

Technical Note 008/2017-GEGAR / GGGAF / DIGES / ANVISA.

Subject: **Information on updating the Surveillance Inspection Fee Sanitary (TFVS).**

Ref. : Interministerial Ordinance MF-MS 45/2017.

1. The General Management of Administrative and Financial Management presents to the sector explanations and procedures to be followed by virtue of the publication of the Interministerial Administrative Order MF-MS n. 45 of January 27, 2017, which monetarily updates the values of the Sanitary Surveillance Inspection Fee (TFVS), provided for in art. 23 of Law no. 9,782 of January 26, 1999, pursuant to art. 8 of Law no. 13,202, dated December 08, 2015.

I. Motivation

2. Law 13202/2015 authorized the Executive Branch to monetarily update the values of several rates, among which the Sanitary Surveillance Inspection Fee (TFVS).

3. Law no. 9.782 / 1999, which established the TFVS, was amended by successive Provisional Measures (MP) that constituted or changed the generating facts initially defined in 1999. For this reason, the Interministerial Administrative Order MF-MS n. 45/2017 provides for separate periods for the accumulation of the index for updating monetary policy. The Ordinance presents the normative frameworks in the paragraphs of art. 2nd to 5th. O cumulative index, limited in the percentage of 50%, established in §1 of art. 8th of the Law n. 13.202 / 2015, appears in the sole paragraph of the respective articles. In short, we have

following indices to be observed:

Regulatory framework	Period	Accumulated percentage	50% limit (Paragraph 1 of Article 8)
Law no. 9,782 / 1999	01/1999 to 06/2015	193.55%	96.77%
MP n. 1.814 / 1999	02/1999 to 06/2015	190,491%	95.24%
MP n. 2.134-26 / 2001	01/2001 to 06/2015	154.59%	77.29%
MP n. 2.134-28 / 2001	03/2001 to 06/2015	152.47%	76.23%

II. Effective date:

4. The Interministerial Administrative Order MF-MS is effective as of 09/02/2017, from which time the values established therein will be required. Likewise, the from that date will be the issuance of a Union Collection Guide (GRU) with the corresponding values, in ANVISA's Petitioning Systems.

5. The definition of validity is contained in article 7 of the standard, which that the Ordinance shall enter into force ten (10) days after the date of its publication, Related searches 21, 1/30/2017, Section 1, p. 35-37.

6. It should also be noted that the values of TFVS, monetarily restated by the aforementioned Ordinance are in force as of the publication of Law no. 13,202 / 2015, that is, their retroactive effects to December 9, 2015, as defined in art. 6 of the standard. For this reason, the refund of amounts collected the greater, in the terms set forth in § 2, Art. 8 of Law 13202/2015, shall exclusively consider the generating facts and respective payments made as of the effective date of this Law, that is, December 9, 2015.

7. The Interministerial Ordinance MF-MS n. 45/2017, in its art. 8, repealed

expressly the Interministerial Ordinance MF-MS n. 701/2015.

III. How to proceed with the issuance and collection of TFVS

** except companies covered by court order*

Situation		What to do
A) GRU pays with value lower than that of the Ordinance MF-MS n. 45/2017	Not Protocolized	Issue Complementary GRU in the Electronic Petition based on value constant of the Table of Values of the Ordinance MF-MS n. 45/2017 and the current size of the company There is no supplementation or refund of values
	Protocolized	
B) GRU pays with value integral to the Ordinance MF-MS n. 45/2017	Protocolized	It can be registered regularly. The partial refund of the value may occur exceeded according to guidelines to be available
	Not Protocolized	
	Protocolized	
C) GRU pays with value higher than the Ordinance MF-MS n. 45/2017	Not Protocolized	It may be partial refund of value exceeded according to guidelines The to be available; or It may not be protocolized and subject to full refund of the amount collected,
	Protocolized	

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D) GRU issued with the other than the defined value at Concierge Interministerial MF-MS n. 45/2017 and NOT PAYABLE		according to guidelines The to be available.
	The issued guide should be disregarded, not generating any onus. Therefore, the interested party must issue a new GRU with the established in Interministerial Administrative Order MF-MS 45/2017 to from 09/02/2017, when it is possible to wait for petition as of that date.	

IV. Repayment of amounts collected the greater

8. ANVISA will shortly disclose the specific procedure for the return of the amounts collected the greater, in compliance with the provisions of paragraph 2 of art. 8 of Law no. 13.202 / 2015 and the Interministerial Ordinance MF-MS n. 45/2017.

9. In any case, it is anticipated that:

(a) shall be entitled to a refund of the amount collected in excess of TFVS, pursuant to §2 of art. 8 of Law no. 13.202 / 2015, companies whose generating events occurred exclusively from 09 December 2015;

b) The interested party does not need to file a Request for Reimbursement of value collected under TFVS, nor transactions to be restored, since collected under the above terms, will be refunded through specific procedure to be disclosed by ANVISA.

(c) the applications for refunds lodged pursuant to Article monetary restatement of amounts shall be subject to loss of object, since the refund will be through a specific procedure to be disclosed by ANVISA.

d) It is essential to maintain the updated banking data of the holder of the payment, since, according to article 55, § 2 of the RDC 222/2006, the restitution of amounts will only be made in current account of the payee holder. Therefore, the interested party should promote the updating of this data in the Companies Register

of this Anvisa, as well as the respective electronic address (e-mail) of the company.

e) The amounts collected the greater will be monetarily restated, at the SELIC rate, from the date of collection, in accordance with Art. 61 of DRC 222/2006.

10. For clarification of doubts should contact the Service Center ANVISA, by telephone no. 0800-642 9782, from 7:30 a.m. to 7:30 p.m., from Monday to Friday, except holidays, free call.

Brasília, January 30, 2017

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