Statutory Cost Regulation relating to vaccines for veterinary use

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"Statutory cost regulation relating to vaccines for veterinary use of 24 November 2011 (Federal Law Gazette I, p. 1637)"

Footnote
(+++ Text reference as from 1 December 2010 +++)

Preamble

Based on Section 5 (2) of the German Animal Disease Act (Tierseuchengesetz) in its version of the announcement of 22 June 2004 (Federal Law Gazette I p. 1260)amended by Article 16a No 2 of the Act of 13 April 2006 (Federal Law Gazette I p. 855) in connection with the second paragraph of the Administrative Costs Act (Verwaltungskostengesetz) of 23 June 1970 (Federal Law Gazette p. 821) the Federal Ministry for Food, Agriculture, and Consumer Protection orders in agreement with the Federal Ministry of Economics and Technology:

Section 1 Scope

This Statutory Regulation lays down the costs (fees and expenses) the Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health, and the Paul-Ehrlich-Institut charge for

the decision on the marketing authorisation for the products laid down in Section 5 (1) Animal Disease Act

the decision on the release of batches for the products in No 1 of the latter section

other tests and examinations pursuant to the Animal Disease Act.

Section 2 List of Fees

Services for which fees are payable and the amount of such fees are laid down in the List of Fees in the Annex to this Regulation.

Section 3 Fee Reductions and Exemptions

(1) Based on an application by the party obliged to pay the fee for performing an official act pursuant to the Annex to this Regulation, fees can be reduced

1. down to a quarter of the rate stipulated or the minimum rate if
   a) the marketing of the medicinal product serves the public interest owing to the product's indication and if the rareness of the product's indications implies that the applicant cannot expect an economic or other benefit in keeping with the costs of the product's development,

   b) if the variation serves the public interest because it leads to an avoidance of animal tests.

or

2. down to half the rate stipulated or the minimum rate if the significance, economic value or other benefits justify the official act performed for the party obliged to pay the fee.

(2) The fees can be waived if in the cases of paragraph 1 No 1 letter a, the expected economic value or other benefit is particularly low.

(3) If the costs to be expected for performing an official duty amount to not more than 30 EUR, the fees can be waived for reasons of the cost effectiveness of the administrative act.

Section 4 Costs for services performed before the coming into force of the Statutory Regulation

(2) Fees pursuant to this statutory cost regulation also apply to official acts as defined in paragraph 1 No 3, 5.3 or 5.4 of the Annex, which were provided before the statutory cost regulation came into force, if the applicant had been informed that appropriate fees would be charged as soon as the new PEI statutory cost regulation came into force. The PEI has to inform the applicant of the probable amount of the applicable fees before providing the official acts in question.

Section 5 Coming into force, repeal

This statutory regulation shall come into force on the day of its announcement. At the same time, the Statutory Cost Regulation relating to Animal Vaccines of 15 May 1998 (Federal Law Gazette I p. 941), last amended by Article 3 Section 8 of the Act of 22 June 2004 (Federal Law Gazette I p. 1248) is repealed.

Annex (of Section 2)
List of fees

(Source: Federal Law Gazette I 2010, 1638 – 1642)

Part 1
Fees for services by the Paul-Ehrlich-Institut with regard to products except for products against exotic animal pathogens, and products not designed for the use in animals

Fee No	Service	Fee in EUR
1	2	3
1	**For the decision on the marketing authorisation pursuant to Section 22 of the Statutory Cost Regulation relating to Animal Vaccines**	
1.1	for monovalent vaccines and immunomodulators, sera and tuberculins with one target animal species	19,500
1.2	for monovalent vaccines and immunomodulators, sera and tuberculins with one animal species, if the decision requires performing a challenge test	26,000 up to 32,500
1.3	in addition to No 1.1 or No 1.2 per additional component (stem or serotype)	2,700
1.4	in addition to No 1.1 or No 1.2 per additional component (stem or serotype), if the decision regarding this additional component requires performing a challenge test	9,500 up to 15,700
1.5	in addition to No 1.1 or No 1.2 per additional target animal species	2,000
1.6	in addition to No 1.1 or No 1.2 per additional animal species, if the decision regarding this additional component requires performing a challenge test	8,500 up to 15,000
	c) if tests on monkeys are required, a surcharge of	
2	**For the decision on the marketing authorisation within the framework of a mutual recognition procedure, if the Federal Republic of Germany, pursuant to Section 24 (2) Statutory Regulation Regarding Animal Vaccines is**	
2.1	the reference member state as defined in Article 32 paragraph 1 of Directive 2001/82/EC[1] notwithstanding the fee pursuant to No 1	9,500
2.2	is a concerned member state and the decision is based on the assessment report of a different member state	

2.2.1	for monovalent vaccines and immunomodulators, sera and tuberculins with one target animal species	5,700
2.2.2	in addition to No 2.2.1 per additional component	1,500
2.2.3	in addition to No 2.2.2. per additional target animal species	1,400
3.	**For the decision on the marketing authorisation within the framework of a decentralised procedure, if the Federal Republic of Germany, pursuant to Section 24 (3) Statutory Regulation Regarding Animal Vaccines is**	
3.1	the reference member state	
3.1.1	for monovalent vaccines and immunomodulators, sera and tuberculins with one target animal species	30,100
3.1.2	for monovalent vaccines and immunomodulators, sera and tuberculins with one target animal species if the decision requires performing a challenge test	36,600 up to 43,100
3.1.3	in addition to No 3.1.1. or No 3.1.2 per additional component (stem or serotype)	2,700
3.1.4	in addition to No 3.1.1. or No 3.1.2 per additional component (stem or serotype) if the decision regarding this additional component requires performing a challenge test	9,200 up to 15,700
3.1.5	in addition to No 3.1.1. or No 3.1.2 per additional component per additional target animal species	2,000
3.1.6	in addition to No 3.1.1. or No 3.1.2 per additional target animal species if the decision regarding this additional target animal species requires performing a challenge test	8,500 up to 15,000
3.2	a concerned member state	
3.2.1	for monovalent vaccines and immunomodulators, sera and tuberculins with one target animal species	12,000
3.2.2	in addition to No 3.2.1 per additional component	2,000
3.2.3	in addition to No 3.2.2 per additional target animal species	1,600
4.	**For a decision concerning the renewal of the duration of a marketing authorisation pursuant to Section 26 Statutory Regulation Regarding Animal Vaccines if the product**	
4.1	is authorised only in the Federal Republic of Germany	1,700 to 11,000
4.2	is authorised only in the Federal Republic of Germany and the decision requires performing a challenge test	8,700 up to 15,200
4.3	authorised within a mutual recognition procedure or a decentralised procedure and the Federal Republic of Germany is	
4.3.1	the reference member state	1,700 up to 11,000
4.3.2	the reference member state and the decision requires performing a challenge test	9,200 up to 15,700
4.3.3	a concerned member state	1,100 up to 2,500
4.3.4	a concerned member state and the decision requires performing a challenge test	7,800 to 14,300
5	**For a decision on a variation**	
5.1	for a major variation as defined in Article 2, No 3 of the Regulation (EC) No 1234/2008[2] – Type II Variation –	
5.1.1	if the product is authorised only in the Federal Republic of Germany	2,500
5.1.2	if the product is authorised only in the Federal Republic of Germany and the decision requires performing a challenge test	9,000 up to 15,000
5.1.3	if the Federal Republic of Germany is the reference member state	3,200
5.1.4	if the Federal Republic of Germany is the reference member state and the decision requires performing a challenge test	9,700 up to 16,200

5.1.5	if the Federal Republic of Germany is a concerned member state	1,600
5.2	in the event of a minor variation as defined in Article 2 No 5 of Regulation (EC) No 1234/2008 – Type IB Variation –	
5.2.1	if the product is authorised only in the Federal Republic of Germany	750
5.2.2	if the Federal Republic of Germany is the reference member state	1,100
5.2.3	if the Federal Republic of Germany is a concerned member state	650
5.3	in the event of a minor variation as defined in Article 2 No 2 of Regulation (EC) No 1234/2008 – Type IA Variation –	
5.3.1	if the product is authorised only in the Federal Republic of Germany	190
5.3.2	if the Federal Republic of Germany is the reference member state	300
5.3.3	if the Federal Republic of Germany is a concerned member state	
5.4	in the event of an extension of the marketing authorisation as defined in Article 2 No 4 in connection with Annex I of Regulation (EG) No 1234/2008	
5.4.1	if the product is authorised only in the Federal Republic of Germany	17,000
5.4.2	if the product is authorised only in the Federal Republic of Germany and the decision requires performing a challenge test	23,500 up to 30,000
5.4.3	if the Federal Republic of Germany is the reference member state	19,000
5.4.4	if the Federal Republic of Germany is the reference member state and the decision requires performing a challenge test	25,500 up to 32,000
5.4.5	if the Federal Republic of Germany is a concerned member state	5,800
5.5	if an application for more than one variation is made or more than one variation is reported for a product pursuant to No 5.1 to 5.4 simultaneously and this involves a considerably lighter workload	
5.5.1	for the variation for which the highest fee is laid down pursuant to No 5.1 to 5.4	the fee laid down in No 5.1 to 5.4
5.5.2	for each additional variation	a quarter up to three quarters of the fee laid down for each variation in No 5.1 to 5.4
5.6	if variations with the same contents are applied for or reported for several products of one pharmaceutical company pursuant to 5.1 to 5.3	
5.6.1	for the variation for which the highest fee is laid down pursuant to No 5.1 to No 5.3	the fee laid down in No 5.1 to No 5.3
5.6.2	for each additional variation	a quarter up to three quarters of the fee laid down for each variation in No 5.1 to No 5.3
5.7	if a variation pursuant to 5.1 to 5.4 leads to a variation of the marketing authorisation relating to the labelling or the package leaflet, for this variation	no fee

6	**For the release of a batch, including the release based on an application for a certificate**	
6.1	for a release based on the evaluation of the documents submitted	
6.1.1	for monovalent vaccines, sera, immunomodulators, and tuberculins	250
6.1.2	in addition to No 6.1.1 per each additional component	50
6.2	for a release based on in-house testing of the batch, if the extent of the experimental testing is limited pursuant to Section 33 (2) sentence 2 Statutory Regulations Relating to Animal Vaccines, in addition to No 6.1	
6.2.1	per in vitro test	1,100
6.2.2	per in vivo test	2,500
6.3	for a release based on the performance of the investigations laid down in Section 33 (2) sentence 1 Statutory Regulations Relating to Animal Vaccines.	500 up to the fee laid down for a marketing authorisation pursuant to No 1
6.4	for the release of a batch for which the Paul-Ehrlich-Institut has already granted a certificate	140
6.5	for a release based on the test results of the competent authority of a different member state	110
6.6	if more than one batch is released simultaneously, and the batches only differ in the batch number, the volume of the final container, or the product name	
6.6.1	for the first batch	the fee laid down in No 6.1 to No 6.3
6.6.2	for each additional batch	110
6.7	taking into account the test results for batch releases already granted	a quarter up to three quarters of the fee laid down in No 6.1 to No 6.3

Part 2

Fees for services by the Friedrich-Loeffler-Institut with regard to products against exotic animal pathogens and products not designed for the use in animals, as well as the examination of animals and products derived from animal designed for imports and exports

Fee No	Service	Fee in EUR
1	2	3
1	**For the decision on the marketing authorisation pursuant to Section 22 of the Statutory Cost Regulation Relating to Animal Vaccines**	
1.1	for the marketing authorisation if the workload is light or average	2,500
1.2	for the marketing authorisation if the workload is increased, in particular, based on extensive tests or multiple tests	3,700
2	**for a decision on the extension of the duration of a marketing authorisation pursuant to Section 26 Statutory Cost Regulation Relating to Animal Vaccines**	2,200
3	**for a decision on the release of a batch pursuant to Section 32 (3) Statutory Cost Regulation Relating to Animal Vaccines**	
3.1	for a test procedure if the workload is light or average	340
3.2	for a test procedure if the workload is increased, in particular, based on extensive tests or multiple tests	510
3.3	for an exemption from batch control testing pursuant	300

Fee No	Service	Fee in EUR
1	2	3
	to Section 33 (3) Statutory Cost Regulation Relating to Animal Vaccines	
4	**For the examination of animals or products derived from animals designed for imports or exports pursuant to Section 4 (2) sentence 2 Statutory Cost Regulation Relating to Animal Vaccines**	
4.1	for the identification of antibodies in the micro neutralisation test	
4.1.1	against one virus	
4.1.1.1	for one sample	80
4.1.1.2	for each additional sample	30
4.1.1.3	for each additional sample if a simplified recording method is used for sampling	10
4.1.2	against each additional virus in the same testing system per sample in addition to the fees pursuant to No 4.1.1	10
4.1.3	for the evaluation of a microneutralisation test by means of the fluorescence method, immunoperoxidase staining, or a similar method, per sample in addition to the fees pursuant to No 4.1.1 and No 4.1.2	10
4.2	for the identification of antibodies in an ELISA system	
4.2.1	against one antigen	
4.2.1.1	for one sample	70
4.2.1.2	for each additional sample	20
4.2.1.3	for each additional sample if a simplified recording method is used for sampling	10
4.2.2	for each additional antigen in the same testing system per sample in addition to the fees pursuant to No 4.2.1	10
4.3	for the identification of antibodies against one antigen or antigens against one antiserum by means of the precipitation test	
4.3.1	for one sample	70
4.3.2	for each additional sample	20
4.4	for the identification of antibodies against one antigen by means of the immunoblot method	
4.4.1	for one sample	70
4.4.2	for each additional sample	20
4.5	for the detection of antibodies by means of the haemagglutination inhibition test	
4.5.1	against one antigen	
4.5.1.1	for one sample	70
4.5.1.2	for each additional sample	10
4.5.2	against each additional antigen	
4.5.2.1	for one sample	20
4.5.2.2	for each additional sample	10
4.6	for the identification of antibodies by means of complement binding reaction	
4.6.1	for one sample	70
4.6.2	for each additional sample	20
4.7	for the identification of antibodies by means of serum slow agglutination	
4.7.1	for one sample	70
4.7.2	for each additional sample	20
4.8	for the identification of antibodies by means of the Rose Bengal Test	
4.8.1	for one sample	20
4.8.2	for each additional sample	10
4.9	for the identification of virus in single-layer cell cultures	
4.10	for the identification of the foot-and-mouth disease virus from animal seeds, per batch	240
4.11	for the specific identification of one nucleic acid	

Fee No	Service	Fee in EUR
1	2	3
4.11.1	for one sample	70
4.11.2	for each additional sample	30
4.12	for a nucleic acid characterisation	140

[1)] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the community Code relating to veterinary medicinal products (OJ L 322 of 28 November 2001, p. 1) in its applicable version.

[2)] Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 of 12 December 2008, p. 7) in its applicable version.