registration certificate;

4. the information presented in the registration documentation, is incorrect.

(2) The order under par. 1 shall be communicated and may be appealed following the provisions of the Code of Administrative procedure.

Art. 410g. (new – SG 7/13) (1) The registration certificate holder shall be obliged to block, to withdraw from the market and to destroy the batch of the in-vitro diagnostic veterinary medicinal aid, where it is identified, that the batch does not meet the registration documentation, and also in cases referred to in Art. 410f, par. 1.

(2) Where BFSA identified incompliances under par. 1, the Managing Director of BFSA by an order shall instruct the registration certificate holder to withdraw the batch from the market.

Art. 410h. (new – SG 7/13) (1) Trade in in-vitro diagnostic veterinary medicinal aids shall be carried out in wholesale and retail trade sites licensed according to the provisions of this law.

(2) The trade under par. 1 may be carried out only in registered under the provision of Art. 410b in-vitro diagnostic veterinary medicinal aids.

(3) Wholesalers and retail traders shall be obliged:

1. to maintain documentation containing information about each concluded transaction, name

of the in-vitro diagnostic veterinary medicinal aid, delivered quantities, name/designation and address/main office of the supplier and of the consignee and batch number of the diagnostic aid;

2. to reject and destroy the in-vitro diagnostic veterinary medicinal aid within 30 days after the expiration of its best before date according to the Law for Waste Management.

(4) Each batch must be accompanied by an analytical quality certificate issued by the manufacturer.

Art. 410i. (new – SG 7/13) In-vitro diagnostic veterinary medicinal aids shall be stored under the conditions, determined by the manufacturer.

Chapter thirteen.
ADMINISTRATIVE – PENAL PROVISIONS

Art. 411. (amend. - SG 14/16, in force from 19.02.2016) A veterinary doctor, who is exercising a veterinary practice, without being registered, as referred to in Chapter Four, shall be fined with 400 BGN, and in case of a second violation – with a fine to the amount of 600 BGN.

Art. 412. (amend. – SG 84/07) A veterinary doctor, who is exercising a veterinary practice in am establishment, which is not in compliance with the requirements, referred to in Art. 26, para 2, shall be punished by a fine from 50 up to 150 BGN, and in case of a second violation – with a fine to the amount of 150 up to 400 BGN.

Art. 413. (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) (1) A veterinary doctor or a manager of a veterinary medical establishment, failing to fulfill their obligations, as referred to in Art. 39, shall be fined from 400 to 2 000 BGN, and in the case of a repeated violation - with a fine from 1 000 up to 4 000 BGN.

(2) When, as a result of failure to fulfill an obligation under Art. 39, significant economic loss or danger to the health of large numbers of people or animals have occurred, if the person under par. 1 is not subject to a more severe penalty, the fine shall be of 5 000 to 10 000 BGN, and for a repeated offense - from 10 000 to 20 000 BGN.

Art. 414. (amend. – SG 84/07) A veterinary technician, who has exceeded his rights, as referred to in Art. 40, para 1, shall be fined with 200 BGN, and in the case of a repeated violation – with a fine to the amount of 400 BGN.

Art. 414a. (new – SG 7/13) (1) (amend. – SG 99/13) A veterinary doctor, failing to fulfill their obligation under a contract under Art. 46f shall be fined from 300 to 1000 BGN, and in the case of a repeated violation - with a fine from 500 to 2 000 BGN.

(2) A veterinary doctor, failing to meet the deadlines for fulfillment of the measures under Art. 46g, determined in the contract, shall be fined from 100 to 500 BGN, and in the case of a repeated violation - with a fine from 200 to 700 BGN.

(3) (amend. – SG 99/13) A veterinary doctor, having submitted incorrect information regarding the implementation of the contract under Art. 46f, where the act does not constitute an offense, shall be fined from 500 to 2000 BGN, and in the case of a repeated violation - with a fine from 700 to 3 000 BGN.

(4) A veterinary doctor, who in the course of exercising a veterinary medicine practice fails to meet veterinary medicine requirements, shall be fined from 150 to 600 BGN, and in the case of a repeated violation - with a fine from 300 to 1 500 BGN.

Art. 415. (1) (amend. – SG 08/11, in force from 25.01.2011) Whoever does not apply a measure, imposed by the Bulgarian Food Safety Agency for the prophylactics, limitation and eradication of a contagious disease on the animals, shall be fined from 50 up to 200 BGN, and in the case of a repeated violation - with a fine to the amount of 300 up to 500 BGN.

(2) Where as a result of the non-implementation of the measure, as referred to in para 1, considerable material damages or a hazard to the health of a large number of people or animals have resulted, and in case the act is not a subject to a greater punishment, a fine from 1000 up to 2 000 BGNshall be charged, and in the case of a repeated violation – with a fine to the amount of 2 000 up to 4 000 BGN.

(3) Where the violation, as referred to in para 1 has been committed by a legal person or a sole proprietor, property sanction shall be imposed, to the amount of from 1 000 up to 5 000 BGN, and in the case of a repeated violation – property sanction to the amount of 5 000 up to 15 000 BGN.

(4) Where as a result of the non-implementation of the measure, as referred to in para 1 considerable property damages or a hazards to the health of a large number of people or animals have been caused, the legal person or the sole proprietor shall be fined with property sanction from 10 000 up to 20 000 BGN, and in the case of a repeated violation – property sanction to the amount of 20 000 up to 40 000 BGN.

Art. 415a. (New - SG 14/16, in force from 19.02.2016) (1) In violation of a prohibition under Art. 49, para. 1, the owner, respectively the user of the livestock site, and the person making the vaccination shall be fined with a fine of 500 to 1 000 BGN, and for a repeated violation - from 3 000 to 5 000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a pecuniary penalty shall be imposed of 1 000 to 5 000 BGN, and for a repeated violation - from 5 000 to 15 000 BGN.

Art. 415b. (New - SG 14/16, in force from 19.02.2016) (1) When any person violates the requirements of Art. 118, para. 5, shall be penalised by a fine of 50 to 200 BGN, and for a repeated violation - from 300 to 1000 BGN.

(2) When, as a result of violation under par. 1, significant economic loss or danger to the health of large numbers of people or animals have occurred, if the person is not subject to a more severe penalty, the fine shall be from 1 000 to 2 000 BGN, and for a repeated offense - from 2 000 to 4 000 BGN.

(3) Where the violation under par. 1 is committed by a legal entity or a sole trader, a pecuniary penalty shall be imposed of 1 000 to 5 000 BGN, and for a repeated violation - from 5 000 to 15 000 BGN.

(4) When, as a result of violation under par. 1, significant economic loss or danger to the health of large numbers of people or animals have occurred, the legal entity or sole trader shall be imposed a proprietary sanction from 10 000 to 20 000 BGN, and for a repeated offense - from 20 000 to 40 000 BGN.

Art. 416. (1) (amend. – SG 7/13) The owners of farm animals, who have not fulfilled their obligations, as referred to in Art. 132, para 1, item 4, 6 – 9, 12, 14, 21 - 23 shall be fined fron 200 to 500 BGN, and in the case of a repeated violation – with a fine from 400 to 1000 BGN.

(2) (amend. – SG 7/13) Where the violation, as referred to in para 1, has been committed by a

legal person or by a sole proprietor, property sanctions shall be imposed from 500 to 3 000 BGN, and in the case of a repeated violation - property sanctions from 1000 to 6 000 BGN.

Art. 417. (amend. – SG 7/13) (1) (suppl. - SG 14/16, in force from 19.02.2016) The owners of farm animals, who have not fulfilled their obligations, as referred to in Art. 132, para 1, item 1 – 3, 5, 10, 11, 13, 15 - 20 and 24 , shall be fined from 500 to 2000 BGN, and in the case of a repeated violation - with a fine from 1000 to 5000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed from 1000 to 3 000 BGN, and in the case of a repeated violation – property sanctions from 2 000 to 10 000 BGN.

Art. 417a. (New - SG 14/16, in force from 19.02.2016) (1) Any person who unlawfully uses the means of identification or unlawfully performs replacement of such means, shall be fined from 200 to 1 000 BGN, and for a repeated offense - from 1 000 to 2 000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a pecuniary penalty shall be imposed of 1 000 to 5 000 BGN, and for a repeated violation - from 5 000 to 10 000 BGN.

Art. 418. An official , who does not fulfill an obligation, as referred to in Art. 133, shall be fined with the amount of 100 up to 300 BGN, and in the case of a repeated violation – with a fine to the amount of 300 up to 500 BGN.

Art. 418a. (New - SG 14/16, in force from 19.02.2016) When any person does not fulfill their obligations under Art. 134, para. 1 and 2, shall be fined, respectively imposed with a pecuniary penalty, from 200 to 500 BGN, and for a repeated offense - from 500 to 1 000 BGN.

Art. 419. (amend. and suppl. – SG 7/13) Whoever organizes an animal market without being registered, as referred to in Art. 137, par. 1 - 9, or in violation the requirements of the ordinance, as referred to in Art. 137, para 10, shall be punished with a fine or a property sanction with the amount of 500 up to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 up to 2000 BGN.

Art. 420. (1) (suppl. – SG 84/07; amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) The owner of animals, who breaches the ban, as referred to in Art. 139, para 1, item 2, items 6 – 11, 14 and 16 shall be fined with the amount of 200 up to 1 000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 2000 BGN.

(2) (amend. - SG 14/16, in force from 19.02.2016) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed from 800 up to 1 500 BGN, and in the case of a repeated violation – property sanctions to the amount of 1 500 up to 4 000 BGN.

Art. 420a. (new – SG 84/07) (1) (amend. - SG 14/16, in force from 19.02.2016) Whoever violates a prohibition as per art. 139, para 1, items 1, to 5, shall be punished by a fine from 300 to 500 BGN, and in case of repeated offence - by a fine from 500 to 1000 BGN.

(2) In case the violation under para 1 has been committed by a sole trader or a legal entity, a property sanction amounting from 1000 to 3000 BGN shall be imposed, an in case of repeated violation – from 2000 to 5000 BGN.

Art. 421. (amend. - SG 14/16, in force from 19.02.2016) A veterinary doctor or a technician,

who violates the ban, as referred to in Art. 139, para 1, item 12 or item 13, shall be fined with the amount of 300 up to 500 BGN, and in the case of a repeated violation – with a fine to the amount of 500 up to 1000 BGN.

Art. 422. (1) (suppl. – 92/11, amend. - SG 14/16, in force from 19.02.2016) Whoever violates the ban, as referred to in Art. 151, shall be fined with the amount of 200 up to 500 BGN, and in the case of a repeated violation – with a fine of 500 up to 1 000 BGN.

(2) (revoked – 92/11)

(3) (revoked - SG 14/16, in force from 19.02.2016)

(4) (amend. - SG 14/16, in force from 19.02.2016) In the cases, as referred to in para 1, the animal can be taken away from its owner to be retained by the government.

Art. 423. (Revoked – SG 27/09)

Art. 424. (1) (amend. - SG 14/16, in force from 19.02.2016) Whoever carries out experiments with animals without a permission or in violation of the ban, as referred to in Art. 158, shall be fined with a fine to the amount of 200 up to 500 BGN, and in the case of a repeated violation - with fine to the amount of 500 up to 1 000 BGN.

(2) Where the violation, as referred to in para 1, has been carried out by a legal person or by a sole proprietor, a property sanction shall be imposed of the amount from 500 up to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 up to 1500 BGN.

(3) In the cases, as referred to in para 1 and para 2, the animal can be taken away from its owner to be retained by the government.

Art. 425. (1) (amend. – SG 7/13) Whoever violates the ban, as referred to in Art. 169, shall be fined with the amount from 300 to 800 BGN.

(2) (amend. – SG 7/13) Where the violation, as referred to in para 1, has been carried out by a legal person or by a sole proprietor, a property sanction shall be imposed of the amount from 1000 to 5000 BGN.

(3) In the cases, as referred to in para 1 and para 2, the animal can be taken away from its owner to be retained by the government.

Art. 425a. (New – SG 17/18, in force from 23.02.2018) (1) Whoever, when transporting animals and at the request of an official veterinarian, does not present the required documents under Art. 4, Art. 5, paragraph 4 or Art. 6, paragraphs 1, 5 and 8 of Regulation (EC) № 1/2005, shall be liable to a fine of BGN 200. For the fine imposed, a ticket shall be issued at the site of the offense by the official veterinarian who has established the violation. The model of the ticket form shall be approved by the Executive Director of the Bulgarian Food Safety Agency, and the instructions in it shall be in Bulgarian and English. Whoever disputes the violation or refuses to sign the ticket shall be presented with an act establishing an administrative violation.

(2) Any natural person transporting animals in violation of the requirements specified in Art. 4 - 11 of Regulation (EC) № 1/2005, shall be liable to a fine of between BGN 1 000 and 3 000, and in the event of a repeated offense - from BGN 3 000 to 5 000.

(3) Where the violation under Para. 2 is committed by a legal person or by a sole trader, a

pecuniary sanction from BGN 5 000 to 10 000 shall be imposed, and in the case of a repeated violation - from BGN 10 000 to BGN 20 000.

Art. 426. (amend. – 92/11) Whoever violates the obligations, as referred to in Art. 172, item 1 and item 2 shall be fined with the amount of 100 BGN.

Art. 426a. (New - SG 14/16, in force from 19.02.2016) If any person does not fulfill the obligation under Art. 173, shall be punished by a fine from 50 to 500 BGN.

Art. 426b. (New - SG 14/16, in force from 19.02.2016) If any person does not fulfill the obligation under Art. 174, para. 4, shall be punishable by a fine of 200 BGN, and for repeated offense – 500 BGN.

Art. 427. (1) Whoever violates the ban, as referred to in Art. 177, para 1, item 1 shall be punished with a fine to the amount from 50 up to 100 BGN, and in the case of a repeated violation – with a fine to the amount of 100 up to 200 BGN.

(2) Where the violation, as referred to in para 1 has been carried out by a veterinary doctor or a technician, a fine shall be imposed of 100 up to 200 BGN, and in the case of a repeated violation – with a fine to the amount of 200 up to 300 BGN.

(3) (revoked – 92/11)

Art. 428. (amend. – 92/11) Whoever violates the ban, as referred to in Art. 177, para 1, item 3 or item 4 shall be punished with a fine to the amount of 100 BGN.

Art. 429. (1) (amend. – 92/11) The owners of the dogs, who violates the requirements, as referred to in Art. 174, shall be punished with a fine to the amount of 200 BGN.

(2) (amend. – 92/11) Where the violation, as referred to in para 1, has been carried out by a legal person or by a sole proprietor, a property sanction shall be imposed of the amount from 200 up to 400 BGN.

Art. 430. (amend. - SG 14/16, in force from 19.02.2016) A veterinary doctor, who has committed an euthanasia, outside the cases, as referred to in Art. 179, para 3 or in violation of the requirements, as referred to in Art. 180, or violates the ban, as referred to in Art. 181, shall be punished with a fine to the amount of 200 up to 300 BGN, and in the case of a repeated violation – with a fine to the amount of 300 up to 500 BGN.

Art. 431. An official veterinary doctor, who has permitted importing, exporting or transit passing of the subjects, as referred to in Art. 184, para 1, in violation of the health and veterinary medical requirements, as a result of which an immediate hazard to the health of people and animals has occurred, if he is not liable to heavier punishment, shall be fined with 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 2000 BGN.

Art. 431a. (New - SG 14/16, in force from 19.02.2016) If a person does not fulfill the obligation under Art. 200, shall be punished by a fine from 20 to 200 BGN, and for repeated offense - from 300 to

1000 BGN.

Art. 432. An official veterinary doctor, who has issued a veterinary medical document in violation of the obligations, as referred to in Art. 101, para 2, Art. 102, Art. 103 and Art. 105, shall be fined with a fee to the amount of 200 up to 500 BGN, and in the case of a repeated violation – the fine shall be doubled in size.

Art. 433. A veterinary doctor, who is registered for the purposes of exercising veterinary practice, who has made a violation, resulting in a mass dissemination of a disease, wherefrom considerable economic damages have been caused, shall be punished with deprivation of the right to exercise the veterinary medical profession for a period of 6 months up to 2 years.

Art. 434. Whoever uses a vaccine against a disease, as referred to in Art. 47, para 1, with the exception of a vaccine against the Newcastle disease in birds, shall be fined to the amount of 200 up to 500 BGN, and in the case of a repeated violation – with a fine to the amount of 500 up to 1000 BGN.

Art. 435. (1) Whoever moves or transports animals between the Republic of Bulgaria and a member state, in violation of Art. 52, para 1, shall be fined to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 2000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, a property sanction shall be imposed to the amount of 1000 up to 2000 BGN, and in the case of a repeated violation – property sanctions to the amount of 2000 up to 5000 BGN.

Art. 436. (1) (amend. – SG 08/11, in force from 25.01.2011) Whoever does not inform the organs of the Bulgarian Food Safety Agency, in the case of a suspicion of a contagious disease, as referred to in Art. 47, para 1, or as referred to in Art. 52, para 2, shall be fined to the amount of 300 up to 500 BGN, and in the case of a repeated violation – with a fine to the amount of 500 up to 1000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, a property sanction shall be imposed to the amount of 1000 up to 2000 BGN, and in the case of a repeated violation – property sanctions to the amount of 2000 up to 5000 BGN.

Art. 436a. (New - SG 14/16, in force from 19.02.2016) If a person does not fulfill the obligation under Art. 55, shall be punished by a fine from 300 to 1 000 BGN, and for repeated offense - from 500 to 2000 BGN.

Art. 437. (1) Whoever, in violation of Art. 58, para 1, places on the market raw materials and foods of animal origin, which do not have health or identification marking, shall be fined to the amount of 50 up to 150 BGN, and in the case of a repeated violation – with a fine to the amount of 150 up to 300 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 up to 3000 BGN.

Art. 438. A veterinary doctor, as referred to in Art. 8, para 1, who violates one of the requirements, as referred to in Art. 67, para 1 and para 2, shall be fined to the amount of 200 up to 500

BGN, and in the case of a repeated violation – with a fine to the amount of 500 up to 1000 BGN.

Art. 439. (1) The persons, carrying out production, trade or placing on the market of raw materials or foods of animal origin, animal by-products and products, received from those, who do not fulfill an obligation, as referred to in Art. 248, item 1, item 2, item 5 to item 7, item 11 and item 12, shall be punished with a fine to the amount of 100 up to 300 BGN, and in the case of a repeated violation – with a fine to the amount of 300 up to 500 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 500 up to 1000 BGN, and at a repeated violation – property sanctions to the amount of 1000 up to 3000 BGN.

Art. 440. (1) Whoever, in violation of the obligation, as referred to in Art. 248, item 3, produces, transports, trades or places on the market raw materials and foods of animal origin, without labelling or with labelling, which contain incomplete or untrue data, shall be punished with a fine to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 2000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 2000 up to 5000 BGN, and in the case of a repeated violation – property sanctions to the amount of 5000 up to 10000 BGN.

Art. 441. (1) Whoever offers to the market or carries out trade in raw materials and foods of animal origin with an expired validity period, shall be punished with a fine to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 3000 BGN.

(2) Where the violation , as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 1000 up to 3000 BGN, and in the case of a repeated violation – property sanctions to the amount of 3000 up to 5000 BGN.

Art. 442. (1) Whoever produces, places on the market or carries out trade of raw materials and foods of animal origin, not intended for human consumption, in an establishment, that is not registered, as referred to in Art. 229, para 1, shall be punished with a fine to the amount of 200 BGN up to 500 BGN, and in the case of a repeated violation – with a fine to the amount of 500 BGN up to 1000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 500 BGN up to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 BGN up to 2000 BGN.

Art. 442a. (new – SG 7/13) (1) Whoever, without being registered in the register under Art. 7, par. 3, item 21 produces or markets animals identification aids, to be used to official identification of animals, shall be imposed a fine from 500 to 2500 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

(2) Where the violation under par. 1 has been done by a legal person or a sole trader, a proprietary sanction shall be imposed in an amount from 1000 to 5000 BGN, and in case of a repeated violation – from 3000 to 10 000 BGN.

Art. 442b (new – SG 7/13) (1) (amend. - SG 99/13, in force from 01.01.2014) Whoever, in violation of Art. 51b or Art. 51c, produces or markets animals identification aids to be used for animals official identification and which are not approved by BFSA shall be imposed a fine from 500 to 2500 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

(2) Where the violation under par. 1 has been done by a legal person or a sole trader, a proprietary sanction shall be imposed in an amount from 1000 to 5000 BGN, and in case of a repeated violation – from 5000 to 10 000 BGN.

Art. 442c. (new – SG 7/13) A producer of a trader of animals identification aids, failing to make a record in the Integrated information system of BFSA of movement of animals identification aids, shall be imposed a fine from 300 to 400 BGN, and in case of repeated violation – from 500 to 2000 BGN.

Art. 442d. (new – SG 7/13) Whoever fails to remove and/or to deliver for eradication materials of specific risk according to the requirements of Attachment V, item 2 - 4 and 8 of Regulation (EC) No. 999/2001 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, herein after referred to as "Regulation (EC) No. 999/2001" shall be imposed a fine from 1000 to 2000 BGN, and in case of repeated violation – from 2000 to 3000 BGN.

Art. 442e. (new – SG 7/13) (1) Whoever launches at the market materials of specific risk and/or meat of ruminants, from which the materials of specific risk for transmissible spongiform encephalopathies have not been removed, shall be penalized with a fine from 1000 to 2000 BGN, and in case of repeated violation – from 2000 to 5000 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 2000 to 3000 BGN, and in case of a repeated violation – from 3000 to 5000 BGN.

(3) In cases referred to in par. 1 and 2 the meat and the materials of specific risk shall be withdrawn and shall be referred for eradication in an animal by-products disposal facility. The cost of eradication shall be charged to the violator.

Art. 442f. (new – SG 7/13) (1) Whoever violates the provision of Art. 9, paragraph 2 of Regulation (EC) No. 999/2001 shall be imposed a fine from 500 to 1000 BGN, and in case of repeated violation – from 1000 to 2000 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 1000 to 2000 BGN, and in case of a repeated violation – from 2000 to 3000 BGN.

(3) In cases referred to in par. 1 and 2 the meat shall be withdrawn and shall be referred for eradication in an animal by-products disposal facility. The cost of eradication shall be charged to the violator.

Art. 442g. (new – SG 7/13) (1) Whoever launches at the market meat of ruminants, which have not been tested for transmissible spongiform encephalopathies according to the provisions of Attachment III, Chapter "A" of Regulation (EC) No. 999/2001, shall be penalized with a fine from 1000

to 3000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

(2) Where the violation under par. 1 has been done by a sole trader of a legal entity, a proprietary sanction shall be imposed in an amount from 2000 to 4000 BGN, and in case of a repeated violation – from 4000 to 6000 BGN.

(3) In cases referred to in par. 1 and 2 the meat shall be withdrawn and shall be referred for eradication in an animal by-products disposal facility. The cost of eradication shall be charged to the violator.

Art. 442h. (new – SG 7/13) A producer or a trader in foods, violating the provisions of Attachment II, Chapter IX, item 1 – 4 of Regulation (EC) No. 852/2004, shall be imposed a proprietary sanction from 100 to 300 BGN, and in case of repeated violation – from 300 to 1000 BGN.

Art. 442i. (new – SG 7/13) (1) Whoever transports raw materials and food of animal origin in violation of Art. 245, shall be imposed a fine from 100 to 300 BGN, and in case of repeated violation - from 300 to 500 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 500 to 1000 BGN, and in case of a repeated violation – from 1000 to 2000 BGN.

Art. 442j. (new – SG 7/13) Whoever accepts an animal for slaughtering in violation of the provisions of Attachment II, Section II of Regulation (EC) No. 853/2004, shall be imposed a fine from 300 to 500 BGN, and in case of repeated violation – from 500 to 2000 BGN.

Art. 442k. (new – SG 7/13) Whoever accepts to a slaughtering house an animal, slaughtered under the condition of emergency slaughtering in violation of the provisions of Attachment III, Section I, Chapter VI of Regulation (EC) No. 853/2004, shall be imposed a proprietary sancion from 200 to 500 BGN, and in case of repeated violation – from 500 to 1000 BGN.

Art. 442l. (new – SG 7/13) A producer of a trader of foods of animal origin, having violated the provision of Art. 4, paragraph 3 of Regulation (EC) No. 852/2004 shall be imposed a proprietary sanction from 500 to 1500 BGN, and in case of repeated violation – from 1500 to 5000 BGN.

Art. 442m. (new – SG 7/13) (1) Whoever violated Art. 13 of Regulation (EO) No. 1760/2000 shall be imposed a fine from 200 to 500 BGN, and in case of repeated violation – from 400 to 800 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 500 to 1000 BGN, and in case of a repeated violation – from 1000 to 3000 BGN.

Art. 442n. (new – SG 7/13) (1) Whoever violates Art. 1 of Commission Regulation (EC) No. 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No. 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products, herein after referred to as “Regulation (EC) No. 1825/2000”, shall be imposed with a fine from

200 to 500 BGN, and in case of repeated violation – from 400 to 800 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 500 to 1000 BGN, and in case of a repeated violation – from 1000 to 2000 BGN.

Art. 442o. (new – SG 7/13) (1) Whoever violates Art. 15 of Regulation (EC) No. 1760/2000 and Art. 2 of Regulation (EC) No. 1825/200, shall be imposed a fine from 200 to 500 BGN, and in case of repeated violation – from 500 to 1500 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 500 to 1000 BGN, and in case of a repeated violation – from 1000 to 3000 BGN.

Art. 442p. (new – SG 7/13) (1) Whoever violates a requirement under Art. 83, 84, 85 or 86, shall be imposed a fine from 300 to 500 BGN, and in case of repeated violation – from 500 to 1000 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 1000 to 2000 BGN, and in case of a repeated violation – from 1500 to 3000 BGN.

Art. 442q. (new – SG 7/13) (1) Whoever violated Art. 113b of Council Regulation (EC) No. 1234/2007 of 22 October 2007 establishing a common organization of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ, L299/1 of 16 November 2007), shall be imposed a fine from 200 to 1000 BGN, and in case of repeated violation – from 500 to 2000 BGN.

(2) Where the violation under par. 1 has been done by a legal entity or a sole trader, a proprietary sanction shall be imposed in an amount from 1000 to 3000 BGN, and in case of a repeated violation – from 2000 to 7000 BGN.

Art. 443. With regard to the owner or the person, who uses a processing (rendering) plant for animal by-products, who allows the transporting of for animal by-products in transport vehicles, in violation of the requirements, provided for in the ordinance, as referred to in Art. 66, para 2, property sanctions shall be imposed to the amount of 100 to 400 BGN, and in the case of a repeated violation – property sanctions to the amount of 400 up to 1000 BGN.

Art. 444. With regard to the owner or the person, who uses a rendering plant for processing of animal by-products, who does not collect the animal by-products from the determined area, which has been determined as his, within the periods, provided for in the ordinance, as referred to in Art. 66, para 2, property sanctions shall be imposed to the amount of 1000 to 2000 BGN, and in the case of a repeated violation – the property sanctions shall be the amount of 2000 up to 3000 BGN.

Art. 445. With regard to the owner or the person, who uses a rendering plant for processing of animal by-products, who has not implemented the system, as referred to in Art. 270, para 1, item 1, shall be imposed a property sanctions to the amount of 500 to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 up to 2000 BGN.

Art. 446. With regard to the owner or the person, who uses a rendering plant for processing of animal by- products, who violates the requirements, provided for in the ordinance, as referred to in Art. 66, para 2, property sanctions shall be imposed to the amount of 100 up to 1000 BGN, and in the case of a repeated violation - property sanctions to the amount of 500 up to 1500 BGN.

Art. 447.(1) Whoever stores animal by-products, in violation of the requirements, as referred to in Art. 272, shall be punished with a fine to the amount of 50 up to 300 BGN, and in the case of a repeated violation - a fine to the amount of 300 up to 500 BGN.

(2) Where the violation , as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 300 up to 500 BGN, and in the case of a repeated violation - property sanctions to the amount of 500 up to 1000 BGN.

Art. 448. (1) Whoever buries specified risk materials, in violation of the requirements of the ordinance, as referred to in Art. 66, para 2, shall be fined to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 1500 BGN.

(2) Where the violation , as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 1000 up to 1500 BGN, and in the case of a repeated violation - property sanctions to the amount of 1500 up to 3000 BGN.

Art. 449. (amend. - SG 14/16, in force from 19.02.2016) (1) Whoever violates the requirements of Art. 7, paragraphs 1-3 of Regulation (EC) № 999/2001, shall be punished with a fine to the amount of 5 000 up to 10 000 BGN, and in the case of a repeated violation – with a fine to the amount of 10 000 up to 20 000 BGN.

(2) Where the violation , as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 10 000 up to 20 000 BGN, and in the case of a repeated violation – property sanctions to the amount of 20 000 up to 50 000 BGN.

Art. 449a. (new – SG 7/13, revoked - SG 14/16, in force from 19.02.2016)

Art. 449b. (new – SG 7/13) (1) (Suppl. - SG 14/16, in force from 19.02.2016) The owner, respectively the operator of a site where animal by-products are received, failing to fulfill their obligation under Art. 275, par. 1, shall be imposed a fine from 200 to 500 BGN, and in case of repeated violation – from 500 to 1000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 500 to 1000 BGN, and in case of repeated violation – from 2000 to 5000 BGN.

Art. 449c. (new – SG 7/13, amend.and suppl. - SG 14/16, in force from 19.02.2016) The owner, respectively the operator of a site for safe disposal of animal by-products, failing to fulfill their obligation under Art. 275, par. 3, shall be imposed a proprietary sanction from 5 000 to 10 000 BGN, and in case of repeated violation – from 10 000 to 20 000 BGN.

Art. 449d. (new – SG 7/13) (1) Whoever fails to conclude a contract under Art. 275, par. 2 and

3, shall be imposed a fine from 1000 to 3000 BGN, and in case of repeated violation – from 2000 to 5000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 3000 to 5000 BGN, and in case of repeated violation – from 4000 to 10 000 BGN.

Art. 450. (suppl. – SG 7/13) Whoever, without having a license, manufactures or places on the market veterinary medicinal products, or offers for use or stores veterinary medicinal products, which have not been licensed for use, shall be punished with a property sanction in the amount from 2 000 to 5 000 BGN, and in the case of a repeated violation – from 5 000 to 10 000 BGN.

Art. 450a. (new – SG 7/13) (1) Whoever without having a license, stores or carries out trade with active substances, intended for the manufacturing of VMP, shall be imposed a fine from 2000 to 3500 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 3000 to 5000 BGN, and in case of repeated violation – from 4000 to 10 000 BGN.

Art. 450b. (new – SG 7/13) (1) Whoever carries out retail trade in violation of Art. 372, par. 1 shall be imposed a fine from 500 to 1000 BGN, and in case of repeated violation – from 2000 to 3000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 450c (new – SG 7/13) A holder of a license for retail trade with VMP, violating the provision of Art. 373, par. 2 shall be imposed a proprietary sanction from 500 to 1000 BGN, and in case of repeated violation – from 2000 to 3000 BGN.

Art. 450d. (new – SG 7/13) A wholesaler of VMP violating the provision of Art. 370, par. 3 shall be imposed a proprietary sanction from 1000 to 2000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

Art. 450e. (new – SG 7/13) A wholesaler of VMP violating the provision of Art. 369 shall be imposed a proprietary sanction from 1000 to 2000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

Art. 450f. (new – SG 7/13) A retail seller of VMP violating the provision of Art. 381 shall be imposed a proprietary sanction from 1000 to 2000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

Art. 450g. (new – SG 7/13) (1) Whoever produces or imports in-vitro diagnostic veterinary medicinal aids without registration certificate, shall be imposed a fine from 2000 to 5000 BGN, and in case of repeated violation – from 6000 to 15 000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 5000 to 10 000 BGN, and in case of repeated violation – from 10 000 to 20 000 BGN.

Art. 450h. (new – SG 7/13) (1) Whoever without a license for wholesale or retail sale of VMP carries out trade or stores in-vitro diagnostic veterinary medicinal aids or carries out trade or stores in-vitro diagnostic aids without registration certificate, shall be imposed a fine from 500 to 1000 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 450i. (new – SG 7/13) Whoever produces, imports, stores and/or carries out trade with in-vitro diagnostic veterinary medicinal aids, which do not comply with the requirements, under which the registration certificate has been issued, shall be imposed a proprietary sanction from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 450j. (new – SG 7/13) Whoever violates a requirement of the provision of Art. 410c, shall be imposed a proprietary sanction from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 450k. (new – SG 7/13) A registration certificate holder, failing to block and withdraw from the market a batch of in-vitro diagnostic veterinary medicinal aids in violation of the provision of Art. 410g, shall be imposed a fine from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 450l. (new – SG 7/13) A trader, failing to fulfill an obligation under Art. 410h, par. 3 shall be imposed a fine from 1500 to 3000 BGN, and in case of repeated violation – from 4000 to 6000 BGN.

Art. 451. Any manufacturer, who manufactures or places on the market veterinary medicinal products, in violation of the requirements, with which the license for use of the veterinary medicinal products have been issued, shall be punished with a property sanction shall be imposed to the amount of 2000 to 5000 BGN, and in the case of a repeated violation - property sanctions to the amount of 5000 up to 10000 BGN.

Art. 452. (1) (suppl. – SG 7/13) Whoever, in violation of Art. 374, para 1, sells veterinary medicinal products without a prescription or in violation of Art. 374, par. 2 issues a prescription, shall be punished with a fine to the amount of 50 up to 100 BGN, and in the case of a repeated violation – with a fine to the amount of 200 up to 500 BGN.

(2) (amend. – SG 7/13) The manager of a veterinary medical pharmacy, who does not fulfill his duties, as referred in Art. 374, para. 5, shall be punished with a fine to the amount of 100 BGN, and in the case of a repeated violation – with a fine to the amount of 500 BGN.

(3) (amend. – SG 7/13) The owner of animals, who does not fulfill his duties, as referred in Art. 374, para. 5, shall be punished with a fine to the amount of 50 BGN, and in the case of a repeated violation – with a fine to the amount of 100 BGN.

Art. 453. Any manufacturer of a veterinary medicinal products, who sells veterinary medicinal products to a person, different from a wholesale trader with veterinary medicinal products, shall be punished with a fine amounting from 1000 up to 2000 BGN, and in the case of a repeated violation – with a fine to the amount of 2000 up to 5000 BGN.

Art. 454. (amend. – SG 7/13) (1) Whoever violates the provision of Art. 359, shall be punished with a fine from 1000 to 1500 BGN, and in the case of a repeated violation – from 2000 to 5000 BGN.

(2) Where the violation under par. 1 is committed by a legal entity or a sole trader, a proprietary sanction shall be imposed from 2000 to 5000 BGN, and in case of repeated violation – from 5000 to 10 000 BGN.

Art. 455. (revoked – SG 7/13)

Art. 456. Any wholesale trader or retail trader, who sells veterinary medicinal products, whose term of validity has expired, shall be punished with property sanction to the amount of 1000 up to 2000 BGN, and in the case of a repeated violation – property sanctions to the amount of 2000 up to 5000 BGN.

Art. 457. (1) Whoever orders or carries out an advertisement of an unlicensed-for-use veterinary medicinal product, shall be punished with a fine to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – with a fine to the amount of 1000 up to 2000 BGN.

(2) Where the violation, as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 1000 up to 2000 BGN, and in the case of a repeated violation – property sanctions to the amount of 2000 up to 4000 BGN.

Art. 458. (1) Whoever carries out an advertisement of veterinary medicinal products, in violation of the ban, as referred to in Art. 329, shall be punished with a fine to the amount of 200 up to 500 BGN, and in the case of a repeated violation – with a fine to the amount of 500 up to 1000 BGN.

(2) Where the violation , as referred to in para 1, has been committed by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 600 up to 1000 BGN, and in the case of a repeated violation - property sanctions to the amount of 1000 up to 1500 BGN.

Art. 459. (suppl. – SG 7/13) Any manufacturer of veterinary medicinal products, who does not fulfill an order, as referred to in Art. 316, para 1 or, as referred to in Art. 317, para 1, or the ban, as referred to in Art. 319, par. 1 shall be punished with a property sanction to the amount of 1000 up to

5000 BGN, and in the case of a repeated violation - property sanctions to the amount of 5000 up to 10 000 BGN.

Art. 460. (1) Whoever is carrying out trade with veterinary medicinal products, in violation of the ban, as referred to in Art. 381, shall be punished with a fine to the amount of 500 up to 1000 BGN, and in the case of a repeated violation – property sanctions to the amount of 1000 up to 2000 BGN.

(2) Where the violation, as referred to in para 1, has been carried out by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 1000 up to 2000 BGN, and in the case of a repeated violation - property sanctions to the amount of 2000 up to 5000 BGN.

Art. 461. (1) (amend. – SG 7/13) Whoever places on the market raw materials or foods of animal origin, intended for human consumption, obtained before the expiry of the withdrawal period, from animals, which have been treated with veterinary medicinal products, shall be punished with a fine from 1000 to 3000 BGN, and in the case of a repeated violation – from 3000 to 5000 BGN.

(2) Where the violation, as referred to in para 1, has been carried out by a legal person or by a sole proprietor, property sanctions shall be imposed to the amount of 5000 up to 10000 BGN, and in the case of a repeated violation - property sanctions to the amount of 10000 up to 20000 BGN.

Art. 462. (revoked - SG 97/12; new – SG – 7/13) Whoever fails to fulfill an obligation under Art. 388, par. 2, shall be imposed a file from 200 to 500 BGN, and in case of repeated violation – from 400 to 1000 BGN.

Art. 463. (revoked - SG 97/12; new – SG 7/13) A qualified person launching on the market VMP in violation of the requirements of Art. 353a, par. 1, item 1 and/or 2 shall be imposed a fine from 2000 to 5000 BGN, and in case of repeated violation – from 5000 to 10 000 BGN.

Art. 464. (revoked - SG 97/12; new – SG 7/13) A qualified person of a holder of license for use of VMP failing to fulfill the obligation under Art. 295, par. 1, item 1 shall be imposed a fine from 500 to 1000 BGN, and in case of repeated violation – from 1000 to 2000 BGN.

Art. 465. (revoked - SG 97/12; new – SG 7/13) A holder of a license for use of VMP failing to fulfill the obligation under Art. 296, par. 1, item 1, 2, 3, 6 and 8 and par. 2 shall be imposed a proprietary sanction from 1000 to 2000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

Art. 466. (revoked - SG 97/12; new – SG 7/13) A holder of a license for use of VMP failing to fulfill the obligation under Art. 298, shall be imposed a proprietary sanction from 1000 to 2000 BGN, and in case of repeated violation – from 3000 to 5000 BGN.

Art. 467. (revoked - SG 97/12; new – SG 7/13) A holder of a license for manufacturing of VMP failing to fulfill the obligation under Art. 354, par.1, item 1, 2, 3, 4, 6 and 7, shall be imposed a

proprietary sanction from 1500 to 3000 BGN, and in case of repeated violation – from 3000 to 6000 BGN.

Art. 468. (revoked - SG 97/12; new – SG 7/13) (1) Whoever in violation of Art. 355 imports VMP shall be imposed a fine from 1000 to 2000 BGN, and in case of a repeated violation - from 2000 to 4000 BGN.

(2) Where the violation, referred to in para 1, has been committed by a legal person or by a sole trader, property sanctions shall be imposed from 2000 to 6000 BGN, and in the case of repeated violation - from 6000 to 10 000 BGN.

Art. 468a. (new – SG 7/13) An importer of VMP, failing to fulfill the obligation under Art. 360, par. 1 shall be imposed a proprietary sanction from 1500 to 3000 BGN, and in case of repeated violation – from 3000 to 6000 BGN.

Art. 468b. (new – SG 7/13) (1) Whoever in violation of Art. 362 transports VMP and/or active substances shall be imposed a proprietary sanction from 500 to 1000 BGN, and in case of repeated violation – from 1000 to 2000 BGN.

(2) Where the violation, referred to in para 1, has been committed by a legal person or by a sole trader, property sanctions shall be imposed from 1500 to 3000 BGN, and in the case of repeated violation - from 3000 to 6000 BGN.

Art. 468c. (new – SG 7/13) An official under Art. 388, par.1, disclosing information obtained during a carried out inspection, shall be imposed a fine from 500 to 1500 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

Art. 468d. (new – SG 7/13) A holder of a license for use of VMP failing to fulfill the obligation under Art. 8 and 9 of Regulation (EC) No. 1234/2008, shall be imposed a proprietary sanction from 800 to 1500 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

Art. 468e. (new – SG 7/13) A holder of a license for use of VMP failing to fulfill the obligation under Art. 10 of Regulation (EC) No.1234/2008, shall be imposed a proprietary sanction from 1500 to 3000 BGN, and in case of repeated violation – from 3000 to 6000 BGN.

Art. 468f. (new – SG 7/13) A legal entity or a single trader, launching on the market VMP, intended for productive animals, the active substance(s) of which exceed the specified maximum allowable values of residues, or VMP, intended for a type of productive animals, for which there are no such specified values in Regulation (EC) No. 37/10, shall be imposed a proprietary sanction from 200 to 4000 BGN, and in case of repeated violation – from 4000 to 10 000 BGN.

Art. 468g. (new – SG 7/13) Whoever carries out therapy or prophylaxis of productive animals with VMP, the active substance(s) of which exceed the specified maximum allowable values of

residues, or VMP, intended for a type of productive animals, for which there are no such specified values in Regulation (EC) No. 37/10, shall be imposed a proprietary sanction from 500 to 1500 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

Art. 468h. (new – SG 7/13) A veterinarian violating the requirements under Art. 322, par. 1 and/or 2 shall be imposed a fine from 800 to 2000 BGN, and in case of repeated violation – from 2000 to 4000 BGN.

Art. 468i. (new – SG 7/13) A veterinarian violating the requirements under Art. 323 shall be imposed a fine from 600 to 1500 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

Art. 468j. (new – SG 7/13) A wholesaler of VMP failing to fulfill an obligation under Art. 371, par. 1 and/or 2 shall be imposed a proprietary sanction from 1000 to 3000 BGN, and in case of repeated violation – from 3000 to 6000 BGN.

Art. 468k. (new – SG 7/13) A retail saler of VMP failing to fulfill an obligation under Art. 380, par. 1 and/or 2 shall be imposed a proprietary sanction from 600 to 1500 BGN, and in case of repeated violation – from 1500 to 3000 BGN.

Art. 469. (1) Whoever does not implement a prescript or an order of a veterinary medical control body, issued in the framework of its capacity under this Act, shall be punished with a fine of 200 to 1000 BGN, and at a repeated violation – with a fine of 400 to 2000 BGN.

(2) Where the violation under para 1 is committed by a juridical entity or sole proprietor shall be imposed property sanctions to the amount of 1000 to 3000 BGN, and at a repeated violation - of 3000 to 10000 BGN.

(3) Where the order, referred to in para 1, is issued for prophylactics , limitation or eradication of contagious disease on the animals, shall be fined to the amount of 3000 to 5000 BGN, and property sanctions - of 5000 to 10000 BGN.

Art. 470. (1) Whoever does not cooperate to a veterinary medical control body at implementation of its activities, shall be punished with a fine to the amount of 50 to 100 BGN, and at a repeated violation - of 100 to 200 BGN.

(2) Where the violation under para 1 is committed by juridical entity, shall be imposed property sanctions to the amount of 500 to 1000 BGN, and at a repeated violation - of 1000 to 2000 BGN.

Art. 471. (1) Whoever prevents a veterinary medical control body at implementation of its capacity, shall be punished with a fine to the amount of 100 to 200 BGN, and on a repeated violation - of 200 to 400 BGN.

(2) Where the violation under para 1 is committed by juridical entity or sole proprietor, shall be imposed property sanctions to the amount of 500 to 1000 BGN, and at a repeated violation - of 1000 to 2000 BGN.

Art. 471a. (new – SG 7/13) (1) For other violations under this law, and also of the acts for its application a fine shall be imposed from 150 to 1000 BGN, unless a more severe punishment is provided.

(2) Where the violation under para 1 is committed by legal entity or sole trader, property sanctions shall be imposed from 500 to 2000 BGN, and in case of repeated violation - from 10 000 to 0 2000 BGN.

Art. 472. (1) (amend. – SG 08/11, in force from 25.01.2011, suppl. - SG 14/16, in force from 19.02.2016) The violations under this Act shall be found out by acts, drawn up by veterinaries of the BFSA, except for the breaches under Art. 426, 426a, 426b, Art. 428 and Art. 429.

(2) (amend. – SG 08/11, in force from 25.01.2011) The penalty acts shall be issued by the directors of RFSD, on which territory the violation has been committed.

(3) The penalty decrees of the acts, issued for breaches, found out during implementation of the state veterinary-sanitary control and the control on the production, use and trade with VMPs on the territory of Capital grand municipality shall be issued by the directors of the respective structural units in the town of Sofia.

(4) (amend.and suppl. - SG 14/16, in force from 19.02.2016) The penalty decrees of the acts for breaches under Art. 426, 426a, 426b, Art. 428 and Art. 429 are drawn up by inspectors from municipalities and regions.

(5) The penalty decrees under Art. 4 shall be issued by the mayors of municipalities and regions. The sums of the fines shall be revenue to the municipality's budget.

Art. 473. The drawing up of acts, issuing, appealing and implementation of the penalty acts shall be carried out under the Administrative Violations and Penalties Act.

Art. 474. (revoked, SG 77/12, in force from 09.10.2012)

Additional provisions

§ 1. In the sense of this Act:

1. "Aggressive dogs" are dogs, which display spontaneous abnormal reaction, turned to people or animals, which depending on power and nature could cause hurt or death.

2. "Accredited laboratory" is a laboratory, that has passed the procedure on accreditation by a national or international body and is acknowledged to it as competent to carry out determined examinations and analyses.

3. "Activity" is the quantity expression of content of active substance, relatively the active substances in one dose veterinary medical product, unit of volume or mass.

4. "Alopathy" is a method of medication, provoking the organism to a condition, contrary to the symptoms of the disease.

5. (amend. – SG 7/13) "Gneneric veterinary-medical product" is a product, which possess the same quantitative and qualitative content of active substances, the same pharmaceutics form as the referent product and whose bio-equivalence with the referent product is proved by bio-availability tests. When in the content of VMP are included salts, esters, isomers or mixture of isomers or derivatives of the active substance, relatively the active substances of the reference VMP and the new substance does not differ significantly in reference to characteristics for safety and/ or effectiveness, the product is generic to the referent one. When certain product is offered in different from the referent product medicinal forms, designed for per oral use, with quick release, the product is generic to the referent one.

6. "Beta-antagonists" are substances of β_2 - adrenomimetic effect, that directly stimulates the β_2 - adrenoreceptors of the smooth muscles.

7. "Bioequivalence" - two VMPs are bioequivalent, where these are pharmaceutically alternative and where the extent and the velocity of the resumption of their active substances, applied in equivocal concentrations and doses, are so much similar, that the effects of their application in reference to efficacy and safety are as a matter of fact alike.

7a. (new – SG 7/13) "Veterinary prescription" is a prescription for sale of VMP, issued by a registered veterinarian.

8. "Veterinary practice" is prophylactics, clinical diagnostics and medication of animal diseases, carried out by registered veterinaries on a definite territory;

9. "Veterinary medical product" is a substance or a combination of substances, which can:

a) be applied for prophylactics or medication of diseases by animals;

b) be administered to animals for recreation or correction or modification of their physiological functions through pharmacological, immunological effect and impact on the metabolism or for diagnostics of animal diseases;

10. "High-tech VMP" is a VMP which:

a). is obtained through the following biotechnological processes:

aa) pre-combination DNA technology ;

bb) controlled expression of genes;

cc) coding biological active proteins in prokaryotes and eukaryotes including mammals cells transformed;

dd) hybridomal technique;

ee) mono colonal antibodies;

b) is obtained through biotechnological method, which constitutes a significant innovation in science;

c) is administrated to animals through new methods assessed as innovation with an exclusive contribution to the veterinary medicinal practice;

d) is completely new indication for administration with significant therapeutic contribution ;

e) is obtained on the base of radioisotopes with significant therapeutic or diagnostic contribution;

f) VMP, for the manufacturing of which have been used methods, estimated as an achievement in the technical progress;

g) VMP for food-producing animals, which contains new active substances, not included in the composition of a VMP, authorized in the EU or in the Republic of Bulgaria.

11. "Importing" is an introduction through approved BIVP of items, subjected to veterinary medical control, intended for free movement on the territory of the country.

12. "Secondary packing" is the packing in which the primary packing is placed.

13. "Ban" is a combination of temporary restrictive measures enforced on animal breeding establishments, settlements, territories where contagious or non-contagious disease has been detected.

14. "Degree day" is the time from the last treatment of fish in water basins with VMP in days, multiplied by the average daily temperature of the water in ?C.

15. "Grave breaches" are breaches of the requirements of this Act or other regulating acts on its application, resulted in an immediate hazard to the health of people, animals, contamination of the environment and/or considerable economic losses.

16. "Devastation" is a complex of methods of combat against the parasitic diseases, directed towards eradication of the invasive agents throughout all the phases of their life cycle.

17. "Insect control" is a combination of methods for eradication harmful insects and ticks.

18. "Disinfection" is a combination of methods and means of discarding of pathogenic microorganisms over live or not live objects.

19. "Deodoration" is a combination of methods for neutralizing of unpleasant smells.

20. "Decorative animals" are wild animals, which do not pose a threat to the health and life of people and animals, and their owners can provide relevant conditions to their physiological and technological peculiarities.

21. "Pest control" is a combination of methods for eradication harmful.

22. "Direct burning" is burning out of the installation for burning or installation for jointly burning.

23. "Good Laboratory Practice" is a system of rules, which contain conditions of work, processes of organizing, carrying out, tracing and documenting of the laboratory and field testings.

24. "Good Manufacturing Practice" is a system of common hygienic and technological rules for limitation to acceptable minimum the risk of contamination of food, feeding stuffs or VMP through processing or human activity. The rules refer to design, conditions and maintaining of the premises, machines, devices, the main and supplementary technical equipment, acceptance and storage of raw materials, the main, supplementary and packing materials, hygiene and training of personnel, system of tracing and control of quality and technological process, documentation.

25. (amend. – SG 7/13) "periodic safety report" is record of all reactions of the administration of VMP, set out in Section VII of Chapter Eleven.

26. European economic space is economic community which includes member states of the European Union and Norway, Iceland and Lichtenstein.

27. "Euthanasia" is slaughter of animals without pain and stress with a licensed medicinal product.

27a. (new – SG 7/13) “The same VMP” are products, having the same qualitative and quantitative content in terms of active substance and/or is offered in the same pharmaceutical form, whereby differences in ancillary substances are allowable, where this does not affect products safety and efficiency.

28. "Extirpation" is a total surgery removal of a given organ of the body.

29. (revoked – SG 7/13).

30. "Epizootic outbreak" is a place of stay of the source of the infection within these location or territories, where it is possible to be transmitted the infectious and parasitic agents to susceptible animals.

31. "Label" is the information on the primary or secondary packing.

32. "Ethology peculiarities" are the peculiarities, relevant to the characteristic behaviour for each animal towards others of the kind towards the similar, the environment and other animal species.

33. "Animals" are mammals, birds, amphibians, reptiles, fish, molluscs, crustaceans, other vertebrates and invertebrates reared by people with commercial and non-commercial purpose or living in the wild nature

34. (amend. – SG 84/07) "Pets" are the animals, reared with non-profit purpose in the home of man.

35. "Farmed animals" are animals, which are reared with the purpose of food- producing or other products of animal origin .

36. "Animal site" is each place where temporary or permanently are reared or kept animals, except for veterinary clinics or ambulances.

37. "Germinal products" semen, ova and embryos for artificial insemination of animals and sprawn.

38. "Health marking" is a marking, which is placed on the raw materials, foodstuffs of animal origin or their packing, thus ensuring that veterinary medical control I has been performed.

39. "Considerable economic losses" are material damage at an amount over 50 000 BGN.

40. "Zoonoses" are contagious diseases, which are transmitted from animals to people.

41. "Identification marking" is the marking that is put on the raw materials and foods of animal

origin or their packing from producers of raw materials and foods of animal origin, which guarantees that raw materials and foods are produced in compliance with legal requirements.

42. "Isolation" is separation of infected or suspicious of being infected animals in a separate premises, fencing or animal site.

43. (revoked – SG 7/13).

44. "Immunobiological VMP" is a veterinary medicinal product:

a) which is administrated to animals, with the purpose of creating in them an active or passive immunity;

b). (amend. – SG 7/13) for diagnostics of the immunity status of the animal.

45. "Immune therapy" is medication of infectious diseases or sick animals with immune sera and immune globulin.

45a. (new – SG 7/13) "in-vitro diagnostic veterinary medicinal aid" is an aid, which is not applied to animals and is a kit (a set of reagents, reference material) or a reagent for testing of samples of tissues and body liquids, including blood and milk, intended only for or mainly for obtaining of information about:

a) physiological or pathological condition, or

b) immunity status, or

c) controlling therapeutic actions.

The products for general laboratory use as chemical reagents and fast tests, intended for non-productive animals, calibrators, tools, facilities of equipment, are not in-vitro diagnostic veterinary medicine aids.

46. "Inspection" is a check, which is aimed at detecting whether the regulation requirements to foodstuffs, feeding stuffs, VMPs, health animal protection and welfare are being met.

47. (amend. – SG 08/11, in force from 25.01.2011) "Inspector" is a veterinary doctor from BFSA, determinate by the Executive director of BFSA for execution of inspection.

48. "Quarantine" is a prophylaxis measure of isolated rearing of animals.

49. (amend. and suppl. – SG 7/13) "Withdrawal period" is the required time interval between the last administration a VMP to animals under normal conditions of their use and slaughter or obtaining of foodstuffs products from them, which is to ensure, that in the food of animal origin residual substances of VMP are not contained in quantities, exceeding the maximal permitted values for active substances, determined in Regulation (EC) No. 37/2010.

50. "Cauterization" is destroying of tissues by burning with heat or chemical burning or searing substances.

51. "Code under ATC" is the code, recorded in the anatomy –therapy classificatory of VMPs.

52. "Compound feeding stuffs" are mixtures of feeding stuff raw materials with or without additives, intended for animal nutrition through mouth in their capacity of sufficiently or supplementary feeding stuffs.

52a. (new – SG 7/13) "Concentration" is the content of active substances in a unit dose, expressed as quantity per unit volume or mass, according to the type of dosage.

53. "Medicinal VMP" is each VMP, except for immunological veterinary medical product.

54. (amend. – SG 713) "Leaflet for use" is a written information, intended for the consumer, which is accompanying the VMP.

55. "Licensed medicinal product" is a licensed VMP means of use in human medicine.

56. "Licensed valuer" is a person, acquired a license under the art. 26, para. 5 of Privatization and Post-Privatization Control Act.

57. "Magisterial prescription" is a prescription for VMP, prepared in a pharmacy under a prescript of a veterinary for a definite animal/animals.

58. "Medicated pre-mix" is VMP, prepared in advance, for the purpose of its input in production of medicated feed.

59. (amend. – SG 7/13) "Medicated feed" is a mixture of a medicated pre-mix and combined feed redy to be launched on the market and intended as food for animals without additional processing, having therapeutic or prophylaxis properties or properties of VMP according to the definition provided in item 9.

60. "International non-patent denomination" is a denomination of an active substance respectively active substances or VMP, recommended by the World Health Organization.

60a, (new – SG 7/13) “The name of VMP” is the name of the VMP which may be:

brand name;

generally accepted name;

scientific name, accompanies by a trade name or the name of the holder of the license for use of VMP.

61. "National reference laboratory" is a laboratory, which consults other laboratories in the country on the application of the standards and the methods of laboratory control, possessing standard reference samples and carrying out and participating in comparative interlaboratory examinations.

62. (amend. – SG 7/13) "Adverse animal reactions" is an adverse and unexpected reaction, having occurred with animals upon administration of VMP according to the prescribed dosages with diagnostic, prophylaxis or medication purpose, or for recovery, adjustment or change of a particular physiological function.

63. (amend. – SG 7/13) "Adverse human reaction" is a reaction, that is harmful and unexpected, and which occurs with humans, as a result of contact with VMITEM

64. "Undesired substances and products" are the substances or products (without pathogenic micro organisms), that are available on the surface or in the feeding stuffs and pose a threat to the health of people, animals and the environment.

65. "Emergency slaughter" is the slaughter ordered by a veterinary, because of an accident or serious physiological and functional disorders in the health status of the animals.

66. "Unexpected adverse reaction" is an adverse reaction, the nature, severity and outcome of which does not comply with the indicated in the approved by the control body short characteristics of the product.

67. "Immediate and big hazard to the health of people and animals" are the cases, where the consumption of raw materials and foods of animal origin can cause a serious harm to the health or death of people or animals.

68. "New active substance" is:

a) a chemical, biological and radiopharmaceutical substance, which is not contained in the VMP, authorized for use in the country;

b) an isomer, a mixture of isomers, a complex, a derivative or a salt /ester of chemical substance, which enters in the composition of the VMP, authorized for use in the country, but differs essentially in regard to the characteristics for safety and efficacy from the authorized for use substance;

c) a biological substance, which enters in the composition of the VMP, authorized for use in the country, but differs essentially in regard to its molecular structure, the source of exit materials or the manufacturing process;

d) a radiopharmaceutical substance, which is a radionuclide, that does not enter the composition of a VMP, authorized for use in the country, or the mechanism of coupling in pairs of the monocular and the radionuclide is new and has not been subjected to authorization in the country;

A fixed combination of active substances is accepted for a new active substance, provided that the proposed combination is not entering the composition of a VMP, authorized for use in the country.

69. "Destruction" is each of following operations:

a) storage in a depot (under the earth);

b) over ground burning (incineration);

c) direct burning;

d) processing;

e) destruction.

70. (amend. – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) "Establishments of epizootic importance" are: animal breeding establishments, pastures, watering places, sites for foddering of carrion birds; milk collecting, milk processing, yielding meat, meat processing and fish processing establishments, bone establishments; establishments for processing of technical animal raw materials, collective items for leather, wool, eggs, warehouses for animal products; establishments for rendering of animal by-products, utilization departments, carcasses abysses, departments for sterilization of kitchen waste, parking lots, depots for waste, establishments for the production of immunologic products and diagnosticums, veterinary institutes and stations; establishments for production and trade, warehouses for the storage of feeding stuffs, feed additives and ready feeds, as well as other establishments where or by which infectious or parasite agents could be spread.

71. "Exchange" is trade in animals and germinal products among Member States of the European Union;

72. "Audit" is a systematic and independent evaluation, which purpose is to find out whether the activities and the results produced comply with the planned ones, whether the activities are applied effectively and are appropriate for achieving of the objectives;

73. "Utilization" is an activity aiming at saling of raw materials and foods from animal origin, animal by-products and products derived from them.

74. "Peculiar cruelty" to animals is:

a) mortifying through strangling, hanging, tearing to pieces, crushing or flogging the animal;

b) skinning, dismembering or evisceration before mortifying;

c) throwing in fire, aggressive medias, from a big heights or under moving vehicles;

d) mortifying through poison or injecting of a substance, that causes a hard and painful death;

e) performing an euthanasia violating this Act;

f) (amend. – SG 84/07) deserting pets, incapable of self survival;

75. (amend. – SG 08/11, in force from 25.01.2011) "Authorized laboratory" is a laboratory, approved by the Executive director of BFSA for the Republic of Bulgaria or the competent authorities of the member states of the European union.

75a. (new – SG 7/13, amend. - SG 14/16, in force from 19.02.2016) “Official identification of animals" is the marking of the animals with a unique means of identification under the conditions and pursuant to Art. 51, para. 5-9 , and the subsequent recording in the Integrated information system of BFSA.

76. "Assessment of the risk extent " is a science-justified process, containing four stages: defining of the hazards, characteristics of the hazards, evaluation of the probability of occurrence and characteristics of the risk.

77. "Batch" is a definite quantity of exit primary material, packaging material or end product, which is characterized by its homogeneity and being produced in one manufacturing process or series of processes and under one and the same manufacturing conditions or within one working shift.

78. "Pathogenic micro organisms" are micro organisms, which on their own or through products of the their living activity cause illnesses on people and/or animals.

79. "Repeated violation" is the violation, committed in one-year period from the entering into force of a punishment act , by which the violator has been punished for a violation of the same type.

79a. (New - SG. 14 of 2016, effective 19.02.2016) "Operator" means any person who carries out, whether for a gain or gratuitously, activity in a site or facility, subject to veterinary control, which is not his property.

80. "Suspected undesirable reaction" is a reaction, for which the holder of authorization for use is considered to be having a cause-consequence connection with the administered VMITEM

81. "Processing" is an activity, which changes the features or content of raw materials and

foods of animal origin, animal by-products and products derived by them as transforming them in raw materials for production of end products or in end products.

82. "Consignment" is a quantity of products of one and the same type, described in one certificate and/or other document and transported in one and the same vehicle.

83. "Premixes" are mixtures of one or more feed additives with a filler, which are intended for input in feeding stuffs.

84. "Processed animal proteins" are meat-bone flour, meat flour, blood flour, dried plasma and other blood products, hydrolyzed proteins, flour of horn formations, flour of subproducts, dry fats, fish flour, dicalcium phosphate, gelatin, obtained from bones and other similar products of animal origin.

85. "Acceptable level of safety" is a level of safety, where the benefit is bigger than the risk at administration of VMP;

86. "Application with zootechnical purpose" is an administration of products and licensed VMPs on productive animals, with the aim of synchronizing of the estrus and the donors, and the recipients for implantation of embryos, and at water animals – application of androgens or fish groups with an aim of inversion of the sex.

87. "Identity check" is establishing through visual inspection the compliance between the content of the documents, accompanying the consignment, with the very consignment.

88. "Production animals" are all animal species, which are used for production of raw materials and products, intended for human consumption.

89. "Long transportation" is transportation of animals extended over 8 hours continuously.

90. "Production" is the producing, handling, processing, packaging, packing and re-packing or separate stages of these processes;

90a. (new – SG 7/13) “Studies, related to market supervision” are pharmacological and epyzootological or clinical tests of VMP, carried out according to the terms and conditions of the license for use for identification and study or the product safety level.

90b. (new – SG 7/13) “Launching on the market” is having in order to sell, offering for sale, the sale, distribution and any other form of transfer against payment and for free of the ownership on sites and/or products subject to veterinary medical control.

91. "Primary packing" is each type of packing, which comes into contact with VMITEM

92. "Advertisement of VMP" is each form of information with the aim of stimulating the prescribing of VMP, increase of the sale and use of VMITEM

93. (amend. – SG 7.13) "Reference VMP" is an original product, which is authorized for use, based on full file.

94. "Risk, relevant to use of VMP" is a risk to animals and people, relevant to the quality, safety and efficacy of VMP and the risk, relevant to undesired effects on the environment.

95. "Sanitary slaughter" is a compulsory measure with the aim of eradication of infected or suspicious infected animals and benefiting of the obtained animal products.

96. (amend. – SG 7/13) "Serious adverse reaction" is a reaction, that leads to a decease, life threatening condition as a result of heavy invalidity or inability to cat, congenital anomaly/congenital defect or which causes permanent or long-lasting health distress in treated animals.

97. "System for self-control" is a system of general and specific measures, which are applied in compliance with the rules for good manufacturing practice and HACCP approach, ensuring safety of feeding stuff, raw materials and foods from animal origin, the by-products and products derived from them.

98. "Regular violations" are three or more violations of the requirements under this Act and the regulating acts on its application, for which to the person have been imposed administrative punishments with entered into force punishing acts.

99. "Regular hindering" is creation of difficulties to veterinary medical specialists at implementation of their activity two or more times within one calendar year.

100. "Special marking" is marking, which guarantees, that foodstuffs are manufactured of raw materials, produced of animals at a sanitary or emergency slaughter.

101. "Specific risk animal materials" are organs and tissues of ruminant animals, in which are accumulated the agents of the transmissive spongiform encephalopathy.

102. "Emergency restrictive/control measure " is a temporary change in the medicinal information, concerning in particular one or more changes in the short characteristics of the product, of limitation of the indications, the dosage, the contra-indications, the warnings, the animal species, for which the VMP is intended, or the withdrawal period because of new information, relevant with the safe use of VMITEM

103. "Specific plant products" are plantation raw materials, that serve to nutrition or bedding of animals.

104. "Animal by-products" are animal carcasses or parts of them, or products of animal origin, which are not intended for human consumption , as well as ova, embryos and semen.

104a. (new – SG 7/13) “Substance” is any substance, regardless its origin, which may be of:

a) human origin, for example human blood or blood products;

b) animal origin, for example micro-organisms, whole animals, parts of organs, animal secretions, extracts;

c) vegetable origin, for example micro-organisms, plants, parts if plants, vegetable secretions, extracts;

d) chemical origin, for example elements available in the nature, chemical materials, and also products, resulting from chemical modification or synthesis.

105. "Raw materials of animal origin " are raw materials, produced from animals, bred by man of economic or non-profit purpose or inhabiting the wild nature.

106. "Assembly centers for animals" are places, where are animals, originating in different animal breeding sites with the aim of forming of a batch, intended for trade.

107. "Correlation benefit-risk" is an assessment of the positive therapy effect of the VMP towards the risk.

108. "Thyreostatics" are substances, which suppress the function of thyroid gland, by which is exerted a stimulating the growth effect.

109. "Third country " is each country, that is not a member of the European Union.

110. "Trader of animals" – is a physical or juridical entity, that is buying or selling animals with a commercial purpose as directly, as well as indirectly, having a regular turn-over of such animals and that in a period of maximum 30 days from the buying of the animals resells these or changes their location place from the places of their initial stay to other places or premises, which are in his ownership.

111. (amend. – SG 7/13) "Wholesale of VMP" are all the, that include purchase and sale, export or any other trade transaction with VMP with or without profit, except for:

a) supply from a manufacturer of VMP, produced by them;

b) retail sale in veterinary medical pharmacies.

112. "Destruction" is rendering, where there is not a possibility forfollowing utilisation.

113. (revoked – SG 7/13).

114. "Conditionally eligible raw materials of animal origin" are raw materials, which can be used for consumption by people after thermal processing, which guarantees their safety.

115. "Complicated epizootic situation" is a danger of arise or occurrence of a mass animal sickness from contagious diseases.

116. "Pharmacopoeia prescription" is a prescription for a VMP, prepared in a pharmacy under the dispensing of an acting pharmacopoeia and intended for a definite animal or animals.

117. "Physical check" is a check for finding out the condition of the consignment and compliance with the conditions of transport, including a a check of the pickings, the temperature at

which the transportation is carried out and sampling for laboratory examinations.

118. "Feed additives" are substances, (included in the list of the authorized feed additives), derivatives of those and products, which are given to animals with the food and drinking water, that can not be applied separately, but included in the feed and applied with the water in the form of premixes:

a) satisfy the foodstuffs needs of the animals and ensure the correct flow of the physiological processes, depending on the species, the age and the specific physiological strain of the animals;

b) influence favourably the stomach – intestine flora and/or the assimilation of the feed;

c) improve the technological quality of the feed;

d) influence positively the animal sensing;

e) improve or change the organo-leptic properties of the feed and the appearance of animal products, intended for human consumption;

f) influence the environment at rearing of the animals;

g) possess coccidiostatic or hystomonostatic effect;

h) are not veterinary-medicine products.

119. "Feed raw materials" are:

a) substances and products of plantation or animal origin in natural or processed type,

b) substances and products of plantation or animal origin after industrial processing;

c) organic or inorganic substances, independently if they contain of additives, intended for immediate nutrition of animals or for manufacturing of end feeding stuffs – like composition in the feeding stuff or as fillers of pre-mixes.

120. "Chemo-prophylaxis" is the use of chemo-preparations for prevention of the animals against contagious diseases.

121. "Chemotherapy" e medication with chemical medication preparations, exerting a specific action on infectious or parasitic agents.

122. (amend. – SG 7/13) "Homeopathic VMP" e VMP, prepared from substances, called homeopathic stock, according to the homeopathic manufacturing procedure, described in the European pharmacopeia, and in case of lack of such procedure - according to the procedure described in a pharmacopeia of a Member State. The homeopathic VMP may contain several constituents.

123. "Hormonal products" are products, which contain substances with hormonal (direct and indirect) estrogenic, androgenic and gestagenic effect.

124. "Foods of animal origin " are raw materials and foods, produced from animals, with or without food additives, that have undergone or not the respective technological processing.

125. (new – SG 25/10) "Genetically modified organisms" shall be the genetically modified feed within the meaning of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

§ 2. (amend. – SG 08/11, in force from 25.01.2011) The models of documents under this Act are to be approved by the Executive director of the BFSA.

Transitional and concluding provisions

§ 3. This Act shall repeal:

1. the Veterinary Medical Activity Act (Prom. SG 42/99, amend. SG 83/03), except for Art. 35 (4) and Art. 70.

2. Decree No 9399 on fight the rabies (Prom. SG 136/48 г.; amend., SG 25/60, SG 17/82).

§ 4. (1) (Amend. – SG 88/06, in force from 01.10.2006) Until January 1, 2007 the import of animals, germinal products, raw materials and foods of animal origin, animal by-products and products, derived there from, specific plant products, feed raw materials, feed additives and pre-mixes, finished and medicated feeding stuffs shall be carried out by physical and corporate bodies, provided that :

1. they have an issued veterinary medical authorization

2. each consignment is accompanied by a veterinary certificate conformed to a specimen;

3. the subjects meet the veterinary medical requirements for importing.

(2) (amend. – SG 08/11, in force from 25.01.2011) For issuing of import license to the persons under para 1 or their representative are to submit an application conformed to a specimen to the Executive director of the BFSA, whereto attached are to be:

1. For animals:

a) a veterinary medical certificate of a quarantine premises under Art. 189, para 1;

b) a certificate from a slaughterhouse for receiving the animals, if they are intended to immediate slaughter;

2. (amend. – SG 08/11, in force from 25.01.2011) for hatching eggs - veterinary medical certificate of the hatchery registered in the BFSA;

3. (amend. – SG 08/11, in force from 25.01.2011) for fish growing and fish stocking material - veterinary medical certificate of the water basin, registered in the BFSA;

4. (amend. – SG 08/11, in force from 25.01.2011) for raw materials and foods of animal origin, animal by-products and products derived from them, specific plant products, feed raw materials, feed additives and premixes, finished and medicated feeding stuffs - veterinary medical certificate of the storehouse, registered in the BFSA.

(3) (amend. – SG 08/11, in force from 25.01.2011) For issuing of permissions for import of feeding stuff raw materials, feeding stuff additives, pre-mixes, compound and medicament feeding stuffs, the persons under para. 1 or their representatives indicate in the application to the Executive director of BFSA also the address of the storage of imported batches.

(4) (amend. – SG 08/11, in force from 25.01.2011) In 10-days period of submission of the application, the Executive director of the BFSA shall issue a license or shall justify the refusal of its issuing, where the subjects for import do not meet the requirements determined in the ordinances referred to in par.6.

(5) (amend. - SG 30/06, in force from 12.07.2006) The refusal under par.4 can be appealed under the Administrative procedure code.

(6) (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, amend. – SG 58/17, in force from 18.07.2017) Veterinary medical requirements of importing the items referred to in para 1 are to be defined with ordinances of the Minister of Agriculture, Foods and Forestry.

§ 5. (1) (amend. – SG 08/11, in force from 25.01.2011) In a period of 3 months of entering into force of the Act, to the veterinary specialists, who have obtained authorization for a private practice under Art. 15 of the repealed Veterinary Medical Activity Act shall submit an application for registration for exercising veterinary practice to the Director of the regional veterinary service.

(2) (amend. – SG 08/11, in force from 25.01.2011) In the cases under para. 1 the Director of RFSD within 7 days period shall enter the names of veterinary doctors in the register under Art. 30 and shall issue certificate for registration, free of charge.

(3) The submitted applications by the entering into force of this Act, for which have not been issued of authorizations for exercising of private practice under the repealed Veterinary Medical Activity Act shall be considered under chapter 4.

§ 6. (1) Contracts for execution of the measures in the state prophylactic program, signed before entering into force of this Act, retain into action until expiring of their deadline.

(2) The announced competitions for issuing of licenses for implementation of the state prophylactic program measures shall be terminated with the entering into force of this Act.

§ 7. The persons, who have acquired dogs till the entering into force of this Act, are obliged to register and ear-tag the animals according to the requirements under Art. 174, in a period of six months of the entering into force of the Act.

§ 8. By 30 November 2006 the owners or users of the processing plants for animal by-products are obliged to introduce the system of HACCP under Art. 270 (1) 1.

§ 9. (1) (prev. § 9 – SG 102/09) The issued till the entering into force of this Act certificates of registration and authorizations for use of VMP are valid to the expiry period, for which they have been issued.

(2) (new – SG 102/09) Holders of authorizations for use and of certificates of registration of VMP under par. 1 may prior to expiration of their validity file an application for granting a license for use of these VMP following the provisions of this Act. In these cases the provision of Art. 289 shall not apply.

§ 10. (1) (amend. – SG 08/11, in force from 25.01.2011) In 6-months period of entering into force of the BFSA Act shall issue officially:

1. licences for manufacturing of VMP to the persons, that have obtained authorizations for manufacturing of VMPs after 01.01.2004 under the repealed Veterinary Medical Activity Act.

2. licenses for wholesale in VMP of the persons, that have obtained authorizations for wholesale in VMP, issued after 23.09.2003 under the repealed Veterinary Medical Activity Act.

3. licenses for retail of VMP of the persons, that have obtained authorizations for veterinary medical pharmacies, issued after 23 September 2003 under the repealed Veterinary Medical Activity Act.

4. Registration certificates for working premises for rendering of by-products from animal origin

(2) For issued under par.1 licenses no fees shall be collected.

§ 11. (1) (amend. – SG 08/11, in force from 25.01.2011) In a 3-months period of the entering into force of the Act the persons, having obtained authorizations for wholesale in VMP and authorizations for veterinary medical pharmacies before 23 September 2003, shall submit to the BFSA an application for issuing of authorization licenses under this Act.

(2) After the expiry period referred to in par.1 the issued authorizations for wholesale in VMP and authorizations for veterinary medical pharmacies shall be considered invalid.

§ 12. The submitted before the entering into force of the Act applications for authorization for use, production and trade with VMP shall be proceeded under this Act.

§ 13. (1) (amend. – SG 08/11, in force from 25.01.2011) Besides the cases under § 5, 10 and 11 the issued by the BFSA permits, certificates and licenses for the activity of the establishments which shall be controlled by the BFSA shall be in force till the expiry of the deadline for which they have been issued.

(2) (amend. – SG 08/11, in force from 25.01.2011) The persons, having obtained termless permits, certificates and licenses for the activity of the establishments under the repealed Veterinary Medical Activity Act for which this Act shall provide for registration or licensing regime within 6 months from the entering into force of this Act the BFSA shall officially issue a license or carry out registration and issue a certificate.

§ 13a. (new – SG 84/07, amend. - SG 14/16, in force from 19.02.2016) In case an annual frame agreement as per Art. 46a has not been concluded, the implementation of the measures under the program for prevention, supervision, control and eradication of animal diseases and zoonoses shall be assigned according to the terms laid down in the contract from the previous calendar year.

§ 13b. (new – SG 84/07) (1) Within a period of three months from the entry into force of the Act on the Professional Organization of Veterinarians in Bulgaria the registered veterinarians shall submit applications for pre-registration according to a model under the terms and following the procedure laid down in Chapter four.

(2) (amend. – SG 08/11, in force from 25.01.2011) The directors of the RFSD shall carry out pre-registration within a period of three months from the submission of the applications referred to in para 1. No taxes are due for pre-registration.

§ 14. Until adoption of the Animal Protection Act, the provisions of chapter 7 shall be applied for strayed animals.

§ 15. In the Foodstuffs Act (prom. SG 90/99; amend. SG 102/03, SG 70/04) following amendments and supplements are made:

1. In Art. 12:

a) para 2 is amended as follows:

"(2) The registration of the establishment for production or trade with foods shall be carried out by the regional inspection for protection and control of human health (RIPCHH), respectively by the regional veterinary service (RVS) at the location of the establishment. The regional inspection for protection and control of human health shall carry out registration of the establishments for production and wholesale trade with foods of non-animal origin, as well as the establishments for retail trade with foods except for the establishments for retail trade where only foods of animal origin are proposed. The regional veterinary service shall carry out the registration of the establishments for yield, production, processing, storage, packaging and repackaging of raw materials and foods of animal origin, of the establishments for wholesale trade with foods of animal origin, as well as the establishments for retail trade in which only foods of animal origin are proposed.";

b) in para. 5 after word "check" is added "on the spot";

c) established is new para 6:

"(6) For the establishments for retail and wholesale trade in which foods of animal origin are

proposed which are subject to registration in RIPCHH in the spot-check under par.5 shall participate a representative of the respective RVS";

d) the prev. para 6 shall become para 7;

e) the prev. para 7 shall become para 8 and in it the words "para 6" shall be substituted by "para 7".

2. in Art. 16:

a) established is a new para 3:

"(3) Where the authorities of The State veterinary-sanitary control establish an infringement under par.2, item 3 - 5 in establishment for retail sale which shall be subject to registration in RIPCHH the Director of the respective RVS shall notify within 7 days the Director of RIPCHH for the established infringement. The Director of RIPCHH within 7 days shall delete the registration";

b) up to now para 3 and 4 shall become respectively para 4 and 5.

3. (revoked – SG 31/06, in force from 14.04.2006)

§ 16. In the Fodder Act (prom. SG 82/99, amend. SG 101/00, SG 58/03, SG 69/05) the following amendments shall be made:

1. in art. 15:

a) para 1 is amended as follows:

"(1) The National grain and fodder service (NGFS) and the National veterinary medical service (NVS) shall perform control at the production, the transportation, the trade, the storage and the use of fodder raw materials, fodder additives, premixes, combined and medicine fodders."

b) established is a new para. 2:

"(2) The bodies under para 1 exercise official control at the introduction and application of the systems for self control at the production, storage, transportation, release to the market, trade and use of fodder raw materials, fodder additives, pre-mixes, compound and medicine feeding stuffs.";

c) the prev. para 2 shall be para 3;

d) the prev. para 3 is repealed.

2. Established are Art. 15b and 15c:

"Art. 15b. (1) The National grain and fodder service shall control:

1. the implementation of the requirements for approval and registration of the manufacturers and traders of animal foods;

2. the circulation of the fodder raw materials;

3. the terms of use and putting and the circulation of the fodder additives;

4. the requirements for trade with combined fodders;

5. the conformity and full value of the fodders with special designation;

6. the compliance with the regulating acts in the field of animal feeding.

(2) The The National grain and fodder service shall:

1. check the documents, accompanying the products;

2. check the identity of the products;

3. carry out physical check on the products through taking samples;

4. carry out laboratory examinations.

5. check the accuracy of data indicated in the declaration under Art. 8, para 1, Art. 10, para. 1 and Art. 12, para 1;

6. control the observance of the requirements under Art. 8, para 3, Art. 9, para 5 and Art. 10, para 4.

(3) The bodies under Art. 15 shall draw up and implement joint Annual plan for control of the fodders.

(4) The conditions and the order for implementing the official control on fodder raw materials,

fodder additives and the combined fodders shall be arranged by an ordinance of the Minister of Agriculture and Forests.

Art. 15c. The requirements for hygiene of the fodders is provided for by the ordinance of Minister of Agriculture and Forests."

3. In § 2 from the transitional and concluding provisions the words "Art. 15, para 3" shall be deleted.

§ 17. In the Act on Limitation of the Administrative Regulation and the Administrative Control over the Business Activity (prom. SG 55/03, corr. SG 59/03, amend. SG 59/03, amend. SG 107/03, SG 39/04, SG 52/04, SG 31/05), in item 25 of the annex to Art. 9, par.1, item 2 after the word "production" shall be added "and use", the words "and active substances for them" shall be deleted and at the end is added "and transportation of animals".

§ 18. (In force from January 1, 2007) In the Local Taxes and Fees Act (prom. SG 117/97; amend. SG 71, 83, 105 and 153/98, SG 103/99, SG 34 and 102/00, SG 109/01, SG 28, 45, 56 and 119/02, SG 84 and 112/03, SG 6, 18, 36, 70 and 106/04) the following amendments and supplements are made:

1. in Art. 6, para. 1:

a) established is new letter "i":

"i) for a possession of a dog;";

b) former letter "i" shall become letter "j".

2. In Chapter three new Section VIII with Art. 116, 117 and 118 shall be created:

"Section VIII

Fee for possession of a dog

Art. 116. (1) For the possession of a dog the owner shall pay fee to the municipality on which territory his permanent address/residence is located.

(2) The owners of dogs under Art. 175, par.2 of the Veterinary Practice Act shall be exempt from fee.

Art. 117. Within 3 months from the date of the acquisition of a dog the owner shall submit a declaration to the municipality of his permanent address/residence.

Art. 118. (1) The fee shall be paid every year till 31 March of the respective year or within one month from the date of the acquisition of the dog when it was acquired after 31 March. For the dogs, acquired during the current year the fee due shall be in amount of 1/12 of the annual one for every month till the end of the year inclusive the month of acquisition.

(2) The income from the collected fees under para 1 shall be used for measures, connected with the decrease of the number of the estray dogs."

§ 19. In the Apiculture Act (SG 57/03) Art. 36 shall be amended as follows:

"Art. 36. (1) The annual prophylactic examinations of the bee families shall be carried out by the veterinary specialists under the requirements of the state prophylactic program under Art. 118, para 1 of the Veterinary Practice Act.

(2) During carrying out of examinations under para 1 bee keepers, controllers proposed by the respective regional structure of the National Apiculture Trade Association may take part."

§ 20. In the Stock-Breeding Act (prom. SG 65/00; amend. SG 18/04) in Art. 13, para 2 second sentence shall be amended as followed: "The data in the register shall be collected officially from the register under Art. 7, para 2, item 1 of the Veterinary Practice Act".

§ 21. In the Waste Management Act (prom. SG 86/03; amend. SG 70/04, SG 77/05) in Art. 80, para 1, item 14 the words "for import of objects under Art. 49, para 1 of the Veterinary Practice Act" shall be substituted by "under Art. 211, para 1 of the Veterinary Practice Act for the import of animal by-products and the products, obtained from them".

§ 22. (In force from 26 October 2005) In § 35. from the transitional and conclusive provisions of the Act amending and supplementing Farm Land Ownership and Use Act (prom. SG 99/02; amend. SG 38/04) shall be amended as follows:

1. In para 1 the words "three year" shall be substituted by "four year".
2. In para 2 the words "the three year" shall be substituted by "the four year".

§ 23. The Council of Ministers shall submit to the National Assembly a draft Animal Protection Act in three-month period of entering into force of this Act.

§ 24. The Council of Ministers shall submit to the National Assembly in six-month period of entering into force of this Act a draft law of National branch organization of the practicing veterinary doctors and the order for exercising veterinary-medical practice

§ 25. The secondary legislation issued before the entering into force of this Act shall be applied as far as they do not contradict it and until their expressly repeal.

§ 26. (1). The Minister of Agriculture and Forests in one –year period of the entering into force of this Act shall issue the ordinances on its implementation.

(2) The Council of Ministers shall in 6 months period after the promulgation of the Act in State Gazette shall adopt the ordinance under Art. 109 and approve the tariff under Art. 14, para 2.

§ 27. The Act enters into force in 6 months term after its promulgation in State Gazette exept for:

1. para 22, which shall enter into force on 26 October 2005;
2. Articles 259 - 275, which shall enter into force on 1 January 2006;
3. Articles 56, 61 and 192, which shall enter into force on 1 October 2006;
4. Articles 52 - 54, Art. 60, Art. 67 - 76, Art. 77, Art. 3, Art. 78 - 100, Art. 112, 175, Art. 195, para 3, items 2 - 4, Art. 199, para 4, item 2 - 4, Art. 269, 289, 330 - 339, 342, Art. 343, para 5, Art. 382, para 1, Art. 401 and 410 and § 18, which shall enter into force on 1 January 2007.

§ 28. (amend. – SG 36/08; amend. – SG 41/10, in force from 01.06.2010, Agriculture, Foods

and Forestry) The implementation of the Act is assigned to the Minister of Agriculture, Foods and Forestry.

The Act was passed by the 40-th National Assembly on 18 October 2005 and it is affixed with the official seal of the National Assembly.

Transitional and concluding provisions TO THE ADMINISTRATIVE PROCEDURE CODE

(PROM. – SG 30/06, IN FORCE FROM 12.07.2006)

§ 28. In the Veterinary Practice Act (SG 87/05) everywhere the words "the Administrative Proceedings Act" shall be replaced by "The Administrative Procedure Code".

. . . . . .

§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:

1. division three, § 2, item 1 and § 2, item 2 – with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 – 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4§ 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 – with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;

2. paragraph 120, which shall enter into force from the 1st of January 2007;

3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

Transitional and concluding provisions TO THE ACT AMENDING AND SUPPLEMENTING THE FOODSTUFFS ACT

(PROM. – SG 31/06, IN FORCE FROM 14.04.2006)

§ 96. The Act shall enter into force from the day of its promulgation in the "State Gazette" except for:

1. § 21, items 3 and 4, § 25, item 2 and § 93, item 1 concerning Art. 257, para 1, item 5 from the Veterinary Practice Act which shall enter into force from May 1st 2006;

2. § 2 concerning Art. 1a, item 2, § 6 concerning Art. 4b, para 6 and 7, § 7 concerning Art. 4c, para 9, § 9, item 3, § 15 concerning Art. 6k, para 6 and Art. 6o, § 18, para 2 – 9, § 22, § 35 concerning Art. 23a, para 1, items 2 and 3, Art. 23c, para 1, Art. 23d, para 1, 3 – 6 and 8 – 11, Art. 23e, Art. 23g and Art. 23h, para 5, § 26, item 2, § 39, § 43 concerning Art. 27a, para 4, § 45 concerning Art. 28a, para 2, § 48 concerning Art. 29g, para 2, 4 and 5, § 53 concerning Art. 32, para 5, § 54 and § 59 concerning Art. 36a, para 4, Art. 36b, para 2, which shall enter into force from January 1st 2007.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE STOCK-BREEDING ACT

(PROM. - SG 51/07, IN FORCE FROM 26.06.2007)

§ 69. This Act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT ON THE PROFESSIONAL ORGANIZATION OF VETERINARIANS IN BULGARIA

(PROM. – SG 84/07)

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§ 10. In the Veterinary Practice Act (prom. – SG 87/05; amend. – SG 30, 31, 55 and SG 88/06 and SG 51/07) shall be made the following amendments and supplements:

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37. The words "pet animals" shall be replaced by "pets" everywhere in the Act.

Transitional and concluding provisions
TO THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS ACT

(PROM. - 13/08, IN FORCE FROM 31.01.2008)

§ 15. (1) The subordinate and other acts on implementation of the Act shall be issued within one month from its entry into force.

(2) By entry into force of the acts under Para 1 the acts issued on implementation of the provisions revoked by § 6, 7, 8, 9, 10, 11 and 12 shall apply as far as they do not contradict to it.

§ 16. This Act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE FISHERY AND AQUACULTURE ACT

(PROM. - SG 36/08)

§ 68. In the Veterinary Practice Act (prom. – SG 87/05; amend. – SG 30, 31, 55 and 88/06, SG 51 and 84/07 and SG 13/08) everywhere the words "the Minister of Agriculture and Forests", "Minister of Agriculture and Forests", "the Ministry of Agriculture and Forests" shall be replaced respectively with "the Minister of Agriculture and Food Supply", "Minister of Agriculture and Food Supply" and "the Ministry of Agriculture and Food Supply".

Transitional and concluding provisions
TO THE ACT ON THE DEFENCE AND ARMED FORCES OF THE REPUBLIC OF

BULGARIA

(PROM. – SG 35/09, IN FORCE FROM 12.05.2009)

§ 46. This Act shall enter into force from the day of its in the State Gazette.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VOCATIONAL EDUCATION AND TRAINING ACT

(PROM. – SG 74/09, IN FORCE FROM 01.10.2009)

§ 48. The Act shall enter into force from the date of its promulgation in the State Gazette, except for § 1, which shall enter into force from the 15th of September 2009 and § 47, which shall enter into force from the 1st of October 2009.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE SEEDING AND PLANTING MATERIAL ACT

(PROM. – SG 41/10, IN FORCE FROM 01.06.2010)

§ 26. In the Veterinary Practice Act shall be made the following amendments:

. . . . . .

4. Everywhere in the Act the word "food supply" shall be replaced by "food".

5. Everywhere in the Act the words "the Institute for control of veterinary medicinal products", "ICVMP" shall be replaced respectively by " the National Veterinary Service " and "NVS".

§ 27. The Act shall enter into force from the date of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE BULGARIAN FOOD SAFETY AGENCY ACT

(PROM. – SG 08/11, IN FORCE FROM 25.01.2011)

§ 7. In the Veterinary Practice Act (prom. – SG 87/05; amend. – SG 30, 31, 55 and 88/06; SG 51 and 84/07; SG 13, 36 and 100/08; SG 27, 35, 74, 95 and 102/09 and SG 25 and 41/10) shall be made the following amendments:

……

16. In the remaining texts of the Act:

a) the words "National Veterinary Service" shall be replaced by "Bulgarian Food Safety Agency" and the abbreviation "NVS" shall be replaced by "BFSA";

b) the words "RVS" shall be replaced by "RFSD";

c) the words "general" shall be replaced by "executive".

……

§ 30. This Act shall enter into force from the day of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ADMINISTRATIVE VIOLATIONS AND PENALTIES ACT

(PROM. - SG 77/12, IN FORCE FROM 09.10.2012)

§ 19. The Act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE FODDER ACT

(PROM. - SG 97/12)

§ 55. Regulations under Art. 400, para. 3 and Art. 407 of the Veterinary Practice Act shall apply till the ordinances under Art.55, para. 2 and Art.55g, para. 3 shall apply, inasmuch as they do not contradict the Fodder Act.

§ 56. (1 Certificates of fodder business operators issued before the entry into force of this Act shall remain in effect.

(2) By March 1, 2013 fodder business operators who have been registered and approved to the date of entry into force of this Act and who use animal by-products or derived products in carrying out their activities as well as the ones who manufacture and / or trade in medicated animal feed shall submit an application for registration or approval pursuant to this Act.

(3) No fees for registration or approval shall be due upon submission of applications under para 2.

(4) On-site inspection of the facility shall not performed for the purposes of approval under para 2.

(5) The proceedings for registration and approval of feed business operators started before the entry into force of this Act shall be completed under the previous order.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VETERINARY PRACTICE ACT

(PROM. - SG 7/13; AMEND. – SG 15/13, IN FORCE FROM 01.01.2014; SUPPL. – SG 80/09; AMEND. - SG 66/13, IN FORCE FROM 26.07.2013)

§ 187. (1) As from the day of entering of this act into force the validity of the annual frame contract for the implementation of the measures under the programs for supervision and liquidation of animal diseases and the state prophylaxis program shall be terminated.

(2) Individual contracts for the implementation of the measures under the state prophylaxis program and programs for supervision and liquidation of animal diseases shall keep their validity for a period of up to three months from entering of this law into force.

(3) Within the period referred to in par. 2 the owners of animal breeding sites, respectively of animals shall conclude contracts subject to compliance with the provision of Art. 137a, respectively Art. 137b with the persons referred to in Art. 46f and 46g.

§ 188. (1) The contracts concluded prior to entering of this act into force by and between BFSA and the facilities for safe disposal of animal by-products shall keep their validity until 1 April 2013.

(2) The contracts under Art. 275, par. 2, 3 and 5 shall be concluded within one month after entering of this act into force and shall become effective from 1 April 2013.

§ 189. (1) The agreed for use veterinarian clinics – state property, concluded prior to entering of this act into force subject to compliance with the provision of § 1, par. 1 of the Supplementary provision of the Law for the professional organization of veterinary doctors in Bulgaria may keep their validity with parties consent and upon signing of a supplementary agreement for use against payment of prices, determined by a licensed evaluator.

(2) The cost of the made improvements of the buildings of veterinary clinics under par. 1 shall be deducted from the rental fee.

(3) Where there is no parties' consent or no supplementary agreement under par. 1 is concluded, within one month after entering of this act into force the contract shall be deemed terminated.

§ 190. (1) Allocation of state aid subject to compliance with the provision of Art. 46d, par.2 and Art. 51, par. 11 shall apply upon issuance of a positive decision by the European Commission for compatibility with the rules in the field of state aids. Allocation of a state aid shall not be allowed until the date of the positive decision of the European Commission.

(2) (amend. – SG 15/13, in force from 01.01.2014) Prior to issuance of a positive decision by the European Commission as referred to in par. 1, the expenditures under Art. 46d, par. 1, the value of the funds and the expenditures under Art. 51, par. 10 shall be financed with BFSA budget funds.

§ 191. (1) The permits and licenses for use issued by BFSA related to in-vitro diagnostic veterinary medicinal aids, shall remain valid until the expiration of the term for which they have been issued.

(2) The applications for issuance of a license for use, related to in-vitro diagnostic veterinary medicinal aids, filed prior to entering of this act into force, shall be considered following the provision of Art. 279.

(3) (new – SG 80/09; amend. - SG 66/13, in force from 26.07.2013) Untill the ordinance under Art. 410c enters into foece, for the purposes of issuing certificates for registration of in vitro diagnostic veterinary devices licensed to be used as veterinary medicinal products, whose license has expired after January 28, 2013, shall be recognized the data, the packaging, the leaflet for use, production and tests with which the license for use has been issued, provided that the quantitative and qualitative composition of the veterinary device has not been altered.

§ 192. Within one year after entering of this act into force the qualified persons, with whom the VMP manufacturing license holders have got a concluded contract, must meet the provisions of Art. 33, par. 2 – 7.

……

§ 194. (1) Within 6 months after entering of this act into force, the Minister of Agriculture and Foods shall issue the ordinances referred to in Art. 7, par. 2, Art. 26, par. 2, Art. 51, par. 5 and 9, Art.

137, par. 10, Art. 284 and 410c.

(2) Within three months after entering of this act into force the Managing Director of BFSA shall approve the standard forms of documents under this act.

Transitional and concluding provisions
TO THE PUBLIC FINANCES ACT

(PROM. – SG 15/13, IN FORCE FROM 01.01.2014)

§ 123. The act shall enter into force from 1 January 2013, except for § 18, § 114, § 120, § 121 and § 122, which shall enter into force from 1 February 2013.

Transitional and concluding provisions
TO THE SPATIAL DEVELOPMENT ACT

(PROM. – SG 66/13, IN FORCE FROM 26.07.2013)

§ 117. The Act shall enter into force from the date of its promulgation in the State Gazette.

Concluding provisions
TO THE VETERINARY PRACTICE ACT
(PROM. – SG 66/13, IN FORCE FROM 26.07.2013)

§ 2. The Act shall enter into force from the date of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION TO THE YOUTH ACT
(PROM. – SG 68/13, IN FORCE FROM 02.08.2013)

§ 55. This Act shall enter into force from the day of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION TO THE VETERINARY PRACTICE ACT
(PROM. – SG 99/13)

§ 12. Within 6 months from the entry into force of the present Act the Bulgarian Food Safety Agency shall provide access to breeding organizations under Art. 51, para 3, item 2 to the data from the Integrated information system.

Transitional and concluding provisions
TO THE SPATIAL DEVELOPMENT ACT

(PROM. – SG 98/14, IN FORCE FROM 28.11.2014)

§ 117. The Act shall enter into force from the date of its promulgation in the State Gazette.

THE ACT AMENDING AND SUPPLEMENTING THE VETERINARY PRACTICE ACT

(PROM. - SG 14/16, IN FORCE FROM 19.02.2016)

§ 94. In other texts of the Act, the words "state prevention program and programs for the supervision and eradication of animal diseases", "state prevention program and under programs for supervision and eradication of animal diseases", "state prevention program and programs for supervision and eradication of animal diseases", "state prevention program" and "the state prevention program and measures for programs on supervision and eradication of animal diseases" shall be replaced by "the program for prevention, supervision, control and eradication of animal diseases and zoonoses", and the words "carcass collection facilities" shall be deleted.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE VETERINARY PRACTICE ACT

(PROM. - SG 14/16, IN FORCE FROM 19.02.2016)

§ 95. The provision of state aid under Art. 275, para. 5, shall apply after a positive decision by the European Commission has been enacted for compatibility with the rules in the area of state aid. State aid shall not be allowed until the date of the positive decision by the European Commission.

§ 96. (1) Within five days of the entry into force of this Act, the BFSA shall draw up a program for prevention, supervision, control and eradication of animal diseases and zoonoses for the period January 1, 2016 - December 31, 2018, and shall submit it to the minister of Agriculture and Food for approval.

(2) The program under par. 1 shall be approved by the Council of Ministers on a proposal by the Minister of Agriculture and Food no later than 20 days after the approval under par. 1, and shall include:

1. a list of diseases, against which the BFSA carries out measures for prevention, supervision, control and eradication of animal diseases and zoonoses;

2. species and number of animals, for which the measures provided for therein;

3. types of measures under item 1, schemes for their implementation and deadlines for their execution;

4. necessary funds for its implementation.

§ 97. Within three months of the entry into force of this Act, the Executive Director of the BFSA shall appoint by an order the teams as per Art. 117, para. 2.

§ 98. Owners of dogs, marked by a tattoo, are obliged, within one year from the entry into force of this Act, to take them to the veterinarian for placing of a microchip.

.....

§ 103. This Act shall come into force from the day of its promulgation in the State Gazette, with the exception of § 24 – with regard to Art. 118, para. 2 and 3, which shall come into force on 1 January, 2018.

Concluding provisions
TO THE ACT AMENDING THE VETERINARY PRACTICE ACT

(PROM. - SG 34/16, IN FORCE FROM 03.05.2016)

§ 2. This Act shall enter into force on the day of its promulgation in the State Gazette.

Concluding provisions
TO THE ACT AMENDING THE ACT ON BULGARIAN FOOD SAFETY AGENCY

(PROM. - SG 58/17, IN FORCE FROM 18.07.2017)

§ 9. Everywhere in the text of Veterinary Practice Act words "Minister of Agriculture and Food" and "Ministry of Agriculture and Food" shall be replaced with words "Minister of Agriculture, Food and Forestry" and "Ministry of Agriculture, Food and Forestry".

.....

§ 76. This Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE RAILWAY TRANSPORT ACT

(PROM. - SG 17 OF 2018, IN FORCE OF 23.02.2018)

§ 13. The Act shall enter into force on the day of its promulgation in the State Gazette, with the exception of § 2 and 4 which shall enter into force three months after its promulgation in the State Gazette.

Concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE FODDERS ACT

(PROM. - SG 17 OF 2018, IN FORCE FROM 23.02.2018)

§ 66. The Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON THE SOWING AND PLANTING MATERIAL

(PROM. - SG 17 OF 2018, IN FORCE FROM 23.02.2018)

§ 38. The Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE CORPORATE INCOME TAXATION ACT

(PROM. - SG 98/18, IN FORCE FROM 01.01.2019)

§ 70. The Act shall enter into force on 1 January 2019 except for:

1. paragraph 43, item 2 - concerning Art. 4, item 65, item 4, letter "a", item 5, letter b), subletter "bb", item 9, item 15, letter "b", items 31 and 34 and § 64, which shall enter into force on the day of the promulgation of the Act in the State Gazette;

2. paragraph 63, which shall enter into force on 18 November 2018.;

3. 41, item 1, § 43, item 36, § 50, items 1 - 3, item 4, letter "a", items 5-10, § 52, item 3, § 53, 1 and 3 and § 65-69, which shall enter into force on 7 January 2019;

4. paragraph 43, item 11 - concerning Art. 47, para. 4, item 1 and para. 5 which shall enter into force on 28 January 2019;

5. paragraph 52, items 1, 2, 4 and 5 and § 53, paragraph 2, which shall enter into force on 20 May 2019;

6. paragraph 43, item 22, § 57, item 9, item 11, letter "c", item 31, items 32 and 37, which shall enter into force on 1 July 2019;

7. Paragraph 50 item 4, letters "c" and "d", which shall enter into force on 1 October 2019;

8. Paragraph 39, item 3, letter "b" - concerning Art. 14, para. 2, which will enter into force on 1 January 2020;

9. Paragraph 43, item 11 - concerning Art. 47, para. 4, item 2, which shall enter into force on 28 July 2020.

Transitional and concluding provisions

TO THE SOCIAL SERVICES ACT

(PROM. - SG 24/19, IN FORCE FROM 01.01.2020)

§ 41. (1) The provisions of the Health Act, the Health Insurance Act, the Employment Promotion Act, the Legal Aid Act, the Local Taxes and Fees Act, the Veterinary Practice Act, the Bulgarian Personal Documents Act, the Civil Registration Act and the Environmental Protection Act applicable to social and integrated health and social services for residential care, to their managers and the persons who use them, shall apply respectively to the homes for children deprived of parental care, their directors and the persons accommodated therein until the closure of these homes.

(2) The provisions of the Health Act, the Health Insurance Act, the Legal Aid Act, the Employment Promotion Act, the Veterinary Practice Act, Employment Promotion Act, the War Disabled and War Injured Persons Act, the People with Disabilities Act and Local Taxes and Fees Act applicable to social and integrated health and social services for residential care and to and the persons who use them shall apply respectively to homes for mentally retarded adults, homes for adults with mental disorders, homes for adults with physical disabilities, homes for adults with sensory disorders and homes for adults with dementia and for the persons accommodated in them, until the closure of these homes.

(3) Until the closure of homes for medical and social care for children, Art. 124, para. 2 of the Health Act applies to children accommodated in these homes.

(4) Up to the closure of homes for children deprived of parental care and of homes for medical and social care for children, Art. 8e, para. 6 of the Family Allowances for Children Act, Art. 22c, para. 2, item 3 and Art. 22d, para. 2, item 3 of the Income Taxes on Natural Persons Act shall apply to the placement of children in these homes.

(5) The provisions of the Income Taxes on Natural Persons Act and the Corporate Income Taxation Act applicable to donations in favor of social and integrated health and social services for residential care shall apply respectively to donations to homes for children deprived of parental care, homes for mentally retarded adults, homes for adults with mental disorders, homes for adults with physical disabilities, homes for adults with sensory disorders and homes for adults with dementia until the closure of these homes.

……

……

§ 45. This Act shall enter into force on January 1st, 2020, with the exception of:

1. paragraph 6, item 5, letter "a", § 7, item 2, letters "a" and "b", item 3, item 6, letter "a", items 9 and 10; § 18, item 2 in the section on "medical-social care homes for children under the Medical Establishments Act" and § 20, item 2 in the section concerning the deletion of the words "and the homes for medical and social care for children", and item 5, letter "c", which shall enter into force on January 1st, 2021;

2. paragraph 3, item 4, letter "f", "g" and "h" and § 28, item 1, letter "a", items 2 and 5, which shall enter into force on January 1st, 2019.

3. Art. 22, Para. 4, Art. 40, Art. 109, Para. 1, Art. 124, Art. 161, Para. 2, § 3, item 6, § 30, 36, 37 and 43, which shall enter into force on the day of the promulgation of this Act in the State Gazette.