

Survey on municipal sanitary licensing: procedures and simplification

Levantamento sobre licenciamento sanitário municipal: procedimentos e simplificação

ABSTRACT

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Introduction: Health licensing is the legal act that allows establishments that perform activities subject to health surveillance to function and the responsibility of States, the Federal District and Municipalities over it. The publication of Anvisa RDC Resolution No. 153/2017 established national criteria for risk classification, simplification and harmonization for health licensing. **Objective:** Obtain information about the health licensing process adopted in Brazilian municipalities and evaluate the implementation and adoption of the criteria of Anvisa RDC Resolution No. 153/2017 by Municipal Health Surveillance. **Method:** The information was obtained by means of a semi-structured virtual form, sent by email to the Municipal Health Surveillance agencies. **Results:** At all, 2,111 municipalities sent information about the knowledge and implementation of the regulation, in addition to procedures adopted for health licensing, such as: phase for document analysis and health inspection, fee collection, average time for granting a health license, digitalization and integration with Redesim. **Conclusions:** Although the regulations are widely known, only 15.4% of the respondent Municipal Health Surveillance agencies adopt simplified procedures for granting the health license for economic activities previously known as low risk. In addition, State relevance in the coordination of municipal visas was ratified and, considering the charging of fees for issuing the health licence by most Brazilian municipalities, there was a potential impact on their collection with the publication of the Economic freedom law. Anvisa is responsible for articulating with the Federal Government and proposing programs to assist articulation between local agencies, to promote exchange of experiences, cooperation and strengthening of the SNVS.

KEYWORDS: RDC nº 153/2017; Sanitary Licensing; Risk Rating; Municipal Health Surveillance

RESUMO

Introdução: O licenciamento sanitário é o ato legal que permite o funcionamento de estabelecimentos que desempenhem atividades sujeitas à vigilância sanitária, sendo competência dos estados, do Distrito Federal e dos municípios. A publicação da RDC Anvisa nº 153, de 26 de abril de 2017, estabeleceu critérios nacionais para classificação de risco, simplificação e harmonização para o licenciamento sanitário. **Objetivo:** Obter informações sobre o processo de licenciamento sanitário adotado nos municípios brasileiros e avaliar a implementação e adoção dos critérios da RDC nº 153/2017 pelas Vigilâncias Sanitárias (Visa) municipais. **Método:** As informações foram obtidas por meio de um formulário virtual semiestruturado enviado por *e-mail* aos órgãos de Visa municipais. **Resultados:** Ao todo, 2.111 municípios enviaram informações acerca do conhecimento e da implementação da normativa, além dos procedimentos adotados para o licenciamento sanitário, tais como: momento de análise documental e inspeção sanitária, cobrança de taxa, tempo médio para concessão de licença sanitária, informatização e integração à Rede Nacional para a Simplificação do Registro e da Legalização de Empresas e Negócios (Redesim). **Conclusões:** Apesar de a normativa ser amplamente conhecida, apenas 15,4% dos órgãos de Visa municipais respondentes adotam procedimentos simplificados para

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concessão da licença sanitária para atividades econômicas até então denominadas de baixo risco. Além disso, ratificou-se a relevância estadual na coordenação das Visa municipais e, considerando a cobrança de taxa para emissão da licença sanitária pela maioria dos municípios brasileiros, verificou-se potencial impacto na arrecadação destes com a publicação da Lei da Liberdade Econômica. À Anvisa cabe a articulação com o Governo Federal e a proposição de programas que auxiliem a articulação entre os órgãos locais, para que promovam a troca de experiências, cooperação mútua e fortalecimento do Sistema Nacional de Vigilância Sanitária.

PALAVRAS-CHAVE: RDC nº 153/2017; Licenciamento Sanitário; Classificação de Risco; Vigilância Sanitária Municipal

INTRODUCTION

As provided for in Federal Law No. 6,360, of September 23, 1976¹, and in Federal Law No. 9,782, January 26, 1999², may only extract, produce, manufacture, transform, synthesize, purify, fractionate, pack, repack, import, export, store or ship medicines, drugs, pharmaceutical, and related supplies, as defined in Federal Law No. 5,991, of December 17, 1973³, as well as hygiene products, cosmetics, perfumes, sanitizing products, products intended for aesthetic correction, and food, companies authorized for this purpose by the Ministry of Health (MS) and whose establishments have been licensed by the sanitary agency federative units in which they are located.

Health licensing is the legal act that permits the operation of establishments, as verified their compliance with legal and regulatory requirements, and the licensing of establishments that perform activities subject to health surveillance is the responsibility of the states, the Federal District, and the municipalities⁴.

As a rule, through sanitary inspection, the Health Surveillance agencies (Visa) evaluated the conditions of the facilities, the technical and operational training of the company, professional responsibility, among others, and the set of requirements for subsequent granting of the sanitary license.⁵

In 2007, Federal Law No. 11,598⁶, of December 3, was published, which established guidelines and procedures for simplifying and integrating the registration and legalization process for businessmen and legal entities, in addition to creating the National Network for Simplification of Registration of Company and Businesses Legalization (Redesim). In its Art. 5, the Law establishes that: “for the purposes of registration and legalization of businessmen and legal entities, the requirements of sanitary security, environmental control, and fire prevention must be simplified, rationalized and standardized by the bodies and entities that compose Redesim, within the scope of their respective competences”.

Since then, there has been a movement to analyze and revise the procedures traditionally adopted by Organs licensing agencies, including Visa, so that they are proportionate to the risk inherent in the economic activities developed. By definition, the sanitary risk is the property that an activity, service, or substance has of producing harmful effects to human health⁷.

In the scope of states and municipalities, the need for Visa’s statement on the risk of economic activities, for the purpose of licensing, was more strongly present in 2010, with the state of

São Paulo being a pioneer in this definition and institution of a rule regulating the issue. Over time, several other states joined the Redesim and the matter in question was regulated by the Resolution of the Committee for the National Network for the Simplification of Registration and Legalization of Companies and Businesses (CGSIM) nº 22, of June 22, 2010⁸ (Redesim Management Committee Regulation), without the participation of Visa representatives and, therefore, without reflecting the understanding of the National Health Surveillance System (SNVS).

Bearing this in mind, based on the classifications already existing in the states and municipalities and after discussions with areas of the National Health Surveillance Agency (Anvisa) and with the state and municipal Visa coordinations, with subsequent public consultation, Anvisa published on April 26, 2017, the Collegiate Board Resolution (RDC) No. 153⁹ which defined the degree of sanitary risk of economic activities of interest to health surveillance and their respective licensing procedures, dividing them into two categories:

- Low risk: economic activities whose establishment will start operating without the need for a sanitary inspection or prior documentary analysis by the agency responsible for issuing the sanitary license;
- High risk: economic activities that require sanitary inspection or prior documentary analysis by the body responsible for issuing the sanitary license, before the establishment’s operation begins.

As provided for in the sole paragraph of Art. 6 of Anvisa’s RDC nº 153/2017⁹, Normative Instruction (NI) nº 16, of April 26, 2017¹⁰ established the list of economic activities subject to health surveillance, by degree of risk, for sanitary licensing purposes.

This regulation proposed to harmonize nationally the risk classification of economic activities subject to health surveillance, divided into low and high risk, and the respective procedures to be adopted, for licensing purposes. It should be noted that, considering the National Classification of Economic Activities (CNAE) as a reference for the classification of health risk, NI nº 16/2017¹⁰ also presents a table of activities said as “Dependent Information”, which covers activities whose framing in the CNAE codes is not sufficiently precise to define whether such economic activity is of high or low risk, or even if that activity falls within those of Visa’s competence. An example of this is the manufacture of rubber products that can serve



both the production of health products and the manufacture of automotive articles, which, in the latter case, is not the scope of health surveillance. Another example is food manufacturing. If it is of industrial size, it is configured as an economic activity of high sanitary risk, for licensing purposes, whereas if the manufacture is artisanal, the activity is classified as low risk.

With this in mind, in order to obtain information on the health licensing process adopted in Brazil, especially in relation to the criteria addressed in Anvisa's RDC No. 153/2017⁹, in order to support national discussions about the theme and enable the development of more assertive strategies that meet SNVS's needs, Anvisa conducted a survey on sanitary licensing with local Visa agencies.

Considering the establishment of a simplified procedure for licensing economic activities of low health risk, proposed by Anvisa's RDC n° 153/2017⁹, and the provision that health surveillance actions related to establishments, products, and low health risk services are carried out by the municipalities, according to Anvisa's RDC n° 207⁴, of January 3, 2018, this survey on sanitary licensing was directed to the municipal Visa agencies.

Thus, the objective of this study was to obtain information on the sanitary licensing process adopted in Brazilian municipalities and to evaluate the implementation and adoption of the criteria of Anvisa's RDC n° 153/2017⁹ by the municipal Visas.

METHOD

Information on municipal health licensing was obtained using a semi-structured virtual form, prepared by Anvisa's National Health Surveillance System Advisory (ASNVs), containing up to 18 questions, presented in the Chart.

The form was sent, via e-mail, to the 26 state coordinators so that, at the request of ASNVs/Anvisa, they could pass it on to all the respective municipal Visa agencies. The form was available for completion from July to September 2019. Subsequently, the data were treated and analyzed.

When more than one record was detected per municipality, by internal standardization, only the most recent contribution was accepted, considering that it could be a rectification of information.

RESULTS AND DISCUSSION

During the survey period, 2,111 municipalities sent information about the procedures adopted for sanitary licensing, making up 37.9% of Brazilian municipalities. Figure 1 shows the relative participation of each state (A), region (B), and population size (C). With the exception of the Midwest Region (22.1%), which was well below the national average (37.9%), the contributions of municipalities by regions of Brazil and by population size were considered relatively satisfactory, as they were above or close to the national average.

The present survey counted on the voluntary contributions of the municipal Visa agencies, through the respective state

coordinators, also on a voluntary basis. The dialogue between the federal level and the state/district level was effective, considering that information was obtained from municipalities in all states and the Federal District.

The proportional contribution of municipalities in each Brazilian state was very heterogeneous, ranging from 5.1%, in the case of the state of Mato Grosso do Sul, to 81.1%, in the state of São Paulo. It is not possible to determine whether the missing municipal Visa agencies did not want to respond to the form or if they did not receive such a request, which could indicate poor communication with the respective state coordinator.

After the deadline for filling out the form, the raw data obtained were forwarded to the state Visa agencies, so that they could carry out local assessments if they deemed relevant.

Regarding the analysis of the information obtained, it is initially worth mentioning that 3.1% of the municipal Visa agencies declared that they did not issue a sanitary license. Of these, 89.4% are municipalities with up to 20 thousand inhabitants. According to data from the Brazilian Institute of Geography and Statistics¹¹, 21.9% of Brazilian municipalities do not have a Sanitary Code and do not use state regulations, the highest percentage of which is from the Northeast Region and inversely proportional to populational size. Jataí's (GO) and Rio do Sul's (SC) Visa informed that, by law, the single permit is issued by the Secretariat of Finance.

Regarding Anvisa's RDC n° 153/2017⁹, the municipal Visa agencies were asked if they knew the Resolution, if there was any training in the classification of the degree of risk for economic activities subject to health surveillance, for licensing purposes, and if the municipality adopted any risk classification, with the following results:

- 77.0% of the municipalities reported knowing the Anvisa's RDC n° 153/2017;
- 39.0% of the municipal Visa agencies reported having received some training in the classification of the degree of risk for economic activities subject to health surveillance, for licensing purposes, distributed as follows: 72.0% were trained by the state Visa, 17.0% were trained by the municipal Visa itself, 10.0% were trained by the Brazilian Micro and Small Business Support Service (Sebrae), 1.0% by Anvisa, and 3.0% by others;
- Of the municipalities that issue a sanitary license, 78.0% declared that their Visa classifies the risk of economic activities, for licensing purposes, and this classification is according to: state regulations (45.0%), Anvisa's RDC n° 153/2017 (43.0%), and municipal regulations (12.0%). It is worth mentioning that at least one municipality in all states mentioned following Anvisa's RDC n° 153/2017. As for population size, there was an increasing trend towards risk classification of economic activities, for licensing purposes, and 76.3% of the municipalities with up to 5,000 inhabitants declared to carry out such classification.



Chart. Questions and answers that make up the semi-structured virtual form prepared by the National Health Surveillance System Advisory of the National Health Surveillance Agency, which was sent to the municipal Health Surveillance through the respective state coordinators.

1. What is your name? (optional)
2. What is the contact email of the Health Surveillance of your municipality?
3. What is your state?
4. What is your municipality?
5. Does the Health Surveillance of your municipality know Anvisa's RDC n° 153/2017?
 - Yes
 - No (skip to 7)
6. Has there been any training in the Health Surveillance of your municipality in relation to the Classification of the Degree of Risk for economic activities subject to health surveillance, for licensing purposes (Anvisa's RDC n° 153/2017)?
 - No
 - Yes, by the Municipal Surveillance
 - Yes, by the State Surveillance
 - Yes, by Sebrae
 - Yes, by Anvisa
 - Yes, by others (which?)
7. Does your municipality's Health Surveillance classify the risk of economic activities for licensing purposes?
(Note: for the purposes of this survey, if the state or municipal orientation is equal to Anvisa's RDC n° 153/2017 and Normative Instruction No. 16/2017, please check the first option)
 - Yes, according to Anvisa's RDC n° 153/2017 and Normative Instruction n° 16/2017
 - Yes, according to state regulations
 - Yes, according to municipal regulations
 - No (skip to 11)
8. When does the documentary analysis of the licensing process by the Municipal Health Surveillance take place for LOW-RISK sanitary activities?
 - There is no documentary analysis
 - Before the grant of the sanitary license
 - After the grant of the sanitary license, in all cases
 - After the grant of the sanitary license, in some cases
9. When does the sanitary inspection by the municipal health surveillance occur for LOW-RISK sanitary activities?
 - There is no sanitary inspection (skip to 11)
 - Before granting the sanitary license (skip to 11)
 - After granting the sanitary license, in all cases (skip to 11)
 - After the grant of the sanitary license, in some cases
10. In which situation(s) is(are) the sanitary inspection carried out by the municipal Sanitary Surveillance for LOW-RISK sanitary activities after sanitary licensing?
 - Based on complaints
 - By sampling
 - According to the action plan defined by the Municipal Health Surveillance
 - Others
11. Are fees charged for municipal health licensing?
 - No
 - Yes, except for Individual Microentrepreneur
 - Yes, even for Individual Microentrepreneurs
12. What is the average time for the licensing of LOW-RISK economic activities with Health Surveillance?
 - Automatic, immediately after data entry in electronic system
 - Within 5 days
 - From 5 to 30 days
 - Over 30 days
 - Does not apply (goes to 14)
13. Do the processes for renewing the sanitary license for LOW-RISK economic activities follow a simplified flow?
 - Yes
 - No
14. What is the average time for the licensing of HIGH-RISK economic activities with the municipal Health Surveillance?
 - Automatic, immediately after data entry in electronic system
 - Within 30 days
 - From 30 to 90 days
 - From 90 to 180 days
 - Over 180 days
 - Does not apply
15. Is the municipal health surveillance integrated into Redesim?
 - Yes, integration is done via web service
 - Yes, integration is done via a service box
 - No, the integration has not been done yet
 - No, all procedures are done manually and on paper
 - No, our municipality is not aware of Redesim

continues



continuation

16. Is licensing with the municipal health surveillance done through a computerized system?
 - No, the Municipal Health Surveillance does not have a computerized system that supports health licensing
 - Yes, in computerized systems at the Health Surveillance counters
 - Yes, on the Health Surveillance website
 - Yes, on the portal of the state integrator of Redesim on the internet
 - No, the Municipal Health Surveillance does not issue a sanitary license (skip to 18)

17. Does the Municipal Health Surveillance guide the entrepreneur on the steps and requirements that must be met for sanitary licensing?
 - No
 - Yes, in person at the Health Surveillance counters
 - Yes, on the Health Surveillance website
 - Yes, on the portal of the state integrator of Redesim on the internet

18. If you want, leave your comment and/or report on the topic. (open field).

Source: Elaborated by the authors, 2020.

RDC: Resolution of the Collegiate Board; Anvisa: National Health Surveillance Agency; Sebrae: Brazilian Support Service for Micro and Small Companies; Redesim: National Network for Simplification of Registration of Company and Businesses Legalization

(A)

State	%
Federal District	100.0
São Paulo	81.1
Bahia	56.6
Amazonas*	51.6
Santa Catarina	48.5
Rio Grande do Norte*	47.9
Tocantins*	43.9
Sergipe	41.3
Acre*	40.9
Espírito Santo	39.7
Maranhão	38.2
Alagoas	38.2
Rondônia*	36.5
Minas Gerais	36.0
Roraima	33.3
Amapá	31.3
Rio Grande do Sul	30.8
Mato Grosso*	29.8
Piauí	28.1
Paraná	25.8
Goiás	22.8
Ceará	12.0
Paraíba	10.3
Rio de Janeiro*	9.8
Pará*	9.7
Pernambuco*	9.2
Mato Grosso do Sul	5.1

* without information from the capital

(B)

Region	%
Southeast	52.2
South	33.5
Northeast	33.1
North	32.2
Midwest	22.1

(C)

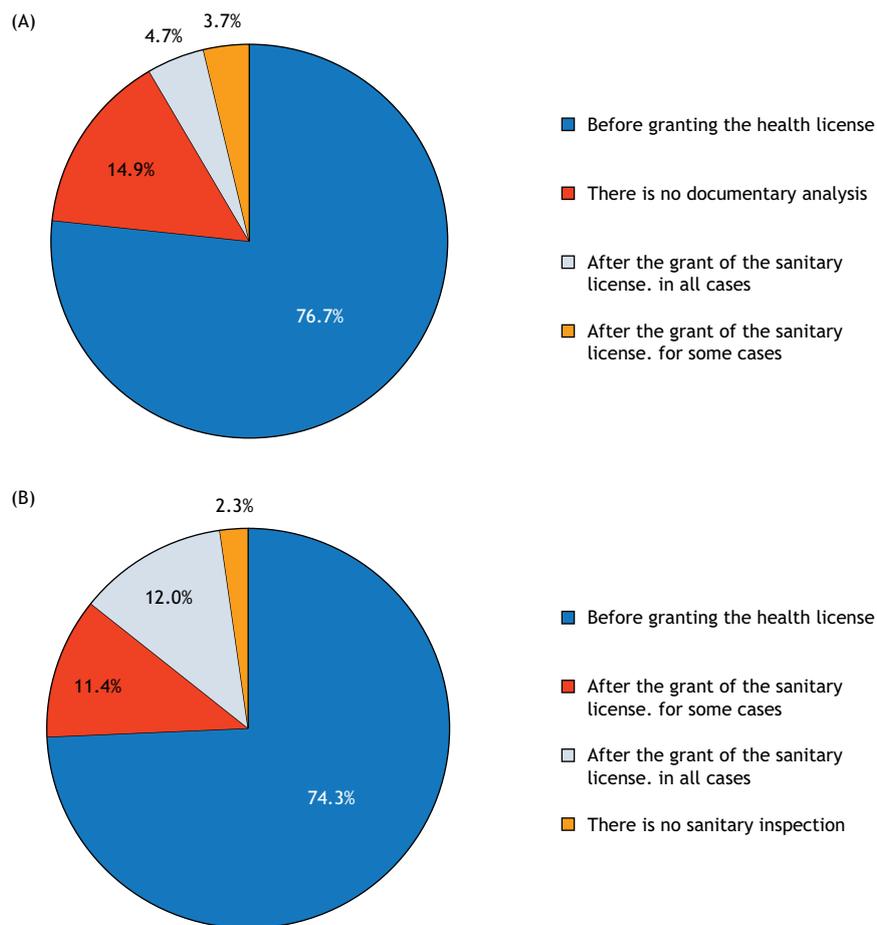
Population size (No. of inhabitants)	%
Up to 5,000	34.0
5,001 to 10,000	34.8
10,001 to 20,000	41.0
20,001 to 50,000	39.4
50,001 to 100,000	42.1
100,001 to 500,000	49.3
Over 500,000	58.3

Source: Elaborated by the authors, 2020.

Figure 1. Proportional participation of municipalities in relation to the return of the virtual form by state (A), region (B), and population size (C). Proportional contribution above (black) and below (red) the national average 37.9%.

In order to verify whether the licensing procedures carried out by municipal visas are consistent with the risk classification of economic activities, it was questioned when documentary analysis and sanitary

inspection for low risk activities were carried out, considering that Anvisa's RDC nº 153/2017⁹ recommends that these be made after the grant of the sanitary license. The results are shown in Figure 2.



Source: Elaborated by the authors, 2020.

Figure 2. Percentage representation of the moment when the documentary analysis (A) or the sanitary inspection (B) is made in the health licensing process for low-risk activities carried out by the Brazilian municipalities issuing the health license.

Although 78.0% of the municipalities declare to classify the risk of economic activities, only 23.3% and 25.7% carry out document analysis or sanitary inspection, respectively, after the grant of the sanitary license.

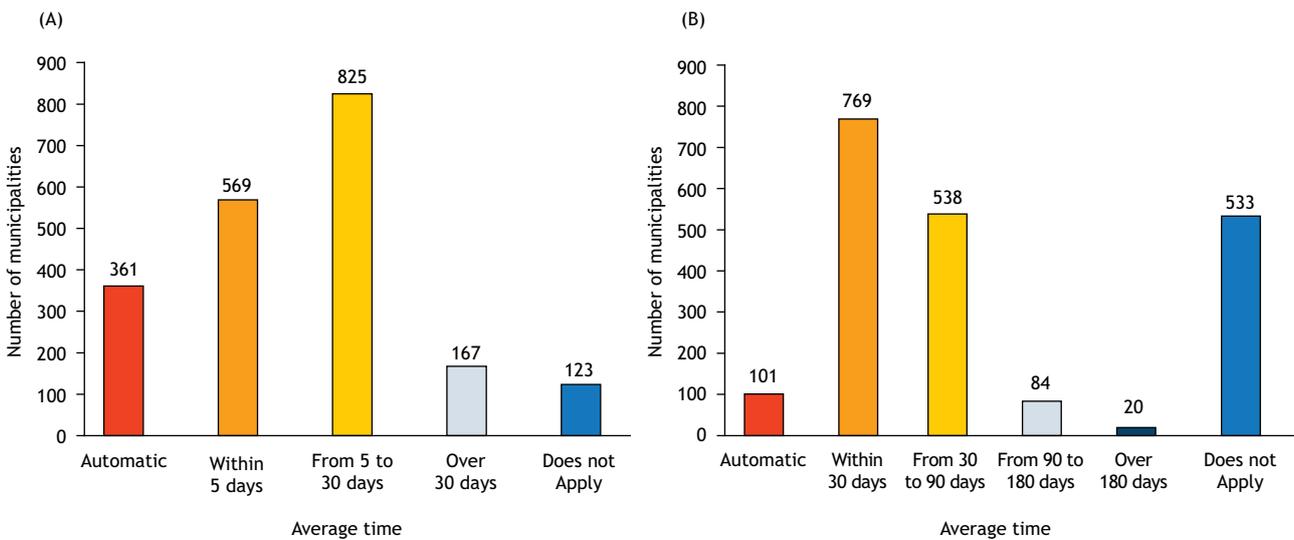
Considering the two variables concomitantly, only 15.4% of the municipal Visa agencies actually adopt a simplified procedure for licensing low-risk economic activities, that is, sanitary licenses are issued and, subsequently, document analysis and/or sanitary inspection. Of these, 65.0% declared that they had not been trained and, of the 25.0% that received training on the theme, 65.7% were trained by the state Visa, showing the effective performance of the states in the coordination of the municipal visas.

Of the 11.4% agencies that declared to carry out sanitary inspection after granting the license in only a few cases, 64.2% follow the action plan defined by the municipal Visa, 12.1% based on complaints, and 6.8% by sampling, demonstrating an effective performance of health surveillance proportional to the risks, maintaining its duty to protect health through state intervention, aiming to prevent possible damages, injuries, or risks to the health of the population¹². In this sense, it is worrying that

2.3% of municipal Visa agencies that adopt a simplified procedure for licensing low-risk economic activities do not carry out health inspections for such activities, under any circumstances. Despite presenting a low sanitary risk, these activities can still cause damage to the health of the population, although with less probability and intensity, and require monitoring of the quality of services subject to health surveillance.

Regarding the time for granting the sanitary license, the municipalities were asked about the average time practiced for issuing the sanitary license for low-risk and high-risk economic activities, as shown in Figure 3.

Of the municipal Visa agencies that issue a sanitary license, 123 responded “not applicable” for the average sanitary licensing time for low-risk economic activities, which may mean that they do not know the deadline for carrying out this procedure. Of the municipalities that reported granting an automatic sanitary license, 167 carried out the documentary analysis and/or prior sanitary inspection, demonstrating that the informed period is incorrect.



Source: Elaborated by the authors, 2020.

Figure 3. Average time for sanitary licensing of low-risk (A) and high-risk (B) economic activities with municipal health surveillance.

As shown in the survey results, most Brazilian municipalities (77.0%) are aware of Anvisa's RDC n° 153/2017⁹. In spite of this, only 15.4% of the municipal Visa agencies that declared to adopt risk classification do simplified procedures for licensing low-risk economic activities. This information is corroborated when we analyze the average time for the grant of the sanitary license. Most sanitary licenses for low-risk economic activities take 5 to 30 days to be issued, as well as high-risk licenses (up to 30 days), suggesting that simplified procedures are not being adopted for sanitary licensing of low-risk activities.

In this context, a better investigation of the reasons why the risk classification adopted by the municipalities does not translate into simplified procedures for the issuance of the sanitary license would be necessary. Anvisa's assessment of its role as coordinator of the SNVS is also appropriate, as provided for in Federal Law No. 9.782/1999², since the standard published by the Agency is widely known by local Visa agencies, but little applied in practice, with regard to simplifying procedures for licensing establishments that perform low-risk activities.

In addition to questions related to the classification of the degree of risk for economic activities subject to health surveillance, for licensing purposes, questions were also asked about the computerization of procedures and integration with Redesim.

Of the municipalities participating in the survey, 62.0% declared to proceed with the licensing with Visa through a computerized system, being distributed as follows: 43.0% in computerized systems at Visa branches; 13.0% on the Visa internet portal and 6.0% on the Redesim state integrator portal on the internet. Despite this, 91.0% personally guide the entrepreneur on the steps and requirements that must be met for sanitary licensing, at the municipal Visa service counters.

As for integration, only 20.2% of the municipal Visa agencies declared to be part of Redesim and 25.0% are unaware of it. In addition, Campinas/SP's Visa reported that in the state integrator module (Via Rápida Empresa - VRE) and Redesim it is only possible to register a legal entity, and the municipalities of the state of São Paulo also license economic activities of individuals, demonstrating the need to adapt Redesim to the reality of some Visa agencies. Another necessary adaptation is the possibility of renewing the sanitary licenses already granted.

Considering this, we found that most municipalities (62.0%) have a computerized system for licensing, indicating the automation of municipal visas. Despite this, the systems are only internal, considering that 91.0% of the guidelines are provided at Visa's service counters. This is another point that deserves the attention of SNVS entities since the wide automation of services can facilitate the simplification of procedures related to health licensing and make the interface with entrepreneurs seeking information to be regularized more agile and efficient.

Regarding the collection of fees, 74.0% of the municipal Visa agencies charge fees for the municipal sanitary licensing, which possibly will lead to a decrease in revenue with the publication of Provisional Measure n° 881, of April 30, 2019¹³, and subsequent sanction of Federal Law No. 13,874, of September 20, 2019¹⁴.

Federal Law No. 13,874/2019¹⁴ establishes the Declaration on the Rights of Economic Freedom, establishes free market guarantees, and changes other provisions. As provided in Article 3 of the Law:

They are the rights of every person, natural or legal, essential for the economic development and growth of the country, observing the provisions of the sole paragraph of Art. 170 of the Federal Constitution:



I - develop low-risk economic activity, for which it uses exclusively its own private property or consensual third parties, without the need for any public acts to release economic activity;

That is, economic activities considered to be low risk, under the terms of Federal Law no. 13,874/2019¹⁴ and complementary regulations CGSIM's Resolution no. 51, of June 11, 2009¹⁵, as amended by CGSIM's Resolution n° 57, of May 21, 2020¹⁶, are exempt from any public act of liberation for its execution, including sanitary license.

It is worth mentioning that the Law respects the autonomy of states, the Federal District, and municipalities since they should only follow federal risk classification rules if they do not have their own rules on the subject. Anyway, there was a change in the procedure to be adopted for low-risk activities, when compared to Anvisa's RDC n° 153/2017⁹ and to the existing state, district, and municipal regulations, since there will no longer be a sanitary license issue in these cases.

The publication of the Economic Freedom Act, as it is called, took some local Visa agencies by surprise, especially municipal ones, which are responsible for the health licensing of low-risk economic activities and will have to review their health surveillance and collection procedures.

As already manifested by some of them, the revision of the work process is fundamental and necessary, presenting its positive aspects for the efficiency of the State, in the search for innovation and greater qualification of the acts. In this sense, since the publication of Anvisa's RDC n° 153/2017⁹, discussions have been held regarding the exemption and agility of the inspection, information provision and document issuance processes by SNVS entities. However, such advances must be conducted in a way that does not compromise the ultimate goal of health surveillance action, which is health protection.

In view of the sanction of Federal Law No. 13,874/2019¹⁴, on September 1, 2020, Anvisa updated its legal regulations on the subject: Anvisa's RDC No. 418/2020 was published¹⁷, which amends Anvisa's RDC n° 153/2017⁹, and published NI n° 66/2020¹⁸, which revokes NI n° 16/2017¹⁰. These regulations follow the risk levels adopted in CGSIM's Resolution n° 57/2020¹⁶ and the relevant licensing procedures at each level.

The exemption of public acts for the release of economic activity does not prevent the performance of health surveillance, which will have to turn its efforts to post-market actions in the inspection of such establishments since the exemption of sanitary license does not release the entrepreneur from complying with the current legislation.

It should be noted that the State's police power, including Visa, can act by normative acts, as well as by administrative acts that consist of preventive measures (authorization, license, inspection, order, notification) or repressive measures (interdiction of activity, seizure of damaged goods, closure of establishment)¹⁹. Visa's regular exercise of police

powers justifies charging a fee for such execution²⁰, even in post-market actions.

At the end of the form, there was a descriptive field for comments and/or reports on the topic to be collected. In this field, 855 municipal Visa agencies expressed their opinion not only on sanitary licensing but in relation to all aspects of their work processes. The comments were categorized into observations (512), demands (265), praise (63), complaints (51), and suggestions (15).

In the "observations" category, additional information on the topic was sent that had not been included in the questionnaire prepared by ASNVs/Anvisa. As for the demands, the most frequent were the training needs on the topic: Anvisa's RDC n° 153/2017⁹ and/or Redesim in addition to other training on the subjects related to health surveillance.

The findings of this survey corroborate the view of Silva et al.²¹, who stressed that the decentralization of health surveillance actions is, in addition to a guiding principle, a strategy for strengthening it in the three government spheres. To be effective, it must be accompanied by financial resources, technical support, and management tools that are necessary to strengthen federated entities.

CONCLUSIONS

Anvisa's RDC n° 153/2017⁹ is widely known by the municipal Visa agencies. Despite this, a small portion of them adopts simplified procedures for granting the sanitary license for economic activities until then called low risk, in view of the procedures adopted and the average time spent in the health licensing of these, when compared to the average time spent for the concession health license for high-risk economic activities in the municipalities that do so. This shows that there is still much to be done in this simplification of procedures proportional to the health risks that economic activities potentially offer.

In addition, another relevant aspect is the collection of a fee for sanitary licensing by the municipal Visa agencies, considering the publication of Federal Law n° 13,874/2019¹⁴. Since the publication of the Economic Freedom Law, SNVS entities, especially municipal ones, are undergoing changes in their work process, in order to align themselves with the Law and maintain the ultimate goal of health surveillance action, which is the protection of health.

The state relevance in the coordination of municipal Visas was ratified, considering the training data and state regulations on the theme, which is an extremely positive point, considering a System composed of 5,570 municipalities²².

Anvisa, as SNVS coordinator, is responsible for articulating with the Federal Government and proposing programs that help articulate state, district, and municipal bodies, to promote the exchange of experiences, mutual cooperation, and strengthening of the SNVS.



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Author's Contributions

Costa AFDV - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Jorge DM - Analysis, data interpretation, and writing of the work. Donagema EA - Conception, planning (study design), and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.



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