


Productive inclusion with safety of small food producers: a look from the National Health Surveillance System

Inclusão produtiva com segurança sanitária de pequenos produtores na área de alimentos: um olhar a partir do Sistema Nacional de Vigilância Sanitária

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ABSTRACT

Introduction: In 2011, the National Health Surveillance Agency (Anvisa), with the purpose of strengthening the country's socioeconomic development actions, released the Sanitary Productive Inclusion Project (PIPSS) to support the sanitary regularization of microentrepreneurs who produce activities and services of health interest. **Objective:** To analyze the formulation stage context and the implementation process of the Project for Productive Inclusion with Safety (PIPSS), considering the food segment, within the scope of the National Health Surveillance System, from the launch of PIPSS, in June 2011, until three months after the project was transformed into a program, in June 2017. **Method:** A descriptive study with a qualitative approach was conducted. The primary data source was 6 interviews with Anvisa professionals and representatives of civil society organizations and, as secondary data source, documentary research (news and official documents) and consultation with the Management Report Support System (SARGSUS). Data collection was conducted from May to August 2017. **Results:** Relevant points of discussion such as the importance of social participation in the process of construction of RDC nº 49/2013 and the dissent among the actors responsible for implementing the actions were identified. Few actions related to productive Inclusion with safety in the three spheres of government were found, prevailing those of training for micro entrepreneurs or state and municipal health surveillance agents, mostly in the planning phase. **Conclusions:** These initiatives undertaken by health surveillance agents in partnership with different actors and institutions mean a lot to health promotion. The transformation of the Project into a Program is expected to tone partnerships, so that this debate reaches civil society and local institutions.

KEYWORDS: Health Surveillance; Productive Inclusion; Health Security; Foods

RESUMO

Introdução: Em 2011, a Agência Nacional de Vigilância Sanitária, com o intuito de fortalecer as ações de desenvolvimento socioeconômico do país, lançou o Projeto de Inclusão Produtiva com Segurança Sanitária (PIPSS), a fim de apoiar a regularização sanitária de microempreendedores que produzem atividades e serviços de interesse à saúde. **Objetivo:** Analisar o contexto da etapa de formulação e o processo de implementação do PIPSS, na área de alimentos, no âmbito do Sistema Nacional de Vigilância Sanitária, de 2011 - ano do lançamento do PIPSS - a junho de 2017, três meses após a transformação do projeto em programa. **Método:** Foi realizado um estudo descritivo, com abordagem qualitativa. Teve como fonte de dados primários seis entrevistas com profissionais da Anvisa e representantes de organizações da sociedade civil e, como fonte de dados secundários, pesquisa documental (notícias e documentos oficiais) e consulta ao Sistema de Apoio ao Relatório de Gestão. A coleta de dados se deu durante o período de maio a agosto de 2017. **Resultados:** Foram identificados relevantes pontos de discussão, como a importância da participação social no processo de construção da RDC nº 49/2013 e o dissenso entre os principais atores responsáveis pela implementação das ações voltadas ao tema da inclusão produtiva com segurança sanitária. Foram encontradas poucas ações, planejadas ou executadas, relacionadas ao tema nas três esferas do governo, das quais prevaleceram as de capacitação aos microempreendedores ou

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agentes de Vigilância Sanitária estaduais e municipais, predominantemente em fase de planejamento. **Conclusões:** É inegável o avanço que essas ações voltadas ao tema da inclusão produtiva com segurança sanitária, realizadas por agentes de Vigilância Sanitária em parceria com diferentes atores e instituições, significam para a promoção da saúde. Espera-se que a transformação do Projeto em Programa tonifique as parcerias para que este debate alcance a sociedade civil e os órgãos locais.

PALAVRAS-CHAVE: Vigilância Sanitária; Inclusão Produtiva; Segurança Sanitária; Alimentos

INTRODUCTION

Brazil's National Health Surveillance System (SNVS) is linked to the Unified Health System (SUS) and acts in a decentralized and integrated manner throughout the Brazilian territory, sharing its responsibilities between the three levels of government: federal, state and municipal. The National Health Surveillance Agency (Anvisa) is responsible for coordinating health activities at the federal level, providing financial, technical, executive and monitoring support for health surveillance policies and initiatives from other levels of government¹.

The SNVS has a multidisciplinary and cross-sector nature. Several sectors of civil society and government interact to carry out health surveillance initiatives, since some are the responsibility of more than one agency, either internal or external to the SUS². More recently, Anvisa has sought to reach small enterprises with inclusive and sustainable promotion initiatives. In this landscape, several public policies - which often overlap - aim to support part of the population in their entrepreneurship initiatives³.

In 2011, the *Brasil sem Miséria Plan* (PBSM) - coordinated by the Ministry of Social Development (MDS) - was launched with the objective of improving conditions of poverty and extreme poverty throughout the Brazilian territory. One of its strategies, the "productive inclusion" track, intended to increase the capacity and the opportunity for work and income generation among the poorest families in urban and rural areas⁴.

On that note, Anvisa made a commitment to integrating itself into the PBSM initiatives, adding the Health Safety term to the Productive Inclusion track, and launched the Productive Inclusion with Health Safety project (PIPSS) in 2011. The project aimed to support socioeconomic development initiatives in Brazil by supporting categories of enterprises that were not addressed by the SNVS and helping them formalize their economic activities and enter the formal market with health safety⁵. These enterprises are individual microentrepreneurs (MEI); self-employed workers with up to one hired employee; family farmers (AF); people who work in rural areas and predominantly use their own family labor; and solidarity economic entrepreneurs (EES), organizations of an associative nature. These undertakings are characterized within the respective legislation, Complementary Law 128, of December 19, 2008⁶, Law n. 11.326, of July 24, 2006⁷ and Decree n. 7.358, of November 17, 2010⁸.

Anvisa's Collegiate Board Resolution (RDC) n. 49, of October 31, 2013⁹, was the first normative instrument that resulted from the PIPSS. It provided for the regularization of activities of health

interest in the aforementioned enterprises. One of its principles is the need for an informative approach to health surveillance with regard to the customs of small-scale production, that is, adapting health requirements without undermining the traditional/craft knowledge of small producers⁵.

Among the areas of coverage and health interest in which health surveillance operates, there is the food area, with regulatory actions from production to marketing¹⁰. However, despite the progress in the field of food health surveillance and its importance for the promotion and protection of the population's health, health standards in the area of food in Brazil and the practices of health surveillance agents are predominantly guided by international standards aimed at large-scale manufacturers, that is, these requirements do not always fit with the small-scale context and raise barriers to the regularization and entry of craft/traditional food into the formal and institutional market^{11,12,13}.

By recognizing Anvisa's effort to include these entrepreneurs who work in the informal sector, the impact of these initiatives for health promotion and the scarce studies that address the topic, the objective of this study was to analyze the context of the formulation stage and the process of implementing the PIPSS in the area of food, within the scope of the SNVS, from 2011 to June 2017.

METHOD

This is a descriptive study, with a qualitative approach. Primary data came from a semi-structured interview with six key respondents, who were selected due to their solid knowledge on the topic and their participation in the process of design and conduction of the initiatives. Three Anvisa professionals and three representatives of civil society organizations were interviewed. These organizations were the Society, Population and Nature Institute (ISPN), the Brazilian Forum on Sovereignty and Food and Nutrition Safety (FBSSAN) and the Slow Food Brazil movement. The interviews were aimed at giving us a better understanding of the incentives in the design stage and the conflicts and challenges of the policy implementation process among the main players.

Secondary data were intended to explore the development of the implementation process at the three levels of government. They were obtained through the online search for news on the topic, between October 2013 and June 2017, with the help of



the following descriptor: “*inclusão produtiva com segurança sanitária and alimentosa*” (productive inclusion with health and food safety) or directly on the state or municipal health surveillance websites, with the same descriptor. In addition to the news, we searched for initiatives in documents, reports, standards or materials related to the topic: 1) Anvisa’s website; 2) SUS Management Report Support System platform (SARGSUS) - based on state health plans (PES) and municipal health plans (PMS), the annual health program (PAS) and annual management reports (RAG) from all states and capital cities from 2014 to 2019; and 3) website of the Brazilian Micro and Small Business Support Service (Sebrae) - Entrepreneur Mayor - based on the list of awarded projects in the Productive Inclusion with Health Safety category in 2016.

Article 19 of RDC n. 49/2013⁹ determines that health surveillance bodies prepare their work plans and initiatives within the scope of SUS management instruments: plans, annual schedules and health management reports. Thus, the search for these actions in the documents available on the SARGSUS platform is justified, since this is the main tool for monitoring health management in municipalities, states, Federal District and Union. On this platform, six documents per state were selected for the research: 2015 and 2016 RAG, 2016-2019 PES, and 2015, 2016 and 2017 PAS. 36 documents were not analyzed, out of a total of 162, because they were not available on the platform in June 2017. Six documents were selected for the research for each capital city: the 2015-2016 RAG, the 2014-2017 PMS and the 2015-2017 PAS. 40 documents were not analyzed, out of a total of 156, because they were not available on the platform in July 2017. The results in these documents have some limitations regarding the absence of documents available on the SARGSUS platform and the possibility that states or municipalities carried out initiatives without reporting them in any document.

The theoretical framework for the analysis of public policy cycles contributed to the understanding of the stages of a policy, its interrelations, incentives, negotiations between stakeholders and the various influences that play out in this process. Based on this theoretical framework, we could emphasize the stages of the PIPSS that would be analyzed, the context of the formulation stage and the implementation process of the initiatives and guide the data analysis process¹⁴. All data collected were analyzed according to the content analysis methodology proposed by Bardin¹⁵.

The research was approved by the Ethics Committee under number: CAAE 67281517.0.0000.5240 in June 2017.

RESULTS AND DISCUSSION

Paths and challenges, from the project design to the implementation process of the PRAISSAN

The collected data enabled us to understand the trajectory and incentives for the creation of the PIPSS and its main developments: RDC n. 49/2013⁹ and the Program for Productive Inclusion and Health Safety (PRAISSAN), launched in 2017, which

will be presented below. We could also identify the main factors and challenges involved in this process: the importance of cross-sector approaches and the challenge of dissent among the players in charge of the implementation. Furthermore, from the exploration of the productive inclusion with health safety initiatives already conducted or in the planning phase, we could identify which initiatives are in progress, what players and institutions are involved and how the process can be improved.

From the analysis of the data, we identified some thematic categories related to our research objective. Four main categories are described below.

The first category related to Productive Inclusion with Health Safety in the SNVS - “Anvisa in line with public policies of the State and society’s demands” - points out two main incentives for the Project. The first is the existence of a favorable political context outside Anvisa that enabled it to work in line with the State’s public policies. Therefore, in 2011, a period in which social public policies and actions were on the rise in Brazil, Anvisa decided to link its actions to the PBSM productive inclusion track, starting with the launch of the PIPSS. “[...] Anvisa’s political option to get involved, to align with the Brazilian government’s project” (key respondent A, Anvisa professional). For this, the institution invited a professional with a background in the social area to join the team and encourage discussion with other players.

Several initiatives aimed at strengthening family farming, like the Food Acquisition Program (PAA) and the National School Meal Program (PNAE) - which, since 2009, determines that the acquisition of at least 30% of the food for school meals come from family farming - depend on the work of health surveillance to enable these products to enter the institutional market, because, without the health regulation of these products, they cannot participate in procurement bids^{16,17}. “[...] as it was, the health issue was a barrier for these products in the institutional market” (Key Respondent D, representative of civil society).

Therefore, the second incentive refers to a strategy to respond to the demand of society and the pressure made by representatives of organizations and entities of civil society. These organizations published several open letters and held many meetings in defense of craft food produced by traditional communities and family farmers. The agenda of the debate questioned the industrial logic of Brazilian health standards in force in the area of food and its requirements, mainly physical and structural, which are not compatible with the small-scale food production system. In addition, they criticized the failure to recognize the cultural practices of traditional production of these food products, such as the use of tools that do not meet some current health quality standards.

The unprecedented opening of the institutional market for the procurement of family farming products, based on the PAA and the changes in the PNAE, strengthened the production and consumption of several food products at the local level, in addition to the recognition of farmers as stakeholders in this process.



These measures reinforce the role of the State not only as a regulator, but as a participant in the construction of an alternative market through the procurement of these food products to supply public services. However, some complementary policies to the procurement of these products are necessary due to the various weaknesses of these producers with regard to supply logistics, accounting and notarial expertise, among others¹⁸.

The second category, “Social participation: shared construction of the standard and initiative implementation”, highlighted social participation and its importance in the fulfillment of RDC n. 49/2013⁹ and in the initiative implementation process.

In 2012, with the assumption that processed food from craft, family and community producers struggles to formalize and adapt to current health standards, the ISPN, the Slow Food Movement, the Marist Institute of Solidarity (IMS) and the National Union of Cooperatives of Family Agriculture and Solidarity Economy (UNICAFES) held a workshop, between September 26 and 28, 2012, with the participation and presence of civil society organizations, craft producers and officials from the executive and legislative branches, among which there were some Anvisa professionals¹⁹.

This workshop enabled social entities and organizations to get closer to Anvisa professionals who were in charge of the project. Therefore, before a Work Group (WG) was created at Anvisa with members representing civil society, Anvisa professionals became familiar with the demands and issues brought up by social movements. This exchange of knowledge enabled the collective construction of a legal instrument, RDC n. 49/2013⁹. “[...] Anvisa did not build this standard alone [...]” (key respondent E, representative of civil society).

The collective construction of the standard was also possible because of the debate promoted by Anvisa through various presentations, meetings, public hearings and seminars in several Brazilian regions, states and municipalities²⁰. Only after this comprehensive debate was the standard submitted to Public Inquiry n. 37/2013, with contributions and the participation of 16 Brazilian states.

It is worth mentioning that the standard was approved by the Anvisa Collegiate Board with broad participation of players from the SNVS, social movements and partner institutions, in a public meeting held at the VI Brazilian Symposium on Health Surveillance (SIMBRAVISA), in Porto Alegre, Rio Grande do Sul²⁰.

As a proposal to expand social participation, in 2014, a WG was created by Anvisa and coordinated by Anvisa’s Articulation and Institutional Relations Advisory (ASREL) to discuss measures that integrated PIPSS initiatives²⁰. The WG held bimonthly meetings and was composed of members of Anvisa and representatives of civil society, with the participation of agents from state and municipal health surveillance bodies and members of other government agencies and partner institutions, as guests.

A significant change in this process was the establishment of the PRAISSAN, published in MS Ordinance n. 523, of March 29,

2017²¹, with the objective of reinforcing the PIPSS strategies and improving the work done by the SNVS. That same Ordinance established, within the scope of the SNVS, the Committee for the Productive Inclusion and Health Safety Program (CISSAN), of an advisory nature, which provided for the representation of members of civil society entities²¹. The purpose was for the WG’s discussions to continue after the definition of the Committee’s members. Until March 2019, this Committee had not been established yet.

Other important steps were the publication of Anvisa RDC n. 153²², on April 26, 2017, which provides for the classification of the degree of risk of economic activities subject to health surveillance, and also Normative Instruction (IN) n. 16, April 27, 2017²³, which established the list of National Classification of Economic Activities (CNAE) subject to health surveillance, sorted by degree of risk and dependent on information for the purposes of health licensing. These publications aim to guide the work process of the Health Surveillance teams and support greater focus on activities that pose high health risk^{22,23}.

However, according to representatives of civil society, although the classification of the degree of risk of the activities done by microentrepreneurs was discussed by the players during the Anvisa WG meetings, the publication of RDC n. 153/2017²² did not have direct social participation like RDC n. 49/2013⁹ did. Somehow, as reported by one of our key respondents, these questions were incorporated into the regulations and some activities carried out by small food producers were considered to be of low risk.

Health surveillance is a space for the exercise of citizenship and social control, since it changes the quality of products, processes and social relations based on interdisciplinary and interinstitutional action²⁴. Society should not be seen only as a validator of the final results, but as being formed by players that strengthen the Agency’s work through participation in all stages of the regulation. Anvisa has made some progress in the transparency of its work, but it still has to improve the instruments and forms of social participation in this process²⁵.

It is interesting to point out that, with regard to the target of the regulation, social movements and Anvisa pay more attention to initiatives aimed at family farming and solidarity economy enterprises, whereas Sebrae and the National Front of Mayors (FNP) have been steady partners ever since the launch of the PIPSS and act primarily in the support to individual microentrepreneurs.

Sebrae works together with the federal government to support entrepreneurship initiatives, especially in less developed urban or rural areas²⁶. For Anvisa professionals, Sebrae plays an important role in these initiatives, not only with funds but also because it is a strategic and pervasive sector that can add this topic to the government’s agenda through the mobilization of several stakeholders that are already engaged with it.



As for civil society representatives, there is a concern that the initiatives emphasize only the MEI. Therefore, some discussions focus more on family farming and solidarity economy (more rural areas) and another approach is geared toward the MEI (more urban areas). “[...] Sebrae has a business-oriented vision, and the logic of smallholders and family farmers is not always that” (key respondent F, representative of civil society).

The third category - “Concept of health risk: culture, traditional knowledge and good practices” - is related to the need to contextualize health risk on a case-by-case basis in small-scale food production and the task of balancing the procedures employed by health surveillance to maintain the health safety of products, “good practices” alongside the practices of these traditional cultures and knowledge. Brazil is home to heterogeneous peoples and cultures. This results in a wide variety of food products that bear the characteristics and customs of each region. Some food products, like craft cheese from the mountains of Minas Gerais and *acarajé* from Bahia, are recognized as cultural heritage by the National Historical and Artistic Heritage Institute, listed in the Knowledge Registry Book²⁷.

In this way, RDC n. 49/2013⁹ has made some progress in respecting the customs of small producers, as mentioned in item V of the 5th article, which says that the initiatives must consider the “protection of craft production in order to preserve traditional customs, habits and knowledge in the perspective of the multiculturalism of peoples, traditional communities and family farmers”.

As exemplified in the guidance booklet on the regulations, transferring the production of *acarajé* marketed outdoors to a closed environment with industrial characteristics is not recommended. This modification would impair the cultural practice of marketing these products in public squares. Thus, some adaptations are necessary, such as careful hygiene of the utensils, good practices for handling food outdoors, storage of ingredients in coolers or closed containers depending on the product, that is, measures that provide health safety for the product and yet conserve the cultural tradition of this practice^{5,28}. “[...] You can adopt good practices, good concepts and techniques even in craft production” (key respondent A, Anvisa professional).

It is interesting to note that RDC n. 49/2013⁹ intends to reinforce the guiding role of the Health Surveillance agent to these undertakings and that the regulation is based on case-by-case health risk assessment. Article 11 of the regulation says that health risk must be considered and that inspection will not be permissive, it will use discretion and guide adjustments according to the economic, social and cultural reality of each entrepreneur. The principle is to change the perception that health surveillance acts only in a police-like and punitive manner and make it be perceived as an advisor to assist in the health regularization of these enterprises.

Still on RDC n. 49/2013, among its guidelines, item VI stands out: “reasonableness regarding the applied requirements”, meaning

common sense to carry out consistent and suitable initiatives to achieve the objectives proposed, like the example of *acarajé* marketed outdoors⁵.

Reasonableness is an indeterminate legal concept that is elastic and variable in time and space. It consists of acting with sensibility, prudence, moderation, taking appropriate and consistent actions, considering the proportional relationship between the means employed and the purpose to be achieved, as well as the circumstances surrounding the action²⁹.

The use of reasonableness toward small-scale food production is debated by representatives of civil society, since, according to them, health risk assessment initiatives are merely focused on the application of check lists to assess good practices in facilities that manufacture or sell food. These initiatives often disregard the broader quality of a product and focus only on its biological risk, based on structural requirements such as the use of certain tools or equipment.

According to Prezotto³⁰, broad quality means considering the ecological, social, appearance and cultural aspects of a product. Good food is not only represented by its health conditions through questions: is it harmful or not? All aspects and factors that affect the production chain and product quality are evaluated³⁰. “[...] quality is built socially, for example, I can value trust as an attribute of quality, it is the trust in knowing who made it, so it is different [...]” (key respondent D, representative of civil society).

Cruz³¹, in her thesis on the quality of production and consumption of traditional food, especially mountain cheese traditionally produced in the highlands of the state of Rio Grande do Sul, concluded that the health standards do not consider the cultural practices involved in the production of these products and apply hygiene procedures based only on physical characteristics, the layout of the environment. In the case of mountain cheese, her analysis concluded that, even when the production did not meet all the health requirements in force, like the use of stainless steel utensils only, the producers had hygiene criteria in each stage of production that they defined as meticulous care and cleaning throughout the process³¹.

The fourth emerging category, “Dissent in the SNVS regarding the principles of the Program for productive inclusion with health safety”, addresses the existence of some dissent among health surveillance players regarding the principles of the current PRAISSAN Project, especially when it comes to the concept of reasonableness.

The discussion on risks, quality and reasonableness of the requirements applied to small-scale food production generated some controversy about the PRAISSAN principles among the agents of the SNVS itself. Especially during the draft of the regulation and its presentation, some health surveillance agents were concerned that these initiative would make health risk a more flexible concept and said this approach had a political



vision of social inclusion that is not necessarily related to the work of health surveillance.

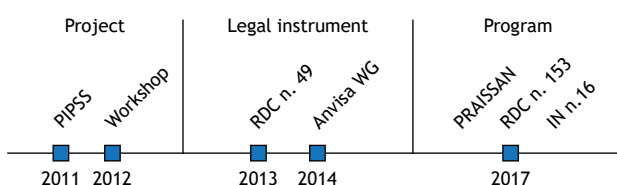
The need to contextualize what health risk is in the context of small-scale food production and to guide hygiene adaptations with reasonableness, as proposed by the PRAISSAN, is still a challenge, especially considering that these enterprises had very little significance in the field of health surveillance until recently. “[...] if you read the RDC, it does not say that that regularizing is mandatory, it only says that we should regularize enterprises that follow good practices, that is basically the issue” (key respondent A, Anvisa professional).

Even so, in the field of action of the SUS and pursuant to its guidelines, health surveillance must always strike a balance and promote health as expected when regularizing these enterprises. “[...] turning a blind eye to them means depriving the population that consumes these products from health surveillance, and this is not fair from the point of view of their social right to health” (key respondent A, Anvisa professional).

Viana³² analyzed the perception of the stakeholders in the public inquiry of RDC n. 49/2013. The group that partially agreed with the proposal believed that we must respect the small scale of these producers by applying the principle of reasonableness as a guide, whereas the opposing group expected negative impact or no impact at all, since they believed that this change in health surveillance would be for the worse and imply “turning a blind eye to irregularities” to “take social action” to the detriment of health³².

Some health surveillance agents argue that this regulation brings technical and legal insecurity to their work, since assessing the health risk in every context requires vast knowledge about the health risks of each product. Furthermore, the players struggle to act with reasonableness in contexts not provided for in health codes or in instruments like check lists, since any occurrence that is harmful to the health of the population is the responsibility of the health surveillance professional.

In summary, the Figure shows three highlights of the process of building productive inclusion initiatives with health safety since the launch of the project in 2011 and its main developments until 2017, which were described throughout the text.



Source: Prepared by the authors, 2017.

PIPSS: Productive Inclusion with Health Safety Project;
RDC: Resolution of the Anvisa Board of Directors; WG: Work Group;
PRAISSAN: Program for Productive Inclusion and Health Safety;
IN: Normative Instruction.

Figure. Main highlights and published standards related to the creation of Anvisa's Productive Inclusion with Health Safety Project by March 2017. Brazil, 2011 to 2017.

The second part of the research aimed to identify the implementation process of the initiatives based on documentary analysis of reports available on the SARGSUS platform, news available online and projects awarded by Sebrae in 2016 related to the topic. The identified initiatives are described below.

SNVS initiatives in relation to the PIPSS: initiatives aimed at the health regularization of entrepreneurs with an emphasis on the food area

Chart 1 presents the description of the initiatives related to productive inclusion with health safety found in the plans, health programs and annual management reports of the Brazilian states and their capitals available on the SARGSUS platform.

Only seven states and two capital cities had described initiatives in this area, that is, few initiatives were found in these instruments despite the recommendation of article 19 of RDC n. 49/2013⁹. Most state initiatives were in the planning stage and identified in documents from 2015 and 2016. As for the initiatives that came about, only the state of Maranhão registered two training sessions on RDC n. 49/2013 in 2016 and the state of Espírito Santo mentioned the revision of a standard related to the topic in 2015. In relation to the capital cities, only planned actions were found, as in the city of Palmas, Tocantins, which provided for PMS courses on good practices for micro-entrepreneurs of food and beauty salons.

All state or municipal initiatives identified in the SUS management documents available on the SARGSUS platform were described objectively without further detail on their conduction. As for the type of initiative, most of them concern the training of health surveillance agents or enterprises or the draft of complementary legislation that is in line with the principles of RDC n. 49/2013⁹.

The search for initiatives related to the topic from an online search engine found only three ordinances/resolutions that considered RDC n. 49/2013. These regulations were published by the State Departments of Health of the states of Piauí and Espírito Santo in 2015 and Paraná in 2017. These standards are intended to regulate health regularization initiatives for micro-enterprises in activities of interest to health in accordance with the principles of RDC n. 49/2013. Considering that each region has its cultural characteristics and other factors that interfere in the type of production of these food items, it is important that each state or municipality creates support tools to guide the work of health surveillance, since RDC n. 49/2013 itself highlights the importance of health risk assessment on a case-by-case basis.

The search for initiatives in online news and projects awarded by Sebrae related to the topic found 65 initiatives. The search pointed out that most of the state or municipal initiatives were prepared as from 2015, which corroborates with the initiatives found in the documents available in the SARGSUS system that say that these initiatives are recent and have been improved over the last two years. Chart 2 summarizes the information found online.



Chart 1. Initiatives related to productive inclusion with health safety described in the documents available on SARGSUS, by state and municipality, 2014 to 2017.

Planned initiatives described in documents	
State	
ES	2015 goal: to design a technical standard for productive inclusion with health safety; 2017 goal: to revise Ordinance n. 32/2015 and risk classification of services of interest to health.
GO	2016 goal: to design the Program for Productive Inclusion with Health Safety; to qualify microentrepreneurs in priority municipalities in partnership with Sebrae.
MA	2015 goal: to implement RDC n. 49/2013 in the state with the training of municipal health surveillance bodies on the licensing of MEI, AF, EES; 2016 goal: to contribute to the fulfillment of RDC n. 49/2013 through training (Expected target: 7; Accomplished: 2); to hire a company to provide training.
MS	2016 goal: creation and distribution of graphic material for training and guidance of health surveillance teams - integrated with Inmetro; formulation of complementary legislation: risk classification of MEI activities; 1 st exhibition of successful experiences with a view to awarding ten municipalities for projects done by health surveillance to help regularize microentrepreneurs.
PB	2017 goal: good practice workshops for food producers in the solidarity economy in three municipalities.
PI	2016 goal: training of technicians from municipal health surveillance bodies on good practices in food manufacturing and marketing and productive inclusion.
TO	2016: participation in event in Brasília/DF: meeting about risk classification for health licensing and workshop on success cases.
Capital cities	
Palmas - TO	2014-2017 goal: training on good handling practices for micro-entrepreneurs in the food trade and beauty salons; training on health risk for health surveillance inspectors.
Florianópolis - SC	2016 goal: to implement a health safety operation with productive inclusion by the health surveillance department.

Source: Prepared by the authors, 2017.

RDC: Resolution of the Anvisa Board of Directors; MEI: individual microentrepreneur; AF: rural family farmer; EES: solidary economic entrepreneur; SEBRAE: Brazilian Micro and Small Business Support Service; Inmetro: National Institute of Metrology, Quality and Technology.

In addition to the SNVS players themselves, some of the most frequent partnerships in these initiatives were with Sebrae consultants. A highlight of this participation is the award known as the “Entrepreneur Mayor Award”, launched by Sebrae in an effort to recognize the administrative performance of public managers in the promotion of small businesses. The creation of the “Productive Inclusion with Health Safety” category, encouraged by Anvisa, awarded 16 projects related to the topic in 2016.

In summary, regarding the initiatives conducted directly for microentrepreneurs in the food area, we identified the frequency of training in good hygiene and food handling practices. Nevertheless, the question asked by one of the key respondents remains: “What kind of training do we want?” (key respondent C, Anvisa professional) mentions the need to evaluate the content of these activities, since most of these courses focus on the principles of RDC n. 216, of September 15, 2004³³, a standard that regulates referenced procedures for food services on a larger scale.

Therefore, it is necessary to verify to what extent these training programs adopt the recommendations of a guiding approach that respects cultural practices in the production of food by small producers in accordance with the principles of the PRAIS-SAN. In addition, strategies other than training are necessary to strengthen these initiatives.

CONCLUSIONS

We must highlight the importance of social participation in this process and the role of the players who are or have been at the forefront of this initiative at Anvisa, which since

2011 opened the discussion for representatives of civil society organizations and other stakeholders in various spaces. The value of this participation should be recognized, because

Chart 2. Synthesis of the types of initiatives, stakeholders and partnerships involved in initiatives of productive inclusion with health safety carried out by the three levels of government. Brazil, 2017.

Types of initiatives
Workshops, seminars, training, lectures, courses or meetings on the principles of RDC n. 49/2013 and/or risk classification of the activities carried out by these enterprises offered to state or municipal health surveillance teams and/or small producers; preparation of booklets on the topic; training on good practices for food entrepreneurs; simplification of health licensing processes; review and amendment to the standards of health surveillance bodies; visits and guiding inspections to entrepreneurs; registration of entrepreneurs; increase in the number of entrepreneurs (rural family farmers) that sell directly to PNAE/PAA; seal of health inspection to the products of these entrepreneurs.
Stakeholders and partnerships
Professionals from the National Health Surveillance System, consultants from Sebrae and the S system, professionals from the state or municipal departments of Agriculture, Environment, Health, Health Surveillance, Economic Development, Municipal Councils and other sectors of the city administration and representatives of civil society organizations.
Regions
11 states: Roraima, Tocantins, Maranhão, Rio Grande do Norte, Paraíba, Sergipe, Goiás, Mato Grosso do Sul, Minas Gerais, Paraná, Santa Catarina. 22 municipalities: Ananindeua (PA), Araguaína (TO), João Lisboa (MA), Água Branca (PI), Ilhéus (BA), Milhã (CE), Sítio Novo (RN), Sossêgo (PB), Garanhuns (PE), Aquidauana (MS), Bodoquena (MS), Uberaba (MG), Paracatu (MG), Serra (ES), Socorro (SP), Trajano de Moraes (RJ), Rio de Janeiro (RJ), Campos dos Goytacazes (RJ), Laranjeiras do Sul (PR), Pinhais (PR), Parobé (RS) and Porto Alegre (RS).

Source: Prepared by the authors, 2017.

RDC: Resolution of the Board of Directors; PNAE: National School Meal Program; PAA: Food Acquisition Program; SEBRAE: Brazilian Micro and Small Business Support Service.



these initiatives involve a series of partnerships and multiple stakeholders, many of them inserted in these organizations. In addition, mapping these enterprises and learning more about the local reality of each region requires time and conversation with various segments, and this will only be possible with continuing social participation.

Perhaps the most important challenge is how to deal with dissent among the players responsible for the implementation process of these initiatives. This dissent comes from the debate about what is health risk in the small-scale food context and how to use the concept of reasonableness without loosening the health risk of these products. It is necessary to contextualize the health risk assessment on a case-by-case basis and to understand the various dimensions of quality at each stage of the production of these products, as well as to balance the hygiene criteria according to the economic, social and cultural reality of these enterprises.

Promoting productive inclusion with health safety for small food producers is a difficult task and should not be the responsibility of health surveillance agents alone, since it involves factors that add complexity to the process. Cross-sector policies and players are necessary to enable these initiatives, however, we must overcome the controversy between SNVS players and build a partnership between the main players in charge of the implementation.

The importance of these initiatives for the promotion of health is undeniable, based on the guarantee of health, food and nutritional safety for the population and the socio-productive inclusion of producers. Therefore, we should encourage the creation of state or municipal committees on the topic, as proposed by the PRAISSAN, so that this debate can reach civil society, different stakeholders and local bodies. This can enable initiatives that meet the needs of each region, since the health risk debate must consider quality, flavors, know-how and the various factors involved in small-scale food production.

REFERENCES

1. Costa EA, organizador. Vigilância sanitária: temas para debate. Salvador: Universidade Federal da Bahia; 2009.
2. Seta MH, Reis LGC, Delamarque E. Gestão da vigilância à saúde. 3a ed rev atual. Florianópolis: Universidade Federal de Santa Catarina; 2014, (Especialização em gestão em saúde).
3. Mizutani LC. A Anvisa e a regulação nas políticas públicas: o fomento dos pequenos empreendimentos. Brasília: Agência Nacional de Vigilância Sanitária; 2015.
4. Ministério do Desenvolvimento Social e Combate à Fome (BR). Brasil sem miséria. Brasília: Ministério do Desenvolvimento Social e Combate à Fome; 2015[acesso 14 out 2016]. Disponível em <http://www.brasilemmiseria.gov.br/>
5. Agência Nacional de Vigilância Sanitária - Anvisa. Cartilha sobre inclusão produtiva com segurança sanitária: orientação para gestores de políticas públicas municipais e trabalhadores da vigilância sanitária. Brasília: Agência Nacional de Vigilância Sanitária; 2014.
6. Brasil. Lei complementar N° 128, de 19 de dezembro de 2008. Altera a lei complementar N° 123, de 14 de dezembro de 2006, altera as leis N° 8.212, de 24 de julho de 1991, 8.213, de 24 de julho de 1991, 10.406, de 10 de janeiro de 2002 Código Civil, 8.029, de 12 de abril de 1990, e dá outras providências. Diário Oficial União. 22 dez 2008.
7. Brasil. Lei N° 11.326, de 24 de julho de 2006. Estabelece as diretrizes para a formulação da política nacional da agricultura familiar e empreendimentos familiares rurais. Diário Oficial União. 25 jul 2006.
8. Brasil. Decreto N° 7.358, de 17 de novembro de 2010. Institui o sistema nacional do comércio justo e solidário SCJS, cria sua comissão gestora nacional, e dá outras providências. Diário Oficial União. 18 nov 2010.
9. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC N° 49, de 31 de outubro de 2013. Dispõe sobre a regularização para o exercício de atividade de interesse sanitário do microempreendedor individual, do empreendimento familiar rural e do empreendimento econômico solidário e dá outras providências. Diário Oficial União. 1 nov 2013.
10. Agência Nacional de Vigilância Sanitária - Anvisa. Relatório anual de atividades de 2006. Brasília: Agência Nacional de Vigilância Sanitária; 2007.
11. Cruz FT, Schneider S. Qualidade dos alimentos, escalas de produção e valorização de produtos tradicionais. Rev Bras Agroec. 2010;5(2):22-38.
12. Cintrão RP. Comida, vigilância sanitária e patrimônio cultural: conflitos e contradições entre políticas públicas. In: Anais do 1° Seminário sobre Alimentos e manifestações culturais tradicionais. São Cristóvão: Universidade Federal de Sergipe; 2012.
13. Viana CE, Triches R. Os conflitos com normativas sanitárias: um debate sobre as diferentes faces da qualidade dos alimentos. In: Anais do 5° Simpósio de Segurança Alimentar Alimentação e Saúde. Bento Gonçalves: Universidade Federal do Rio Grande do Sul; 2015.
14. Baptista TWF, Rezende M. A ideia de ciclo na análise de políticas públicas. In: Mattos, RA, Baptista TWF, organizadores. Caminhos para análise das políticas de saúde. Porto Alegre: Rede Unida; 2015. p. 221-72.
15. Bardin L. Análise de conteúdo. Lisboa: 70; 2010.
16. Ministério do Desenvolvimento Social (BR). Cartilha sobre o programa de aquisição de alimentos da agricultura familiar: renda para quem produz e comida na mesa de quem precisa! Brasil: Ministério do Desenvolvimento Social; 2010.
17. Brasil. Lei N° 11.947, de 16 de junho de 2009. Dispõe sobre o atendimento da alimentação escolar e outras providências. Diário Oficial da União. 17 jun 2009.



18. Perez-Cassarino J, Michelato A, Triches R, Porto S. A promoção da soberania e segurança alimentar e nutricional (SSAN) por meio do mercado institucional: a experiência brasileira. In: Bezerras I, Perez-cassarino J. Soberania alimentar (Sobal) e segurança alimentar e nutricional (SAN) na América Latina e Caribe. Curitiba: Universidade Federal do Paraná; 2016. p. 223-46.
19. Instituto Sociedade População e Natureza - ISPN. Relatório final da oficina normas sanitárias para alimentos de produção artesanal, familiar e comunitária. Brasília: Instituto Sociedade População e Natureza; 2012.
20. Agência Nacional de Vigilância Sanitária - Anvisa. Proposta para transformação do projeto inclusão produtiva com segurança sanitária em programa: grupo de trabalho da Portaria 1.346/14. Brasília: Agência Nacional de Vigilância Sanitária; 2015.
21. Agência Nacional de Vigilância Sanitária - Anvisa. Portaria Nº 523, de 29 de março de 2017. Institui o programa para inclusão produtiva e segurança sanitária (Praisson). Diário Oficial União. 30 mar 2017.
22. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução Nº 153, de 26 de abril de 2017. Dispõe sobre a classificação do grau de risco para as atividades econômicas sujeitas à vigilância sanitária, para fins de licenciamento, e dá outras providências. Diário Oficial União. 27 abr 2017.
23. Agência Nacional de Vigilância Sanitária - Anvisa. Instrução normativa Nº 16, de 26 de abril de 2017. Dispõe sobre a lista de classificação nacional de atividades econômicas CNAE classificadas por grau de risco para fins de licenciamento sanitário. Diário Oficial União. 27 abr 2017.
24. Lucchese G. Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil [tese]. Rio de Janeiro: Fundação Oswaldo Cruz; 2001.
25. Miranda AMB. Transparência na gestão da Anvisa: uma análise dos espaços de participação social [dissertação]. Recife: Fundação Oswaldo Cruz; 2010.
26. Serviço de Apoio às Micro e Pequenas Empresas - Sebrae. Home page. Brasília: Serviço de Apoio às Micro e Pequenas Empresas; 2018[acesso 12 dez 2018]. Disponível em <http://www.sebrae.com.br>
27. Santili J. O reconhecimento de comidas, saberes e práticas alimentares como patrimônio cultural imaterial. Demetra Alim Nutr Saude. 2015;10(3):585-606.
28. Agência Nacional de Vigilância Sanitária - Anvisa. Cartilha sobre inclusão produtiva com segurança sanitária: orientação para os empreendedores: para microempreendedores individuais, empreendimentos de economia solidária e da agricultura familiar. Brasília: Agência Nacional de Vigilância Sanitária; 2014.
29. Resende AJC. O princípio da razoabilidade dos atos do poder público. Rev Legis. 1999;(26):55-8.
30. Prezotto L. Qualidade ampla: referência para a pequena agroindústria rural inserida numa proposta de desenvolvimento regional descentralizado. In: Lima DA, Wilkinson J. Inovação nas tradições da agricultura familiar. Brasília: Conselho Nacional de Desenvolvimento Científico e Tecnológico; 2002. p. 285-300.
31. Cruz FT. Produtores, consumidores e valorização de produtos tradicionais: um estudo sobre qualidade de alimentos a partir do caso do queijo serrano dos Campos de Cima da Serra, RS [tese]. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2012.
32. Viana CL. Inclusão produtiva com segurança sanitária: uma análise crítica da percepção dos atores sociais sobre os possíveis impactos da RDC Nº 49 publicada em 2013 pela Anvisa [dissertação]. São Paulo: Universidade de São Paulo; 2017.
33. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução Nº 216, de 15 de setembro de 2004. Dispõe sobre Regulamento Técnico de Boas Práticas para Serviços de Alimentação. Diário Oficial União. 16 set 2004.

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Authors' Contribution

Hunger R - Acquisition, analysis, interpretation of data and writing of the paper. Pepe VLE, Reis LGC - Writing of the paper. All authors approved the final draft of the paper.

Conflict of interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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