Republic of Latvia

Cabinet

Regulation No. 681

Adopted 17 December 2019

**Regulations Regarding the Procedures for Calculating and Making Payments for the Activities of State Supervision and Control and Paid Services of the Food and Veterinary Service**

*Issued pursuant to*

*Section 21.1, Paragraph nine of the Law on the Supervision of the Handling of Food, Section 12 of the Veterinary Medicine Law, Section 19.1 of the Law on Circulation of Animal Feedingstuffs, Section 26.1, Paragraph five of the Animal Protection Law, Section 12, Paragraph two of the Pharmaceutical Law, and Section 5, Paragraph nine of the Law on Budget and Financial Management*

1. The Regulation prescribes:

1.1. the procedures for calculating a charge and making a payment for the activities of State supervision and control carried out by the Food and Veterinary Service (hereinafter – the Service) laid down in Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (hereinafter – Regulation No 2017/625), and in the Law on the Supervision of the Handling of Food, the Veterinary Medicine Law, the Law on Circulation of Animal Feedingstuffs, and the Pharmaceutical Law;

1.2. the amount of the charge and the procedures for paying it:

1.2.1. for the issuing of a permit for the use of an animal in an experimental project procedure, and also for amending and renewing the abovementioned permit;

1.2.2. for the hiring of experts (researchers) necessary for assessing the experimental project;

1.3. the types of paid services provided by the Service and the price list.

2. The charge for the activities of State supervision and control to which the charge specified in Annex IV to Regulation No 2017/625 is not applied shall be determined in such an amount as to cover the expenditures of the Service in accordance with Articles 81 and 82 of Regulation No 2017/625.

3. The Service shall collect the charge for the activities of State supervision and control in meat cutting plants and game-processing plants in the amount specified in Chapter II, Parts II and III of Annex IV to Regulation No 2017/625.

4. The Service shall collect the charge for the implemented activities of State supervision and control (except for activities pertaining to the border control of animals and goods) specified in the laws and regulations regarding the circulation of food and animal feedingstuffs, animal health and protection in the amount specified in Annex 1 to this Regulation.

5. The charge for the paid services provided by the Service shall be collected in the amount specified in Annex 2 to this Regulation.

6. The charge for the activities of State supervision and control pertaining to the border control of animals and goods shall be collected in the amount specified in:

6.1. Chapter I, Parts I, II, III, IV, V, VI, and VII of Annex IV to Regulation No 2017/625 – for the importation of consignments (cargoes) containing live animals and meat, including meat products, containing poultry, game meat, rabbit meat and farmed game meat, animal by-products, animal feedingstuffs of animal origin, fishery products and other products of animal origin intended for the use as food that are not meat products from third countries, and also for the consignments (cargoes) of such animals and goods from third countries which are carried in transit or transhipped;

6.2. Annex 3 to this Regulation – for the consignments (cargoes) of goods not referred to in Sub-paragraph 6.1 of this Regulation.

7. The charge for the border control of consignments shall be calculated according to the net weight and number of consignments (cargoes).

8. The charge for paid services provided in the circulation of veterinary medicinal products shall be collected by the Service in accordance with Annex 4 to this Regulation.

9. The party receiving the service shall cover the charge for the activities of State supervision and control and the paid services referred to in this Regulation:

9.1. by using a payment card at the Service;

9.2. by transferring the payment to the account of the Service with the intermediation of such payment institution which has the right to provide payment services within the meaning of the Law on Payment Services and Electronic Money.

10. The party receiving the service shall pay for the activities of State supervision and control and the paid services referred to in this Regulation according to an invoice prepared by the Service.

11. If, upon request of the party receiving the service, the Service sends the invoice for the services provided, the marketing authorisation, or another document by post, a charge for the postal services according to the rates of the postal merchant shall be collected from the party receiving the service.

12. On the basis of an application by the party receiving the service, the Service and the party receiving the service may agree on the transfer of the financial resources to the account of the Service before performance of the activities of State supervision and control and provision of services, and also before receipt of the relevant invoice.

13. Cabinet Regulation No. 1083 of 8 October 2013, Procedures for Making Payment for the Activities of State Supervision and Control and Paid Services of the Food and Veterinary Service (*Latvijas Vēstnesis*, 2013, No. 199, 250; 2015, No. 178; 2016, No. 107; 2017, No. 26; 2018, No. 96), is repealed.

14. The Regulation shall come into force on 1 January 2020.

Prime Minister A. K. Kariņš

Minister for Agriculture K. Gerhards

**Annex 1**

Cabinet Regulation No. 681

17 December 2019

**Charge for the Activities of State Supervision and Control of the Food and Veterinary Service Specified in the Laws and Regulations Regarding the Circulation of Food and Animal Feedingstuffs, Animal Health and Protection**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Supervision and control activity | Unit of measurement | Price (in EUR)1 |
| **I. Preparation and issuing of a veterinary (health) certificate2** |
| 1. | Preparation and issuing of a veterinary (health) certificate of animals, including inspection of animals before and during quarantine (according to the actual time of control per working hour): |
| 1.1. | during standard working hours | hour | 17.60 |
| 1.2. | outside working hours on working days and on weekends | hour | 23.63 |
| 1.3. | during night hours | hour | 26.65 |
| 2. | Veterinary (health) certificate for pets – preparation and issuing | certificate | 7.50 |
| 3. | Veterinary (health) certificate for products of animal origin, reproductive products, and animal by-products and derived products not intended for human consumption – preparation and issuing: |
| 3.1. | during standard working hours | consignment | 31.60 |
| 3.2. | outside working hours on working days and on weekends | consignment | 42.46 |
| 3.3. | during night hours | consignment | 47.89 |
| 4. | Veterinary (health) certificate for animal feedingstuffs of animal and plant origin (according to the actual time of control per working hour) – preparation and issuing: |
| 4.1. | during standard working hours | hour | 17.60 |
| 4.2. | outside working hours on working days and on weekends | hour | 23.63 |
| 4.3. | during night hours | hour | 26.65 |
| **II. Preparation and issuing of a certificate of conformity, a control authorisation, and other attestations, certificates, and statements related to supervision and control**2 |
| 5. | Preparation and issuing of a plant-care product certificate of conformity: |
| 5.1. | grain and consignment of processed grain products without packaging: |
| 5.1.1. | weighing up to 60 tonnes | consignment | 19.92 |
| 5.1.2. | weighing 61 to 1000 tonnes | tonne | 0.33 |
| 5.1.3. | weighing 1001 to 5000 tonnes | tonne | 0.30 |
| 5.1.4. | weighing 5001 to 10 000 tonnes | tonne | 0.23 |
| 5.1.5. | for a batch weighing more than 10 001 tonnes | tonne | 0.20 |
| 5.2. | grain and consignment of processed grain products in packaging: |
| 5.2.1. | for a batch weighing up to 60 tonnes | consignment | 24.19 |
| 5.2.2. | for a batch weighing 61 to 1000 tonnes | tonne | 0.40 |
| 5.2.3. | for a batch weighing 1001 to 5000 tonnes | tonne | 0.36 |
| 5.2.4. | for a batch weighing 5001 to 10 000 tonnes | tonne | 0.28 |
| 5.2.5. | for a batch weighing more than 10 001 tonnes | tonne | 0.21 |
| 5.3. | for other plant-care products | consignment | 11.65 |
| 6. | Preparation and issuing of a mushroom and wild berry certificate | consignment | 23.30 |
| 7. | Preparation of a certificate of conformity or a control authorisation for the compliance of imported or exported fresh fruit and vegetables with the trade standards specified in Parts A and B of Annex I to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors (hereinafter – Regulation No 543/2011), and issuing thereof for a consignment: |
| 7.1. | weighing up to 1000 kg (per cargo) | consignment | 11.65 |
| 7.2. | weighing more than 1001 kg (for every subsequent 1000 kg over the first 1000 kg) | 1000 kg | 0.90 |
| 8. | Preparation of a control authorisation for a repeat conformity assessment of fresh fruit and vegetables with the trade standards specified in Parts A and B of Annex I to Regulation No 543/2011 (on the non-conforming consignment), and issuing thereof for a consignment weighing: |
| 8.1. | up to 100 kg | consignment | 17.40 |
| 8.2. | from 101 to 1000 kg | consignment | 26.20 |
| 8.3. | from 1001 to 10 000 kg | consignment | 34.90 |
| 8.4. | from 10 001 to 25 000 kg | consignment | 43.60 |
| 8.5. | 25 001 kg and more | consignment | 52.30 |
| 9. | Preparation of a certificate of conformity and a special certificate for agricultural and processed agricultural products that are eligible for export refunds (according to the actual costs of control per working hour), and issuing thereof | hour | 17.60 |
| 10. | Preparation and issuing of an attestation or a certificate related to control and supervision, including intervention measures (per working hour): |
| 10.1. | during standard working hours | hour | 17.60 |
| 10.2. | outside working hours on working days and on weekends | hour | 23.63 |
| 10.3. | during night hours | hour | 26.65 |
| 11. | Preparation and issuing of an attestation or a certificate related to border control of animals and goods, or approval of an extract from the certificate | consignment | 23.30 |
| 12. | Preparation and issuing of various attestations, certificates, extracts from an inspection protocol, and statements related to supervision and control (if no special inspection of the facility under supervision or other activities (laboratory tests) are necessary) | document | 2.95 |
| **III. Assessment (inspection) and recognition of a facility under supervision specified in laws and regulations and approval of a control authority (in the food and veterinary field)** |
| 13. | Preparation and issuing of an authorisation of recognition or approval: |
| 13.1. | entry and updating of information in databases | entirety of information | 9.96 |
| 13.2. | preparation and issuing of an authorisation | authorisation | 2.50 |
| 14. | Making of variations in an authorisation of recognition or an authorisation of approval of a control authority: |
| 14.1. | entry and updating of information in databases | entirety of information | 5.69 |
| 14.2. | preparation and issuing of an authorisation | authorisation | 2.50 |
| 15. | Costs of one working hour of the inspector for an assessment (inspection) before recognition, registration or before approval of a control authority (in the food and veterinary field), and for a repeat assessment (inspection) if a non-compliance is found | hour | 17.60 |
| 16. | Preparation and issuing of a marketing authorisation | authorisation | 2.50 |
| 17. | Costs of one working hour (not including lodging costs) of the inspector (expert) for inspecting an establishment (object) or documents for the receipt of various attestations or for lifting restrictions, and also for taking of samples (upon a written request by the client) | hour | 17.60 |
| 18. | Recognition of an establishment for export to third countries | according to corroborative documents or according to the expert conditions and rates set by the consigning country |
| **IV. Inspection of fishery products** |
| 19. | Inspection of fishery products at landing sites | tonne | 3.27 |
| **V. Activities of State supervision and control in slaughterhouses**3, 4, 5 |
| 20. | Charge for the control of slaughtered animals (per animal), except for the case referred to in Paragraph 21 of this Annex: |
| 20.1. | beef: |
| 20.1.1. | adult cattle | unit | 5.70 |
| 20.1.2. | young cattle | unit | 2.28 |
| 20.2. | equine animal meat | unit | 3.42 |
| 20.3. | pork – animals of a slaughter weight of: |
| 20.3.1. | up to 25 kg | unit | 0.57 |
| 20.3.2. | 25 kg or more | unit | 1.14 |
| 20.4. | lamb and goat meat – animals of a slaughter weight of: |
| 20.4.1. | up to 12 kg | unit | 0.17 |
| 20.4.2. | 12 kg or more | unit | 0.29 |
| 20.5. | poultry meat: |
| 20.5.1. | poultry of the *Gallus* genus, and guineafowl | unit | 0.006 |
| 20.5.2. | ducks and geese | unit | 0.012 |
| 20.5.3. | turkeys | unit | 0.029 |
| 20.5.4. | quails and partridges | unit | 0.002 |
| 20.6. | farmed rabbit meat | unit | 0.006 |
| 21. | Charge for the time of control if the payment per animal specified in Paragraph 20 of this Annex does not cover the actual costs (according to the actual time of control per working hour) | hour | 11.77 |
| 22. | Charge for idle time if the idle time exceeds one hour (according to the actual time per hour) | hour | 11.77 |
| **VI. Assessment of the activities of an organic farming control authority in a third country** |
| 23. | Inspection of the submitted documents and preparation of a report after assessment of the activities of the control authority | report | 557.77 |
| 24. | Assessment of the activities of the control authority in a third country (according to the actual working time) | hour | 17.60 |
| daily allowance of a business trip, travel expenditures, lodging, and other expenditures according to the corroborative documents and set rates |
| **VII. Supervision of food quality schemes** |
| 25. | Certification of products in food quality scheme, annual inspection and repeat inspection if non-compliance is found in Latvia (according to the actual working time) | hour | 17.60 |
| 26. | Certification of products in food quality scheme, annual inspection and repeat inspection if non-compliance is found in another European Union Member State (according to the actual working time) | hour | 17.60 |
| daily allowance of a business trip, travel expenditures, lodging, and other expenditures according to the corroborative documents and set rates |
| **VIII. Issuing of an experimental project permit for the use of an animal in a procedure** |
| 27. | Assessment of an experimental project and the documents related thereto and issuing of an experimental project permit (if no additional documents are necessary for the assessment) | project | 57.79 |
| 28. | Assessment of additionally submitted documents necessary for the experimental project | entirety of documents | 36.12 |
| 29. | Remuneration of the expert (researcher) involved in the assessment of the experimental project (per project) | one expert | 180.07 |
| 30. | Amending of an experimental project permit | permit | 21.67 |
| 31. | Renewal of an experimental project permit | permit | 36.12 |
| **IX. Unscheduled activities of State supervision and control in case of non-compliance (in accordance with Article 79(2)(c) of Regulation No 2017/625)** |
| 32. | Costs of one working hour of the inspector when performing unscheduled control and implementing measures in case of non-compliance | hour | 17.60 |
| 33. | Laboratory testing when performing unscheduled control and implementing measures in case of non-compliance | according to the actual costs of laboratory testing |

Notes.

1 Value added tax shall not be imposed in accordance with Section 3, Paragraph eight of the Value Added Tax Law.

2 The charge shall include taking of official samples.

3 The charge shall include diagnostics of *trichinellosis* at the slaughterhouse laboratory.

4 The control costs are partially covered in the support measure ‘Support for partial covering of veterinary expert-examination costs’ specified in the laws and regulations regarding annual State support to agriculture and the procedures for the granting of such support.

5 Upon calculating the costs, in addition to the charge specified, a charge shall be calculated for any work carried out outside the stated working hours, on official holidays, and during night hours, in accordance with the laws and regulations governing employment relationships.

Minister for Agriculture K. Gerhards

**Annex 2**

Cabinet Regulation No. 681

17 December 2019

**Price List of Paid Services of the Food and Veterinary Service**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| No. | Type of service | Unit of measurement | Price without VAT (in EUR) | VAT (in EUR) | Price with VAT (in EUR) |
| 1. | Report on measurement and testing results | report | 17.48 | 3.67 | 21.15 |
| 2. | Distribution of forms of the documents involved in the circulation of veterinary supervision: |
| 2.1. | pet passport | passport form | 0.92 | 0.19 | 1.11 |
| 2.2. | veterinary prescriptions | set of forms | 0.08 | 0.02 | 0.10 |
| 2.3. | requests for medicated feedingstuffs | set of forms | 0.08 | 0.02 | 0.10 |
| 2.4. | special veterinary prescriptions | set of forms | 0.21 | 0.05 | 0.26 |
| 3. | Copying: |
| 3.1. | A4 format | page | 0.19 | 0.04 | 0.23 |
| 3.2. | A3 format | page | 0.25 | 0.05 | 0.30 |
| 4. | Rental of equipment, devices (for example, a projector) | hour | 4.39 | 0.92 | 5.31 |
| 5. | Rental of a meeting room at a territorial unit | hour | 7.17 | 1.51 | 8.68 |

Minister for Agriculture K. Gerhards

**Annex 3**

Cabinet Regulation No. 681

17 December 2019

**Charge for the Activities of State Supervision and Control in the Border Control of Goods**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Type of supervision and control | Unit of measurement | Price (in EUR)1 |
| 1. | Food safety control (except for the food the payment for the control of which is specified in Regulation No. 2017/625): |
| 1.1. | consignment transported in one road vehicle/automobile or container, weighing up to 5000 kg (except for the food referred to in Sub-paragraph 1.5 of this Annex) | consignment | 19.45 |
| 1.2. | consignment transported in one road vehicle/automobile or container, weighing 5001 kg or more (except for the food referred to in Sub-paragraph 1.5 of this Annex): |
| 1.2.1. | for 5000 kg | consignment | 19.45 |
| 1.2.2. | for every additional 1000 kg (over 5001 kg) | 1000 kg | 5.84 |
| 1.3. | consignment in one or multiple containers on the same ship (one customs clearance document), per consignment (except for the food referred to in Sub-paragraph 1.5 of this Annex): |
| 1.3.1. | for 5000 kg | consignment | 19.45 |
| 1.3.2. | for every additional 1000 kg (over 5001 kg) | 1000 kg | 3.57 |
| 1.4. | consignment in one or multiple railway wagons within the same train (one customs clearance document), per consignment (except for the food referred to in Sub-paragraph 1.5 of this Annex): |
| 1.4.1. | for 10 000 kg | consignment | 19.45 |
| 1.4.2. | for every additional 10 000 kg (over 10 001 kg) | 10 000 kg | 5.84 |
| 1.4.3. | maximum charge for the consignment referred to in Sub-paragraphs 1.4.1 and 1.4.2 | consignment | 118.73 |
| 1.5. | salt consignment regardless of the type of vehicle | consignment | 19.45 |
| 2. | Safety control for a consignment of materials and articles intended to come into contact with food: |
| 2.1. | weighing up to 5000 kg | consignment | 19.45 |
| 2.2. | weighing 5001 kg or more: |
| 2.2.1. | for 5000 kg | consignment | 19.45 |
| 2.2.2. | for every additional 1000 kg (over 5001 kg) | 1000 kg | 1.95 |
| 2.2.3. | maximum charge for the consignment referred to in Sub-paragraphs 2.2.1 and 2.2.2 | consignment | 126.70 |
| 3. | Safety control of non-food products for a consignment of medicinal products and plant protection products: |
| 3.1. | for cargo weighing up to 5000 kg | consignment | 19.45 |
| 3.2. | for cargo weighing 5001 kg or more: |
| 3.2.1. | for 5000 kg | consignment | 19.45 |
| 3.2.2. | for every additional 1000 kg (over 5001 kg) | 1000 kg | 1.95 |
| 3.2.3. | maximum charge for the consignment referred to in Sub-paragraphs 3.2.1 and 3.2.2 | consignment | 126.70 |
| 4. | Control of animal feedingstuffs (except for feedingstuffs of animal origin the payment for the control of which is specified in Regulation No 2017/625) for a consignment: |
| 4.1. | weighing up to 10 000 kg | consignment | 19.45 |
| 4.2. | for cargo weighing 10 001 kg or more: |
| 4.2.1. | for 10 000 kg | consignment | 19.45 |
| 4.2.2. | for every additional 10 000 kg (over 10 001 kg) | 10 000 kg | 5.84 |
| 4.3. | maximum charge for the consignment referred to in Sub-paragraphs 4.2.1 and 4.2.2 | consignment | 118.73 |
| 5. | Control of a consignment of reproductive products (semen intended for artificial insemination, ova and embryos, eggs for hatching) (except for the reproductive products the payment for the control of which is specified in Regulation No 2017/625) | consignment | 19.45 |
| 6. | Control of the goods referred to in Paragraphs 1, 2, 3, and 4 of this Annex in international postal consignments, weighing up to 30 kg | consignment | 19.45 |
| 7. | Costs of one working hour of the inspector (expert) for taking samples and sending samples for laboratory testing upon request of the owner (authorised representative) of the consignment | hour | 19.45 |

Note. 1 Value added tax shall not be imposed in accordance with Section 3, Paragraph eight of the Value Added Tax Law.

Minister for Agriculture K. Gerhards

**Annex 4**

Cabinet Regulation No. 681

17 December 2019

**Paid Services of the Food and Veterinary Service in the Circulation of Veterinary Medicinal Products**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Item of expenditures | Unit of measurement | Price (in EUR)1 |
| **I. Registration, re-registration, and supervision of registration of veterinary medicinal products** |
| **1. National registration procedure** |
| 1.1. | Expert examination of the application and attached documentation for the registration of veterinary medicinal products: |
| 1.1.1. | for the first pharmaceutical form and strength submitted | application | 750.00 |
| 1.1.1.1. | for every additional pharmaceutical form2 | application | 320.00 |
| 1.1.1.2. | for every additional strength of the medicinal product2 | application | 235.00 |
| 1.1.2. | for homeopathic medicinal products | application | 160.00 |
| 1.2. | Expert examination of the application and attached documentation for the re-registration of veterinary medicinal products: |
| 1.2.1. | for one pharmaceutical form and strength | application | 320.00 |
| 1.2.1.1. | for every additional pharmaceutical form2 | application | 160.00 |
| 1.2.1.2. | for every additional strength of the medicinal product2 | application | 96.00 |
| 1.2.2. | for homeopathic medicinal products | application | 96.00 |
| **2. Mutual recognition procedure** |
| 2.1. | Expert examination of the application and attached documentation for the registration of veterinary medicinal products: |
| 2.1.1. | for the first pharmaceutical form and strength submitted | application | 1565.00 |
| 2.1.2. | for every additional pharmaceutical form2 | application | 785.00 |
| 2.1.3. | for every additional strength of the medicinal products or for every application for medicinal products with identical registration documentation, but different names of medicinal products, and with an identical or different owner of registration (for an iterative application), if submitted at the same time2 | application | 525.00 |
| 2.1.4. | for the reference Member State procedure, per application (in addition to the expert examinations referred to in Sub-paragraphs 2.1.1, 2.1.2, and 2.1.3 of this Annex) | number of the procedure | 1955.00 |
| 2.2. | Expert examination of the application and attached documentation for the re-registration of veterinary medicinal products: |
| 2.2.1. | for the first pharmaceutical form and strength submitted | application | 1045.00 |
| 2.2.2. | for every additional pharmaceutical form2 | application | 655.00 |
| 2.2.3. | for every additional strength of the medicinal product or sales packaging or for every application for medicinal products with identical registration documentation, but different names of medicinal products, and with an identical or different owner of registration (for an iterate application), if submitted at the same time2 | application | 265.00 |
| 2.2.4. | for the reference Member State procedure, per application (in addition to the expert examinations referred to in Sub-paragraphs 2.2.1, 2.2.2, and 2.2.3 of this Annex) | number of the procedure | 1955.00 |
| **3. Decentralised registration procedure** |
| 3.1. | Expert examination of the application and attached documentation for the registration of veterinary medicinal products in the decentralised procedure: |
| 3.1.1. | for the first pharmaceutical form and strength submitted | application | 1565.00 |
| 3.1.2. | for every additional pharmaceutical form2 | application | 785.00 |
| 3.1.3. | for every additional strength of the medicinal products or for every application for medicinal products with identical registration documentation, but different names of medicinal products, and with an identical or different owner of registration (for an iterative application), if submitted at the same time2 | application | 525.00 |
| 3.1.4. | for the reference Member State procedure, per application (in addition to the expert examinations referred to in Sub-paragraphs 3.1.1, 3.1.2, and 3.1.3 of this Annex) | number of the procedure | 1955.00 |
| 3.2. | Expert examination of the application and attached documentation for the re-registration of veterinary medicinal products: |
| 3.2.1. | for the first pharmaceutical form and strength submitted | application | 1045.00 |
| 3.2.2. | for every additional pharmaceutical form2 | application | 655.00 |
| 3.2.3. | for every additional strength of the medicinal product or sales packaging or for every application for medicinal products with identical registration documentation, but different names of medicinal products, and with an identical or different owner of registration (for an iterate application), if submitted at the same time2 | application | 265.00 |
| 3.2.4. | for the reference Member State procedure, per application (in addition to the expert examinations referred to in Sub-paragraphs 3.2.1, 3.2.2, and 3.2.3 of this Annex) | number of the procedure | 1955.00 |
| **4. Issuing of authorisations and certificates** |
| 4.1. | Issuing of a marketing authorisation of veterinary medicinal products in paper form | authorisation | 15.00 |
| 4.2. | Issuing of an export certificate of a product (veterinary medicinal product) | certificate | 140.00 |
| 4.3. | Issuing of an abbreviated certificate of a product (veterinary medicinal product) (certificate of free trade or statement on the registration status of the veterinary medicinal product) | certificate | 41.50 |
| **5. Post-registration supervision** |
| 5.1. | Annual charge4 or: |  | 235.00 |
| 5.1.1. | annual charge if the total turnover from the relevant veterinary medicinal products distributed in Latvia in the previous calendar year exceeds EUR 2000.00 | registration number | 235.00 |
| 5.1.2. | annual charge if the total turnover from the relevant veterinary medicinal products distributed in Latvia in the previous calendar year is EUR 1000.01 to EUR 2000.00 | registration number | 100.00 |
| 5.2. | Analysis of the periodic safety report – in-depth expert examination5 | report | 275.00 |
| 5.3. | Review of the periodic safety report without an in-depth expert examination | report | 75.00 |
| **6. Making of variations in the registration documents of veterinary medicinal products** (for each product) |
| 6.1. | Minor variations of Type I A | one variation | 132.50 |
| 6.2. | Minor variations of Type I B | one variation | 199.50 |
| 6.3. | Major variations of Type II if an in-depth scientific assessment of the documents or an expansion of the registration is necessary | one variation | 391.50 |
| 6.4. | Major variations of Type II if an in-depth scientific assessment of the documents is not necessary | one variation | 229.00 |
| 6.5. | Major variations of Type II related to the change of the owner of the marketing authorisation (the new owner of the marketing authorisation is not the same person) | one variation | 132.50 |
| 6.6. | Approval of the uniform labelling of veterinary medicinal products of the Baltic States | expert examination | 132.50 |
| 6.7. | Approval of the labelling mock-up | expert examination | 135.50 |
| 6.8. | Variations in the labelling mock-up | expert examination | 41.50 |
| **II. Issuing of permits in the circulation of veterinary medicinal products** |
| **7. Parallel-imported veterinary medicinal products** |
| 7.1. | Expert examination of the application and attached documentation for the distribution of parallel-imported veterinary medicinal products in Latvia | expert examination | 225.00 |
| 7.2. | Making of variations in the instructions for the use of parallel-imported veterinary medicinal products | expert examination | 65.50 |
| 7.3. | Making of variations in the labelling of parallel-imported veterinary medicinal products | expert examination | 65.50 |
| 7.4. | Making of variations in the documentation of parallel-imported veterinary medicinal products (change of the legal address of the merchant) | expert examination | 26.50 |
| 7.5. | Issuing of a permit for the distribution of parallel-imported medicinal products in Latvia | permit | 6.65 |
| **8. Distribution of veterinary medicinal products not registered in the state** |
| 8.1. | In-depth scientific assessment of the application and documents submitted for the issuing of a permit for the importation and distribution for ensuring veterinary medical practice (for each product) | expert examination of one product | 70.00 |
| 8.2. | Expert examination of the application and documents submitted for the issuing of a permit for the importation and distribution for ensuring veterinary medical practice, without in-depth scientific assessment (for each product) | expert examination of one product | 35.00 |
| 8.3. | Making of variations in a permit for the importation and distribution for ensuring veterinary medical practice (for each product) | expert examination of one product | 15.00 |
| 8.4. | Permit for the importation and use in exceptional cases (also for immunological veterinary medicinal products), if requested by a wholesaler or importer (for each product) | permit for one product | 28.15 |
| 8.5. | Permit for the importation and use in exceptional cases (also for immunological veterinary medicinal products), if requested by a veterinary medical care institution or a practising veterinarian (for each product) | permit for one product | 5.85 |
| 8.6. | Permit for the importation and use of an immunological veterinary medicinal products in exceptional cases, if the immunological veterinary medicinal products are necessary for systematic vaccination | permit | 28.15 |
| 8.7. | Making of variations in a permit for the importation and use in exceptional cases, also for immunological veterinary medicinal products (for each product) | permit for one product | 15.00 |
| 8.8. | Issuing of a permit for the distribution of non-registered veterinary medicinal products (in addition to the activities referred to in Sub-paragraphs 8.1, 8.2, and 8.3 of this Annex) | permit | 6.65 |
| **9. Assessment of product compliance** |
| 9.1. | Evaluation of a product to determine its compliance with the definition of a veterinary medicinal product (without laboratory tests) | expert examination | 275.00 |
| **10. Clinical trial** |
| 10.1. | Application for a clinical trial and attached documents – review (assessment): |
| 10.1.1. | productive animals | application | 376.25 |
| 10.1.2. | other animals | application | 270.00 |
| 10.2. | Application for amendments to a clinical trial permit and attached documents – review (assessment): |
| 10.2.1. | productive animals | application | 160.00 |
| 10.2.2. | other animals | application | 130.00 |
| 10.3. | Issuing of a clinical trial permit | permit | 6.65 |
| **11. Issuing of other permits** |
| 11.1. | For the importation of a sample of veterinary medicinal products: |
| 11.1.1. | expert examination of the application and documents for the importation of a sample of veterinary medicinal products | expert examination | 135.50 |
| 11.1.2. | issuing of a permit for the importation of a sample of veterinary medicinal products | permit | 6.65 |
| 11.2. | For the distribution of remaining reserves: |
| 11.2.1. | expert examination of the application and attached documentation for the distribution of the remaining reserves of veterinary medicinal products | expert examination | 26.50 |
| 11.2.2. | issuing of a permit for the distribution of the remaining reserves of veterinary medicinal products | permit | 6.65 |
| **III. Assessment of conformity, registration and licensing of the operation** |
| **12. Assessment of conformity** |
| 12.1. | Assessment of conformity of documents | expert examination of documents | 40.00 |
| 12.2. | Assessment of conformity in a veterinary pharmacy (including the assessment of documents and the preparation of a protocol) | 1 pharmacy | 52.95 |
| 12.3. | Assessment of conformity in a wholesaler of veterinary medicinal products (including the assessment of documents and the preparation of a protocol) | 1 wholesaler | 210.60 |
| 12.4. | Assessment of conformity of such person who is not engaged in veterinary practice, but is entitled to purchase veterinary medicinal products from a wholesaler for ensuring its operation without the right to further distribute the veterinary medicinal products (according to the actual time of the inspection, per working hour for one inspector) | 1 hour | 17.60 |
| **13. Good manufacturing practice** |
| 13.1. | Inspection to assess compliance in an importation/production undertaking of veterinary medicinal products, assessment of the provision of good manufacturing practice (in a state of the European Economic Area) at the production undertaking of veterinary medicinal products or at a laboratory that conducts quality control for the production undertaking, according to a contract, if the inspection at the facility (without including the travel costs and the costs of hired experts3) takes: |
| 13.1.1. | one day (one inspector) | 1 importation/production undertaking | 350.00 |
| 13.1.2. | two days (one inspector) | 1 importation/production undertaking | 444.00 |
| 13.1.3. | three days (one inspector) | 1 importation/production undertaking | 538.00 |
| 13.1.4. | four days (one inspector) | 1 importation/production undertaking | 632.00 |
| 13.1.5. | five days (one inspector) | 1 importation/production undertaking | 726.00 |
| 13.2. | Assessment of compliance in an importation/production undertaking of veterinary medicinal products, assessment of the provision of good manufacturing practice (in a state that is not a member of the European Economic Area) at the production undertaking of veterinary medicinal products or at a laboratory that conducts quality control for the production undertaking, according to a contract, if the inspection at the facility (without including the travel costs and the costs of hired experts3) takes: |
| 13.2.1. | one day (one inspector) | 1 importation/production undertaking | 525.00 |
| 13.2.2. | two days (one inspector) | 1 importation/production undertaking | 666.00 |
| 13.2.3. | three days (one inspector) | 1 importation/production undertaking | 807.00 |
| 13.2.4. | four days (one inspector) | 1 importation/production undertaking | 948.00 |
| 13.2.5. | five days (one inspector) | 1 importation/production undertaking | 1088.50 |
| 13.3. | Issuing of a certificate of good manufacturing practice of veterinary medicinal products | certificate | 40.00 |
| 13.4. | Assessment of the documents of good manufacturing practice of veterinary medicinal products | expert examination of documents | 142.30 |
| **IV. Control of samples of veterinary medicinal products** |
| **14. Samples of veterinary medicinal products** |
| 14.1. | Taking of a sample | sample | 17.60 |
| **V. Processing of statistical data of veterinary medicinal products** |
| **15. Statistics, information** |
| 15.1. | Information upon request (subject to agreement), for every working hour | 1 hour | 15.00 |

Notes.

1 Value added tax shall not be imposed in accordance with Section 3, Paragraph eight of the Value Added Tax Law.

2 Shall be applicable if the application is submitted concurrently with the first pharmaceutical form and strength of the veterinary medicinal product of the same name.

3 The travel costs, costs of a business trip, and costs of hired experts – according to the corroborative documents and tariffs specified in the laws and regulations regarding the procedures for reimbursing the expenditures related to business trips.

4 The owner (holder) of the marketing authorisation of veterinary medicinal products shall be exempted from the annual charge or a relief is granted to the annual charge in accordance with the laws and regulations regarding the registration of veterinary medicinal products.

5 Initial expert examination or in case if new scientifically supported data pertaining to the safety or effectiveness of the veterinary medicinal product have been submitted.

Minister for Agriculture K. Gerhards