

**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.<sup>1</sup>, Paragraph nine of the Law on the Supervision of the Handling of Food, Section 12 of the Veterinary Medicine Law, Section 19.<sup>1</sup> of the Law on Circulation of Animal Feedingstuffs, Section 26.<sup>1</sup>, 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

**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) <sup>1</sup>
<b>I. Preparation and issuing of a veterinary (health) certificate<sup>2</sup></b>			
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
<b>II. Preparation and issuing of a certificate of conformity, a control authorisation, and other attestations, certificates, and statements related to supervision and control<sup>2</sup></b>			
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	document	2.95

	supervision or other activities (laboratory tests) are necessary)		
<b>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)</b>			
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	
<b>IV. Inspection of fishery products</b>			
19.	Inspection of fishery products at landing sites	tonne	3.27
<b>V. Activities of State supervision and control in slaughterhouses<sup>3, 4, 5</sup></b>			
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 <i>Gallus</i> 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
<b>VI. Assessment of the activities of an organic farming control authority in a third country</b>			
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	
<b>VII. Supervision of food quality schemes</b>			
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	
<b>VIII. Issuing of an experimental project permit for the use of an animal in a procedure</b>			
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

<b>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)</b>			
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.

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

<sup>2</sup> The charge shall include taking of official samples.

<sup>3</sup> The charge shall include diagnostics of *trichinellosis* at the slaughterhouse laboratory.

<sup>4</sup> 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.

<sup>5</sup> 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



### 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

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### **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) <sup>1</sup>
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. <sup>1</sup> 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

## 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) <sup>1</sup>
<b>I. Registration, re-registration, and supervision of registration of veterinary medicinal products</b>			
<b>1. National registration procedure</b>			
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 form <sup>2</sup>	application	320.00
1.1.1.2.	for every additional strength of the medicinal product <sup>2</sup>	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 form <sup>2</sup>	application	160.00
1.2.1.2.	for every additional strength of the medicinal product <sup>2</sup>	application	96.00
1.2.2.	for homeopathic medicinal products	application	96.00
<b>2. Mutual recognition procedure</b>			
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 form <sup>2</sup>	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 time <sup>2</sup>	application	525.00
2.1.4.	for the reference Member State procedure, per application (in addition to the expert examinations referred to in Sub-	number of the procedure	1955.00

	paragraphs 2.1.1, 2.1.2, and 2.1.3 of this Annex)		
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 form <sup>2</sup>	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 time <sup>2</sup>	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
<b>3. Decentralised registration procedure</b>			
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 form <sup>2</sup>	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 time <sup>2</sup>	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 form <sup>2</sup>	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	application	265.00

	an identical or different owner of registration (for an iterate application), if submitted at the same time <sup>2</sup>		
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
<b>4. Issuing of authorisations and certificates</b>			
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
<b>5. Post-registration supervision</b>			
5.1.	Annual charge <sup>4</sup> 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 examination <sup>5</sup>	report	275.00
5.3.	Review of the periodic safety report without an in-depth expert examination	report	75.00
<b>6. Making of variations in the registration documents of veterinary medicinal products (for each product)</b>			
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
<b>II. Issuing of permits in the circulation of veterinary medicinal products</b>			
<b>7. Parallel-imported veterinary medicinal products</b>			
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
<b>8. Distribution of veterinary medicinal products not registered in the state</b>			
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	permit for one product	15.00

	for immunological veterinary medicinal products (for each product)		
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
<b>9. Assessment of product compliance</b>			
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
<b>10. Clinical trial</b>			
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
<b>11. Issuing of other permits</b>			
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
<b>III. Assessment of conformity, registration and licensing of the operation</b>			
<b>12. Assessment of conformity</b>			
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
<b>13. Good manufacturing practice</b>			
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 experts <sup>3</sup> ) 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 experts <sup>3</sup> ) 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
<b>IV. Control of samples of veterinary medicinal products</b>			
<b>14. Samples of veterinary medicinal products</b>			

14.1.	Taking of a sample	sample	17.60
<b>V. Processing of statistical data of veterinary medicinal products</b>			
<b>15. Statistics, information</b>			
15.1.	Information upon request (subject to agreement), for every working hour	1 hour	15.00

Notes.

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

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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