ARTICLE
https://doi.org/10.22239/2317-269X.02139

The Program for Productive Inclusion and Health Security (PRAISSAN): between the reasonableness of health requirements and the cultural traditions of family farming

O Programa para Inclusão Produtiva e Segurança Sanitária (PRAISSAN): entre a razoabilidade das exigências sanitárias e a tradição cultural da agricultura familiar

Raquel Hunger*

Rosana Magalhães

Delaine Martins Costa

Programa de Pós-Graduação da Escola Nacional de Saúde Pública Sergio Arouca, Fundação Oswaldo Cruz (ENSP/Fiocruz), Rio de Janeiro, RJ, Brasil

* **E-mail:** raqhunger@gmail.com

Received: Nov 23, 2022
Approved: Jul 18, 2023

How to cite: Hunger R, Magalhães R, Costa DM. The Program for Productive Inclusion and Health Security (PRAISSAN): between the reasonableness of health requirements and the cultural traditions of family farming. Vigil Sanit Debate, Rio de Janeiro, 2023, v.11: e02139. https://doi.org/10.22239/2317-269X.02139

ABSTRACT

Introduction: In 2017, the Program for Productive Inclusion and Sanitary Security (PRAISSAN) was institutionalized by the National Health Surveillance Agency (Anvisa) with the purpose of socially and productively including individual micro-enterprises, solidarity economic enterprises, and family farmers through sanitary regularization of their activities. **Objective:** This study aimed to understand the articulation between the norms and guidelines that structure the design of PRAISSAN and the dynamics of implementation in different local contexts. **Method:** This is an evaluative research developed based on the theoretical framework of the so-called theory-driven evaluation. The set of theoretical premises that shape the design of the intervention and the results of a multiple case study developed in three Brazilian municipalities, starting in 2017, with emphasis on the process of sanitary regularization of food produced by family farmers are discussed. **Results:** PRAISSAN provided a change in the approach of health surveillance agents and family farmers. A focus on the practice of health surveillance professionals was identified. The guiding approach non-punitive on the practice of health surveillance professionals promoted a greater adequacy to the sanitary requirements by family farmers and facilitated the management of local actions. However, disagreements and challenges regarding productive inclusion, income generation and food marketing remain. **Conclusions:** The theory of the program must be improved, in the direction of explaining how habits can be preserved without increasing the health risk in the production process. In addition, systematic investigations and evaluative research should be encouraged in order to advance understanding of program limits and strengths.

KEYWORDS: Evaluative Research; Theory-driven Evaluation; Individual Microenterprises; Solidarity Economic Enterprises

RESUMO

Introdução: Em 2017 foi institucionalizado o Programa para Inclusão Produtiva e Segurança Sanitária (PRAISSAN), pela Agência Nacional de Vigilância Sanitária (Anvisa), com o propósito de fortalecer a inclusão social e produtiva de microempreendimentos individuais, empreendimentos econômicos solidários e agricultores familiares por meio da regularização sanitária de suas atividades. **Objetivo:** Foi realizado estudo visando compreender a articulação entre as normas e diretrizes que estruturam o desenho do PRAISSAN e a dinâmica da implementação em diferentes locais. **Método:** Trata-se de uma pesquisa avaliativa desenvolvida com base no referencial teórico da chamada avaliação orientada pela teoria (*theory-driven evaluation*). Foi discutido o conjunto de premissas

teóricas que conformaram o desenho da intervenção e realizado um estudo de caso múltiplo em três municípios brasileiros, a partir de 2017, com ênfase no processo de regularização sanitária de alimentos produzidos por agricultores familiares. **Resultados:** O PRAISSAN proporcionou uma mudança na abordagem dos agentes de vigilância sanitária e agricultores. Identificou-se um enfoque principal no que se refere à prática dos profissionais da vigilância sanitária. O enfoque orientador propicia uma maior adequação às exigências sanitárias pelos agricultores familiares e facilita a gestão das ações locais. No entanto, permanecem dissensos e desafios no que se refere à inclusão produtiva, a geração de renda e a comercialização dos alimentos. **Conclusões:** A teoria do programa deve ser aprimorada, na direção de explicitar como hábitos e costumes podem ser preservados sem ocorrer o aumento do risco sanitário no processo produtivo. Além disso, investigações sistemáticas e pesquisas avaliativas devem ser estimuladas a fim de avançar na compreensão dos limites e avanços do PRAISSAN.

PALAVRAS-CHAVE: Pesquisa Avaliativa; Avaliação Orientada pela Teoria; Microempreendimentos Individuais; Empreendimentos Econômicos Solidários

INTRODUCTION

On March 29, 2017, the Brazilian National Health Surveillance Agency (Anvisa) instituted the Program for Productive Inclusion and Health Security (PRAISSAN)[1]. The aim of the program is to expand access to products and services offered by individual micro-entrepreneurs (MEI), rural family farmers, and solidarity economic enterprises, based on the sanitary regularization of their activities. The resolution covers activities carried out by enterprises classified as low health risk and under the supervision of Anvisa, i.e., processed foods of plant origin. The Committee for the Management of the National Network for the Simplification of Registration and Legalization of Companies and Businesses (CGSIM), of the Ministry of Economy, is responsible for publishing the list of activities with information on the respective risks. Foods classified as high health risk continue to be inspected under ordinary regulations, while animal products, juices and pulps, and beverages are under the supervision and health inspection of the Ministry of Agriculture, Livestock and Food Supply (MAPA).

The intervention represents a milestone in Anvisa's trajectory, as it was aligned with the Brazil without Misery Plan (PBSM), a federal program set up in 2011, which sought to contribute to health promotion and income generation for the socially vulnerable population.

To a large extent, PRAISSAN was intended to respond to the demands of representatives of civil society organizations seeking sustainable alternatives for rural development, such as the Institute for Society, Population and Nature (ISPN) and the National Confederation of Agricultural Workers (CONTAG)[2,3]. By drawing attention to the barriers encountered in the process of sanitary regularization of food produced by family farmers and, consequently, their limited participation in public tenders, these entities highlight the challenge of productive inclusion. Anvisa, with the support of these entities and relevant social actors, launched a regulation aimed at the health regularization of these enterprises: Collegiate Board Resolution (RDC) No. 49 of October 31, 2013, which established the principles and guidelines for the PRAISSAN implementation process[4,5]. The Resolution recognizes the importance of these actions for health promotion, since they encourage formalization, income generation, social inclusion and access to social benefits for micro-entrepreneurs. At the same time, the regulations seek to increase the consumption of diverse, fresh, regional and health-safe food.

Since the publication of RDC 49/2013, there has been disagreement among health surveillance agents about some of the guidelines of the regulation, such as the "reasonableness of the requirements applied" and the "protection of artisanal production, in order to preserve customs, habits, and traditional knowledge from the perspective of the multiculturalism of peoples, traditional communities, and family farmers". Although these guidelines continue to underpin the development of PRAISSAN's main activities, local implementation reveals the emergence of new interpretations, controversies, and lessons learned[4,6].

Using the conceptual-methodological framework of *theory-driven* evaluation[7], it was possible to understand the theoretical consistency of the program in relation to the nature of the problem in local dynamics, as well as the challenges and limits of the actions.

Theoretical-methodological approach

According to Pawson and Tilley[8], *theory-driven evaluation* was introduced by Chen and Rossi in 1981. The authors were pioneers in the debate about the limitations of the experimental approach marked by the search for statistically significant regularities and the positivist understanding of the nature of social causation in the field of social program evaluation.

According to Weiss[9], social programs are complex interventions, that is, "they are an amalgam of dreams and personalities, rooms and theories, paper clips and organisational, structure, clients and activities, budgets and photocopies and grand intentions". Programs therefore incorporate a variety of components, agents, organizations, structures and activities. However, their objectives are not always clear. This complexity requires an effort, both for the social groups involved and for the evaluators themselves, to understand what the

program intends to achieve and how it intends to achieve effective change[9,10].

Based on this approach, every program incorporates a theory of change that must be reproduced in the local context. According to Pawson[11], "programs are embodied theories and evaluation seeks to discover whether programs work, so evaluation is the evaluation is theory-testing". In this way, program theory reveals causal associations linking *inputs* to *outputs*, shedding light on the mechanisms triggered in implementation contexts which explain the intended and unforeseen effects of each intervention. According to Pawson and Tilley[8], the mechanisms are not confused with the program's activities and resources but involve a relationship between the agents' choices regarding the strategies triggered by the program and the collective capacity to develop the activities in the local context. It is therefore a relationship between agency (*stakeholder choices*) and structure (*capacities and resourcers*).

In this sense, when evaluative research explores both the theory of the program's official design and the underlying theories that emerge during the implementation process at the local level, it deals with what Weiss[9,10] has defined as theories of change. An analysis of the program theory seeks to specify what the program is and how it intends to achieve the results, avoiding treating the intervention as a *black box* and the evaluation only as a final step. Implementation theory, on the other hand, focuses on the dynamics of program implementation. In other words, it seeks to understand effects and changes by examining the process of local development of the actions. This approach analyzes gaps, limits, and achievements during the implementation process. This information is fundamental for the implementing agents as it helps them to reformulate and redesign the program in the light of the provisions, opportunities, and challenges of the local context[10,11,12].

From this perspective, the aim of this paper is to discuss the results of an evaluation study into the process of implementing PRAISSAN in 2017, with an emphasis on the health regularization of food produced by family farmers in three Brazilian municipalities.

METHOD

Based on this theoretical-methodological framework, the evaluation research was carried out in two stages. In order to identify the main objectives and components of the program's theory at the federal level, ordinances, resolutions, booklets, legal provisions and publicly accessible documents made available by Anvisa were analyzed. In order to analyze how the program was implemented in different local contexts (implementation theory), a multiple case study was carried out on the process of sanitary regularization of food produced by family farmers in the municipalities of: Realeza (Paraná), Terenos, and Caracol (Mato Grosso do Sul).

As for the criteria for selecting municipalities, after a documentary analysis of management reports for 2017 available on the Management Report Construction Support System (SARGSUS) and news published online between 2014 and 2017 on the development of initiatives on the subject in local contexts[13], relevant experiences were selected for the development of a case study. The criteria for this choice were: municipalities that were already carrying out health regularization activities for family farmers (not just planned actions), small and large cities and/or cities close to capital cities, in order to assess the contextual interferences of predominantly rural or urban environments, and the presence of key informants from the academic field who could help during the research.

At the local level, data collection involved systematizing the main narratives present in the municipal operationalization of PRAISSAN by conducting semi-structured *online* interviews between 2020 and 2021 with relevant actors in the process of implementing the actions. Four health surveillance agents, a professor from the Federal University of Fronteira Sul (UFFS) and 11 family farmers were interviewed, eight from Realeza and three from Terenos. The family farmers interviewed are fruit, vegetables and bakery producers. The interviews, conducted via *Google Meet* or *WhatsApp* platforms, were scheduled according to the availability of the participants. It should be noted that, with the worsening of the COVID-19 pandemic since March 2020 and the adoption of stricter measures such as *lockdown*, many activities have been adapted to the *online* work modality. The pandemic has impacted the development of academic research, especially field research. Methodological strategies had to be reformulated in order to continue the research, such as the decision to conduct the interviews *online*. Even with the new strategy adopted, it was difficult to get in touch to schedule interviews, especially among family farmers who lived in places far from the urban center, with a poor internet signal or their own mobile phone. Although the data has limitations, given that it was not possible to follow the routine of the professionals, nor the health regularization activities carried out in person in the rural settlements, the results made it possible to uncover the main advances and limits of the PRAISSAN implementation process.

An evaluation matrix was adapted to support data analysis, an instrument proposed by Magalhães[14] which helped to draw up the interview scripts, systematize the program information and advance the analysis of the validity of the theory, the implementation process and the effects and scope of the actions in the local context (Chart 1).

It is important to note that, during the development of the research, all ethical precepts were followed according to the criteria established by the Resolutions of the National Health Council, No. 466, of December 12, 2012, and No. 510, of April 7, 2016[15,16]. The research was approved by the Research Ethics Committee of the National School of Public Health of the Oswaldo Cruz Foundation, under CAAE number: 26678019.2.0000.5240, on November 12, 2020. In addition, the information regarding local actors and services was analyzed in aggregate form, seeking to guarantee confidentiality and protect the identity of individuals.

Chart 1. Evaluation matrix for the Productive Inclusion and Health Security Program. Brazil, 2022.

Evaluation matrix	Validity of program theory	Implementation process	Effects and scope: articulation and interdependence between theory and the implementation process
Context background	What are the components, activities, actors, and institutions involved in regulatory design? What are the main tensions and controversies surrounding the design of the program? Is the program theory consistent with the nature of the problem and the local context?	What are the challenges to guaranteeing sustainability in the process of productive inclusion with health security? What are the challenges of intersectoral coordination at local level? What skills and capacities are fostered in the local context? Are there any barriers that affect implementation? What and how were the alternatives adopted?	How are the planned actions developed in the local context? What are the main scope and limits of the intervention in the local context? What changes in the behavior of the actors? What are the effects of this change? What are the obstacles to adapting the program in the local context?
Data sources: documentary analysis, interviews	Data sources: ordinances, normative documents, working group reports.	Data sources: interviews, management reports, information available on different platforms such as IBGE, SARGSUS, E-Gestor Atenção Básica, and DAP consultation available on the MDA website.	Data sources: interviews and management reports.

Source: Adaptation of the evaluation matrix drawn up by Magalhães[14].
IBGE: Brazilian Institute of Geography and Statistics; SARGSUS: Management Report Construction Support System; Pronaf: Program to Strengthen Family Farming; DAP: Declaration of Aptitude to Pronaf; MDA: Ministry of Agrarian Development and Family Agriculture.

RESULTS AND DISCUSSION

PRAISSAN: theory and intended changes

In order to understand the theory behind PRAISSAN and the potential for change in the planned mechanisms, it is necessary to delve more deeply into the context that led to the creation of the program. In 2011, Anvisa's management was in favor of developing studies and research in the social area,and implementing intersectoral actions focused on promoting health and equity. At the same time, rural social movements, led by ISPN, the *Slow Food* Movement, the Marist Solidarity Institute (IMS) and the National Association of Cooperatives of Family Agriculture and Solidarity Economy (Unicafes) were critical regarding health and food rules. For these actors, these requirements (which included structural changes to production sites) hindered the regularization process of artisanal food producers[4].

In 2012, social movements led by these civil society organizations held a workshop in Brasilia (Federal District) on "fair and inclusive health standards", including the participation of public authorities such as professionals from Anvisa and MAPA[3]. The workshop helped bring Anvisa's health surveillance agents and representatives of civil society organizations closer together, enabling the formation of a working group that was later responsible for the collective construction of a normative instrument aimed at the health regularization of these micro-enterprises, the current RDC/Anvisa No. 49/2013.

The analysis of the text justifying the transformation of the project into a program (PRAISSAN) made it possible to understand the theory of the program, the theory of implementation, and its main mechanisms. It can be said that the main social change sought by the programme is to promote productive inclusion by regularizing the health of family farmers, MEIs, and solidarity economy activities. As a result, PRAISSAN aims to help reduce the rural exodus, unemployment, and poverty. Another intended change is to reorient the focus of technical visits, reinforcing a guiding perspective. Criticism of the punitive nature of technical visits was seen by Anvisa as "the great differential of RDC No. 49/2013: the paradigm shift contained in the healthy educational, guiding and facilitating spirit that should guide health inspections"[17]. The focus has become changing the behaviour of health surveillance agents during the process of regularizing the health of products.

Another important mechanism for generating change intended by the program is related to compliance with the "reasonableness of the requirements applied". However, RDC No. 49/2013 does not clearly specify the meaning of this programmatic guideline. The guidance booklet for municipal managers only states that "reasonableness is a legal concept aimed at defining the ways in which public administration acts"[17].

Given the importance of the dimension of reasonableness, further reflection is necessary. In artisanal or traditional food production, structures, equipment, and utensils are used based on cultural practices that have their own characteristics in each region. It is not possible for the legislator to completely standardize the structural conditions of the production process. Therefore, it is understood that, in the absence of uniform criteria in health legislation, the surveillance agent must make use of the legal principle of discretion, in other words, having the autonomy to assess which conducts are most appropriate, within the legal framework, by means of a judgment of convenience, justice, and social equity. Taking the public interest into account, the surveillance agent must visit production sites and assess whether or not the practices adopted and the existing structural conditions pose a health risk to the consumer.

This discretionary power is justified by the main mechanism for social change envisaged in PRAISSAN: promoting social and productive inclusion. Therefore, using social, economic, and cultural values, the surveillance agent must apply the health requirements in a "reasonable" way, in order to contribute to

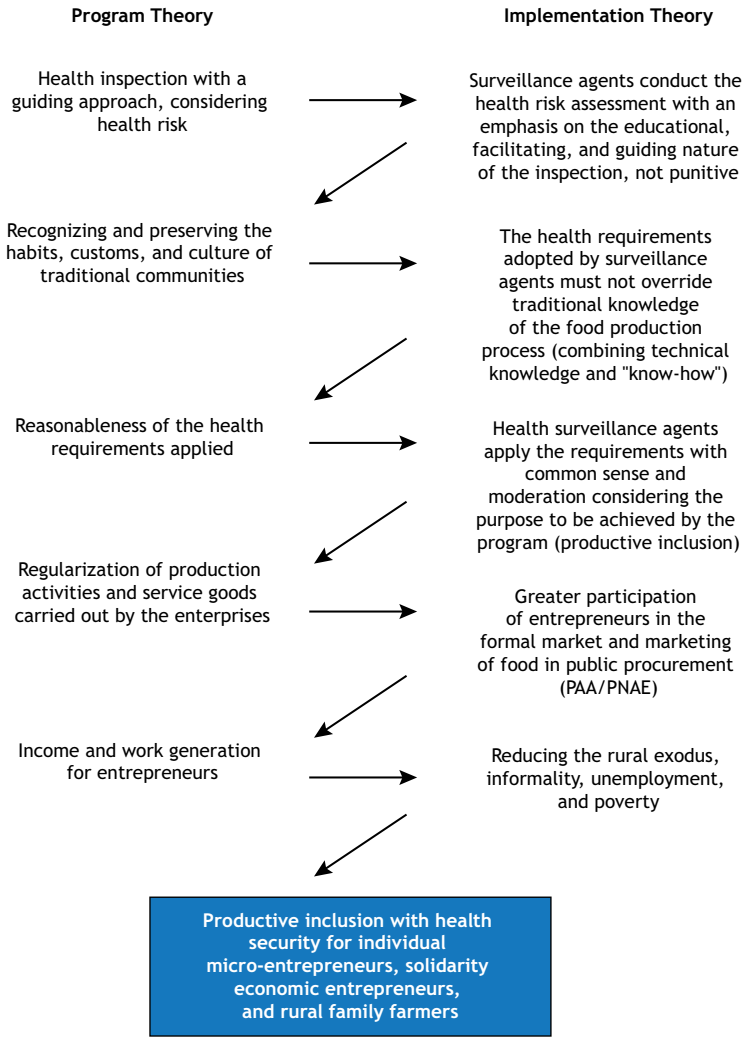
social inclusion and income generation. However, the legal principle of reasonableness can limit discretionary power[18]. This means that the surveillance agent must consider the health risk when making decisions. According to Anvisa's statement, "the rule is supportive and facilitating but it is not permissive"[17].

Both principles are linked to another PRAISSAN guideline, the "protection of artisanal production in order to preserve customs, habits and traditional knowledge from the perspective of the multiculturalism of peoples, traditional communities and family farmers."[5] It is through the principle of reasonableness that we hope to combine the main objectives of PRAISSAN, the preservation of "know-how", i.e., artisanal and traditional techniques, as well as good sanitary practices during the food production process. The program aims to promote the inclusion of family farmers in the formal market and, at the same time, access to diverse and better quality food, from a sanitary point of view.

Figure 1 summarizes the main axes of the program theory and the mechanisms of change envisaged.

According to Pawson[11], "programs are active interactive sequences of theories: if we implement A, this should achieve our intervention objective B, and once B is in place, we will be in a position to try C, which will activate the next output D, and so on". Evaluation consists of investigating each stage of this process to allow reflection on the theory that informs the design and implementation of the program.

In the case of PRAISSAN, it is important to reflect on the limits to achieving productive inclusion for the three categories of enterprises envisaged. In the planning reports for the productive inclusion project proposed by Anvisa and in the booklets on RDC 49/2013, these categories are identified as "small businesses", "small producers", or "enterprises". Family farmers are defined as those linked to a "rural family enterprise". However, there are different conceptions and purposes of productive insertion for each group. While public policies aimed at MEIs support a discourse of "entrepreneurship" and the possibility of entering the market based on individual motivation,



Source: Prepared by the authors, adapted from Weiss[9].
PAA: Food Acquisition Program; PNAE: National School Feeding Program.

Figure 1. Theories on the changes sought by PRAISSAN: program theory and implementation theory.

solidarity economic entrepreneurs demand a form of associative and solidarity work. Family farmers, meanwhile, are fighting for access to land and the permanence of the cultural characteristics of their production.

Since the publication of the public consultation on RDC No. 49/2013, it has been possible to identify disagreements between health surveillance agents regarding the purpose of the regulations[4,6]. These disagreements involve the applicability of the concept of reasonableness of health requirements. For some health surveillance agents, the measure makes health requirements more flexible and makes it possible to increase the health risk of products. For other surveillance agents, the regulation harmonizes procedures and contributes to the productive inclusion of family farmers, who face difficulties in formalizing their activities. There are a number of relevant social factors in the local dynamics that interfere with achieving the changes intended by the program. These factors can compromise the local decision-making process. The next section presents an analysis of the PRAISSAN theory based on the implementation process in the three selected municipalities.

Analysis of the PRAISSAN implementation process in the selected municipalities

The municipality of Realeza is located in the Southwest Mesoregion of the state of Paraná, in a territorial unit area of 353.416 km². According to the Brazilian Institute of Geography and Statistics (IBGE), it has an estimated population (2021) of 16,976 inhabitants, ranking 108th in the state. The municipality of Terenos, on the other hand, is located in the Midwest region of the state of Mato Grosso do Sul, close to the capital Campo Grande, in a territorial area corresponding to 2,845.723 km². According to the IBGE, it has an estimated population (2021) of 22,721, ranking 34th in the state. Finally, the municipality of Caracol, also located in the state of Mato Grosso do Sul, is situated in a territorial area of 2,943.206 km² and has an estimated population (2021) of 6,247 people, ranking 69th in the state[19]. The distance between the two municipalities is around 400 km.

Based on the research carried out in 2018 by the IBGE[20], Area of Influence of Cities (Regic), which identified and analyzed the Brazilian urban network, establishing a hierarchy of urban centers and their relationships between the regions of influence of the cities, it was concluded that the small number of inhabitants of up to 25,000 people in the three municipalities and the low supply of goods and services contribute to the low occupancy rate of the population. In addition, the Gini index showed income inequality in the three municipalities (between 0.4334 and 0.5206), and two municipalities had a medium municipal human development index (MHDI) (between 0.658 and 0.722). Another relevant fact is the high rate of revenue from external sources (between 79.9% and 92.9%)[20]. Furthermore, the three municipalities had significant percentages of households located in rural areas (between 40.0% and 72.0%). Data from the Survey of Basic Municipal Information (MUNIC) carried out by the IBGE[21] in 2017 also showed that the water distribution network and the sewage collection network did not cover most of the rural area.

The data collected in the Productive Inclusion Supplement, carried out by MUNIC in 2014, indicated the development of actions aimed at generating work and income for family farming in the three municipalities. However, according to the survey, there was no provision of rural credit lines, support for transportation and marketing of products, technical assistance, or loan/financing lines to improve infrastructure conditions[21].

The 2017 Agricultural Census carried out by the IBGE[22] showed significant numbers of agricultural establishments (between 472 and 2,603) and a similar profile among farmers in the three municipalities. In general terms, in the three municipalities there is a predominance of producers who carry out their activities in partnership with other people or individually, males aged between 45 and 65 and with low levels of schooling. It is worth noting, however, that in the municipality of Terenos, 403 producers were identified with a higher level of education (graduation). However, although there are differences in some socio-economic characteristics, the three municipalities have similar social indicators.

Chart 2 systematizes the main theoretical elements of PRAISSAN and its operationalization strategies at the local level. By studying the three dimensions of the evaluation matrix together, it was possible to understand what worked, for whom and under what circumstances.

Based on this systematization, it can be said that the three experiences were similar in terms of the process of implementing the actions. In all three cases, the health surveillance agents were interested in working with family farming in a guiding approach. But there are also singularities. In Realeza, the partnership established since 2012 between researchers from the Federal University of Fronteira Sul (UFFS) and the Municipal Health Department has provided greater visibility and strengthened the production of food produced by family farming. In addition, the State Health Department has encouraged the health regularization of activities carried out by rural family businesses, with the publication of a state resolution (SESA No. 004/2017)[23].

In the state of Mato Grosso do Sul, the State Health Department held a competition in 2015 to select projects aimed at implementing RDC No. 49/2013 and drawn up by municipal health surveillance teams. The selected projects were awarded a vehicle for the exclusive use of municipal health surveillance teams. As well as spreading the word about the regulations, the competition helped to reduce the initial resistance of some agents to working with family farming in rural areas. Considering the tensions and conflicts present among health surveillance agents, it is recognized that networks of partnerships, incentives, and financial stimuli contribute to a more effective rapprochement between surveillance agents and family farmers in the process of implementing PRAISSAN.

Chart 2. Evaluation matrix of the PRAISSAN implementation process applied to the municipalities selected in this study. Brazil, 2022.

Background
2003: Fome Zero Program: reference to the term "productive inclusion" and greater visibility for the promotion of FNS on the government agenda.
2004: Bolsa Família Program: development of professional qualification and formalization actions for beneficiaries of the program.
2011: Brazil without Extreme Poverty Plan: a proposal to overcome the situation of poverty and extreme poverty of the population by offering opportunities for occupation and income through the promotion of urban and rural productive inclusion.
2011: Project for Productive Inclusion with Health Security set up at Anvisa in partnership with the Brazil without Poverty Plan.
2012: Social mobilizations led by various civil society organizations to draw up "inclusive" health standards - Workshop on Health Standards for Artisanal, Family and Community Foods (September 2012), with the participation and presence of civil society organizations, artisanal producers and authorities from the executive and legislative branches.
2013: Resolution of Anvisa's Collegiate Board of Directors No. 49, of October 31, 2013, which provides for the regularization of individual micro-entrepreneurs, rural family enterprises and solidarity-based economic enterprises, and makes other provisions. The construction of the rule involved intense social participation, from health surveillance agents to representatives of civil society.
2017: Institutionalization of PRAISSAN through Ordinance No. 523, of March 29, 2017, with the premise of strengthening the actions of the National Health Surveillance System aimed at the health regularization of these enterprises.
Validity of the theory
Activity: The rule allows for the sanitary regularization of activities carried out by individual micro-entrepreneurs, solidarity economic enterprises, and rural family enterprises that process and market food considered to be of low sanitary risk.
Key players: Municipal health surveillance agents, individual micro-entrepreneurs, solidarity economic entrepreneurs and family farmers.
Institutions and sectors of interest: Federal, state, and municipal health agencies, Sistema S de Ensino, technical assistance agencies (EMATER/AGRAER), universities, non-governmental organizations, associations, and cooperatives of family farmers.
Theoretical premises that support the program's resources, activities and goals: **a)** entry of micro-entrepreneurs into the formal market through the sanitary regularization of their activities, therefore greater participation in public purchases, consequently greater autonomy and income generation; **b)** adoption of good sanitary practices by micro-entrepreneurs, resulting in the marketing of products with less sanitary risk to the health of consumers; **c)** the effectiveness of the program requires an educational approach during the orientation of good sanitary practices and the application of reasonable sanitary requirements, in order to preserve the habits, customs and culture of traditional communities and **d) the** articulation of intersectoral policies aimed at promoting productive inclusion and guaranteeing sanitary security, for example: improving basic sanitation conditions, enabling marketing channels and strengthening public food purchases through institutional markets, reducing bureaucracy in access to credit lines and consolidating rural technical assistance; **e) the** ability of municipal bodies to establish partnerships with other institutions and sectors of interest.
Main tensions and controversies surrounding the design of the program: Enforcement of the reasonableness of sanitary requirements without overlapping traditional knowledge and cultural production habits; dissent among surveillance agents over the principles of the program.

Municipalities	Realeza	Terenos	Caracol
Implementation process			
Challenges to guarantee sustainability in the process of productive inclusion with health security	• Lack of a *checklist* aimed at family-based production units (difficulty in applying reasonable requirements without overlapping with traditional/cultural knowledge); • Map family farmers working in the informal sector.	• Continue with actions after the COVID-19 pandemic.	• Lack of a *checklist* aimed at family-based production units (difficulty in applying reasonable requirements without overlapping with traditional/cultural knowledge); • Continue with actions after the COVID-19 pandemic; • Mapping family farmers who work in the informal sector (those who do not have health regularization and market their products).
Challenges of intersectoral coordination at local level	• Limited but existing partnerships: support from the university and local cooperatives.	• Limited but existing partnerships: support from the Municipal Rural Development Council and AGRAER.	• Without established partnerships and with the support only of professionals from the Municipal Health Department.
Capacities boosted in the local context	• The surveillance agent's interest in working with family farming; • Knowledge of RDC 49/2013; • Organization of farmers' work in cooperatives (technical assistance support).	• The surveillance agent's interest in working with family farming; • Knowledge of RDC 49/2013 and PRAISSAN; • Organization of farmers' work in cooperatives or family-based/rural settlements (technical assistance support); • Technical safety of the surveillance agent to apply reasonable sanitary requirements without the use of a specific inspection script;	• The surveillance agent's interest in working with family farming; • Knowledge of RDC 49/2013 and PRAISSAN.
Barriers/ obstacles	• Reduced health surveillance team; • Lack of specific financial resources for the development of activities; • University partnership project suspended.	• Reduced health surveillance team; • Lack of specific financial resources for the development of activities.	• Reduced health surveillance team; • Lack of specific financial resources for the development of activities; • No evidence in the municipality of farmers' associations or cooperatives and/or rural settlements; • Incipient technical assistance.

Continue

Continuation

Alternatives adopted	• Partnership established with the university; • Technical visits in a guiding approach; • Decrease in structural health requirements.	• Partnership established with AGRAER; • Technical visits in a guiding approach; • Decrease in structural health requirements.	• Marketing channels - fixed fair (temporary); • Technical visits in a guiding approach; • Decrease in structural health requirements.
Articulation between program theory and the implementation process			
Developing actions in the local context	Guiding technical visits; training on good practices; an affordable deadline for meeting the health requirements and obtaining the health permit.		
Scope/limits of the intervention	**Achievements:** Sanitary regularization of activities classified as low health risk carried out by assisted family farmers. **Limits**: Availability of time and staff for frequent technical visits to production sites; approaching and monitoring all farmers in the municipality; mobilization of food marketing channels (increasing the volume of public purchases/fairs); farmers' lack of financial resources for investment in the agro-industry (difficulty in accessing federal government credit line programs); farmers whose homes are not even able to be adapted for the minimum guarantee of health safety.		
Changes/effects in actors' behavior	Closer ties between health surveillance agents and family farmers; a guiding approach to technical visits; a focus on identifying health risks and advising on hygiene practices during the production flow; and a reduction in structural health requirements (reasonableness of health requirements).		

Source: Prepared by the authors, adapted from the evaluation matrix prepared by Magalhães[14].
PRAISSAN: Program for Productive Inclusion and Health Security; EMATER: Institute of Technical Assistance and Rural Extension; AGRAER: Agrarian Development and Rural Extension Agendy; RDC: Collegiate Board Resolution.

Adopting a guiding approach during the health inspection also had an important effect in terms of strengthening ties between the agent and the family farmer:

> If you're going to use a word, you have to have a *feeling*, to be able to make the person not feel embarrassed, it's the way you speak [...] you have to act differently, you have to take off your inspector's clothes and talk to the producer because he's afraid of the inspection [...] sometimes even the language we use is too complicated for him, so I can say that it's taking off your inspector's clothes, if you're going to do 49's job dressed as an inspector you won't do it (Health surveillance agent).

There are significant obstacles in this process of local implementation. Although the principle of reasonableness has contributed to a reduction in sanitary requirements, especially those of a structural nature and linked to the new approach to hygiene in the production process, there is still technical uncertainty among surveillance agents. This insecurity is associated with the lack of a *checklist* that standardizes structural conditions and sanitary conduct, since these criteria make decision-making easier: "we don't have a specific *checklist* for them [...] RDC 49, if you read it, is totally open, it says do it how you think it should be done, it's become complex to interpret" (Health surveillance agent).

Autonomy in decision-making is not always exercised. On a daily basis, health surveillance agents use *checklists* for health risk assessment, based on criteria determined by RDC No. 275, of October 21, 2002, a standard aimed at industrial food producing establishments[24]. There is therefore a roadmap to follow and the structural conditions are detailed. For example, the "existence of bulging angles between the walls and the floor and between the walls and the ceiling" is assessed. Decision-making is subject to the structural parameters in the regulations. However, failure to comply with this structural requirement minimally affects the health safety of the final product (processed food), and it is more appropriate to adapt sanitization operations during food processing to reduce any possible existing risk. In addition, the items on the *checklist do* not take into account the characteristics of family farming food production units.

According to Eduardo and Miranda[25], health inspection requires epidemiological and regulatory knowledge, as well as an understanding of the scope of each activity. In a rural setting, the surveillance agent can only assess whether or not such equipment poses a health risk when evaluating the production process. Insofar as artisanal and traditional techniques are used in the production process, a standardized *checklist* is unlikely to be enough to support the assessment of the practices and structural conditions found in the different local contexts.

In the research, one of the surveillance agents revealed the need to study the processing of rapadura before visiting a family farmer's production unit. After her visit, she built a flowchart of the activity that allowed her to identify the critical points in the production process and assess the health risk at each stage. Decision-making was therefore based on the agent's technical knowledge of the procedures and practices applied in the production flow of artisanal rapadura, and not just on predefined criteria in a *checklist*. This approach, however, requires time:

> It's very easy for an inspector to take the 275, which has a *checklist*, put it under his arm, and go to the agro-industry and apply, "yes, yes, no, no", you have to comply with everything here otherwise you won't be able to [...] now you go as an inspector, you look at the structure, you monitor, that's what I deduce as reasonableness, you monitor the production of that farmer and see if in that production flow there is a risk or not, regardless of the structure he has (Health surveillance agent).

In the three cases analyzed, the alternatives adopted to promote the process of regularizing the health of activities were similar, such as establishing partnerships for the development of actions, carrying out technical visits in a guiding approach to family-based units and reducing structural health requirements. However, the reconfiguration of structural health requirements was justified, in most cases, by the recognition of the economic and social limitations faced by family farmers in adapting their production units to the criteria laid down in current health legislation. The need to preserve cultural habits did not play a major role and the requirements to change from wooden materials to *stainless* steel utensils or other materials considered easy to sanitize during the production process remained.

Some important measures to promote productive inclusion have been implemented, such as the development of marketing channels for family farmers. In the municipality of Caracol, public agents set up a permanent market to sell fruit and vegetables. However, there have been difficulties in continuing this experience in the region. Initially, the street market was planned to sell fruit and vegetables made available by rural producers but there was more interest from MEIs in offering sweets, snacks, and other processed products. The locations of the fairs were far from the rural settlements and family production units, so there wasn't a favorable or attractive cost-benefit ratio for farmers to participate, since there was a good flow of sales of their products from "door to door". As a result, the municipal administration adapted a food court for the marketing of products processed by MEIs, which was held periodically during festivities in the municipality.

In Caracol, public officials pointed out the lack of participatory spaces such as farmers' associations or cooperatives, as well as the low volume of production by farmers, which made it difficult for them to participate in public purchases. On the other hand, in Terenos and Realeza, the volume of production was considerable and allowed associated producers, cooperatives and individual farmers to participate in public purchases. However, farmers reported low demand from public bodies linked to the National School Feeding Program (PNAE) and the Food Acquisition Program (PAA):

> The producer produces, right. The problem is marketing, which is weak, and the municipalities themselves, who don't just buy directly from the producer, there are intermediaries in the middle (Farmer 1).

> I don't think it's the cooperative's problem. I think it's the municipality's nutritionist. She gives more preference to products from the market than from farmers (Farmer 2).

Based on the analysis of the evaluation matrix, it can be said that there are several weak points in the process of implementing PRAISSAN in the municipalities surveyed. The small number of professionals in the health surveillance teams and the lack of time available for technical visits to the production units to provide guidance hindered the progress and effectiveness of the actions. The guidance provided by the health surveillance agents made it possible for the family farmers assisted by the program to become sanitary regularized. Figure 2 shows the main generative mechanisms of the program responsible for the results achieved in the three municipalities.

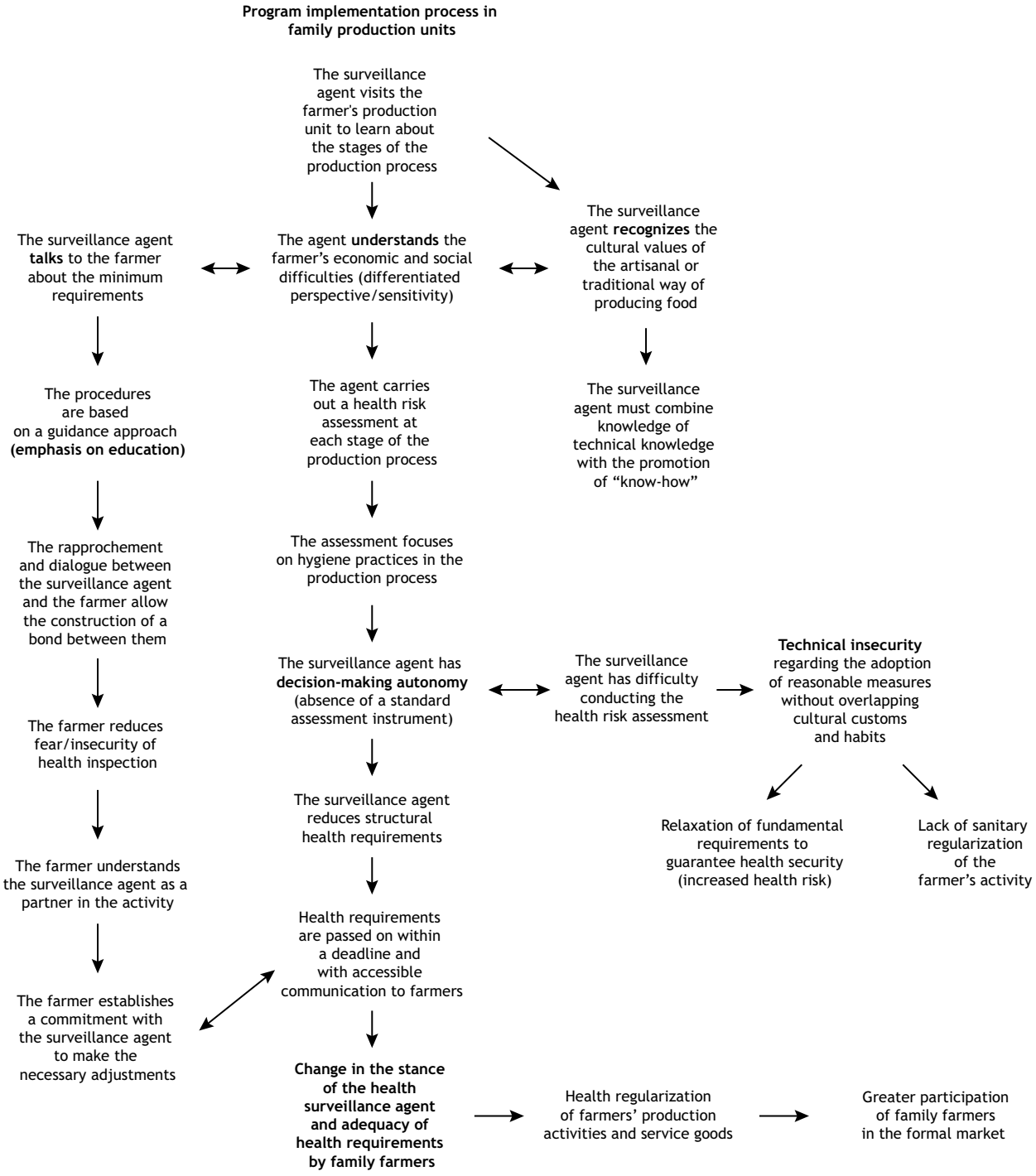
According to Figure 2, one of the key components of PRAISSAN occurs during the visit of health surveillance agents to family-based production units. As the surveillance agent talks to the farmer, a number of simultaneous processes take place. Before imposing any measures, the health surveillance agent approaches the farmer, gets to know their production methods and all the stages of the production process. At the same time, they try to understand the economic and social difficulties they face. In addition, while learning about production methods, they recognize the importance of cultural values, which guide the artisanal or traditional techniques used. The agents interviewed described this process as the need to have a "sensitivity and a different look" during the health regularization process during technical visits to family-based production units.

In the three experiences analyzed, the reasonableness of the health requirements was accepted by the agents as a process of assessing the health risk at each stage of the production process, based on a guiding approach and the reduction of health requirements related to local physical and structural conditions. Once the health risk assessment had been carried out, the surveillance agents had greater autonomy in making decisions, since there was no standardized inspection script or *checklist*.

The family farmers understood that the health inspection did not have a merely "punitive or police-like" character, so their fear and insecurity during the regularization process diminished. As a result, it was possible to establish a partnership with the health surveillance agent. All the mechanisms were triggered simultaneously and the main result of this process was a change in the health surveillance agent's attitude during the health inspection and the farmer's commitment to complying with health requirements.

Health regularization did not provide better income conditions for all the family farmers in the three cases analyzed. Due to the difficulty of participating in marketing channels directly to the consumer and via public purchases through the PNAE or PAA, the objective of generating income was weakened in the local scenario.

Figure 2 illustrates the moment when PRAISSAN's theory is out of step with the practices that can be adopted by health surveillance agents in local dynamics. From the program's perspective, health surveillance agents should apply health requirements reasonably in order to contribute to social inclusion and income generation for micro-enterprises, while preserving traditional customs, habits and knowledge. However, as the researched experiences illustrated, there are difficulties in maintaining a commitment to both objectives. According to Astbury and Leeuw[26], programs involve an assumption or a set of assumptions about how the activities and resources will bring about change, but often these assumptions are not made explicit or tested robustly. In this sense, when the program has an inconsistent theory it will not achieve the desired changes, regardless of how well the action is implemented.



Source: Prepared by the authors, 2022.

Figure 2. Analysis of the PRAISSAN implementation process in the three case studies.

In the case of PRAISSAN, based on the analysis of the cases, although the agents recognized the cultural values of artisanal practices, reasonable measures were adopted "as long as the farmer's culture didn't get in the way of good practices", according to the following excerpt: "They're doing it in wood, using their culture, as soon as their culture gets in the way of health, if they're contaminating the food, then it gets complicated, but they're not contaminating, their culture doesn't get in the way, then there's no problem" (Health surveillance agent).

Cruz[27] carried out an ethnographic study on handmade serrano cheese made from raw milk in Campos de Cima da Serra, in the northeast of Rio Grande do Sul. Although it is a product considered to be of high health risk, the study provided some good

reflections on the difficulties faced by family farmers during the process of regularizing the health of their activities. According to the author, the norms and guidelines contained in the health regulations imply notions of hygiene linked to structural characteristics such as "high ceilings", the presence of bathrooms, the definition of the materials that cover the floor and walls, in favor of an environment free of chemical, physical, and microbiological contamination. However, in addition to the financial costs involved in building a small agro-industry with these characteristics, these procedures do not take into account the artisanal practices of this mode of production.

Even in production units that had wooden tables or other equipment, the farmers' hygiene behavior remained "capricious" at every stage of the production process. In fact, the farmers' cleaning criteria were stricter in places where wooden equipment prevailed, precisely because of the difficulty of sanitizing the surface of these utensils. Therefore, according to the author[27], special attention should be paid to the hygiene behavior of the handlers rather than just the structural conditions present.

According to Niederle and Wesz Junior[28], there is a rigorous application of hygiene criteria during large-scale food production; on the other hand, there is excessive use of food additives that are potentially harmful to health. In the perception of some of the farmers interviewed, the quality of their products is attributed to production methods and the origin of the raw material, i.e., whether the product is homemade, fresh, organic and without chemical additions, according to their reports:

> No, because I don't use any chemicals. It's all natural (Farmer 5).
>
> Because I make everything fresh [...] we buy quality everything, quality flour, quality sugar (Farmer 8).
>
> I don't think so, the way we do it, we don't use any chemicals, it's all homemade, I don't think there's any risk (Farmer 6).

This does not mean that farmers in the municipalities analyzed were unaware of the hygiene practices needed to keep their products safe from a health point of view. Some farmers stressed the importance of hygiene and temperature control when handling food: "I do everything hygienically" (Farmer 8); "In my opinion, I don't think there's any risk, because they're well-baked products" (Farmer 5). It should be noted that in all three municipalities the farmers were assisted by the municipal health surveillance team and were offered training in good health practices. Although this study did not observe the practices adopted *on site*, the health surveillance agents confirmed in the interviews that all the production stages carried out by the farmers were hygienically adequate.

Although there is recognition of the importance of preserving these habits, there are still obstacles to achieving a better balance between the "technical knowledge" of the agent and the "know-how" of the farmer. The challenge of conducting the health risk assessment without the use of evaluation instruments (a standard associated with technical uncertainty in adopting reasonable measures) can result in a relaxation of fundamental requirements for guaranteeing health safety and, consequently, an increase in the health risk during the production process. It is also accepted that the continued high level of requirements, in terms of local structures, tends to hinder the health regularization process.

Each context presents different barriers and opportunities for promoting the productive inclusion of family farmers and ensuring the health safety of these products. As discussed above, there are precarious basic sanitation conditions in the three municipalities, especially in rural areas. Not all family farmers have access to rural technical assistance and credit lines for investments in agricultural equipment and machinery. In addition, there are too few health surveillance professionals to carry out the ongoing education and frequent technical visits to family-based production units recommended by PRAISSAN.

Finally, since the publication of Ordinance No. 523 of March 29, 2017, there has been no progress on actions at the federal level. The Committee for the Productive Inclusion and Health Security Program (CISSAN), a collegiate body suggested by the ordinance, has not been set up, and therefore no action plan has been drawn up for monitoring actions at the local level. It is possible that the change of public officials in Anvisa's management since 2018 has weakened the visibility of the issue on the agenda of actions at federal level.

CONCLUSIONS

Since 2011, Anvisa has been promoting initiatives to foster the productive inclusion of micro-enterprises in urban and rural areas. Although the purpose of PRAISSAN is to strengthen these interventions through the articulation of various social actors and intersectoral policies, there are challenges and limits to the development of these actions at the local level.

Based on the evaluative research guided by the program theory and the analysis of the implementation process in the three municipalities, it can be concluded that the program theory needs to be improved in order to explain how habits and customs can be preserved without increasing health risk in the production process. There is a fine line between preserving cultural habits and ensuring health safety. This dynamic is still unclear and tensions and conflicts arise between health surveillance agents. Furthermore, actions weakness cannot be justified solely by the absence of a specific *checklist* for family production units and a shift in surveillance approach; there are multiple political, social, and economic factors at play. The reasonableness of sanitary requirements, in the way they have been applied to local dynamics, is only achievable in production units that already have structural characteristics similar to agro-industries or aimed at family farmers who have sufficient financial resources to make the intended changes to the structure of production environments.

In this sense, the question arises: how does the program intend to reach socially vulnerable family farmers who have production units with physical structural conditions considered insufficient for food safety?

It is recommended that the arenas for collective participation be revived, prioritizing the resumption of actions based on the formalization of committees with the presence of relevant social actors. At the municipal level, it is important to ensure the construction of Technical Chambers or Intersectoral Work Groups (GTI) to develop the strategic planning of actions and a joint alignment of the work process with representatives from different bodies and sectors.

The importance of PRAISSAN for small producers' access to the market, adding value to their products and greater financial investment in improvements at their production site is undeniable. However, promoting productive inclusion with health security also involves facing the challenge of intersectorality. In this sense, the success of the programme depends on the articulation of multiple policies (basic sanitation, technical assistance, social assistance, such as the expansion of credit lines for the purchase of inputs or machinery, income transfer, the mobilization of marketing channels based on public purchases, and the promotion of food and nutritional security). In other words, the participation of the health surveillance agent in the process of regularizing these activities is extremely important, but if there is no coordination with other public bodies and policies, it will be difficult to make effective progress.

Without claiming to have exhausted the debate, this study sought to raise new questions and learnings about the implementation of PRAISSAN, including the tension between the reasonableness of health requirements and the cultural tradition of family farming. It also pointed out the relevance of evaluative research guided by the theory of programs aimed at promoting productive inclusion, income generation, and food and nutritional security.

REFERENCES

1. Agência Nacional de Vigilância Sanitária – Anvisa. Portaria Nº 523, de 29 de março de 2017. Institui o Programa para Inclusão Produtiva e Segurança Sanitária (PRAISSAN). Diário Oficial União. 30 mar 2017.
2. Schottz V, Cintrão RPZ, Santos RM. Convergências entre a política nacional de SAN e a construção de normas sanitárias para produtos da agricultura familiar. Vigil Sanit Debate. 2014;2(4):115-23. https://doi.org/10.3395/vd.v2n4.461.
3. 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.
4. Hunger R, Pepe VLE, Reis LGC. Inclusão produtiva com segurança sanitária de pequenos produtores na área de alimentos: um olhar a partir do Sistema Nacional de Vigilância Sanitária. Vigil Sanit Debate. 2020;8(1):62-70. https://doi.org/10.22239/2317-269x.01316
5. 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 providencias. Diário Oficial União. 1 nov 2013.
6. Viana CL. Inclusão produtiva com segurança sanitária: uma análise crítica da percepção dos atores sociais sobre os possíveis impactos da RDC N° 49 publicada em 2013 pela Anvisa [dissertação]. São Paulo: Universidade de São Paulo; 2017.
7. Chen H. Theory-driven evaluations. London: Sage; 1990.
8. Pawson R, Tilley N. Realistic evaluation. London: Sage; 1997.
9. Weiss CH, Weiss CH. Evaluation: methods for studying programs and policies. 2a ed. Upper Saddle River: Prentice Hall; 1998.
10. Weiss CH. Theory-based evaluation: past, present, and future. New Direct Eval. 1997;(76):41-55. https://doi.org/10.1002/ev.1086
11. Pawson R. Nothing as practical as a good theory. Evaluation. 2003;9(4):472-90. https://doi.org/10.1177/135638900300900407
12. Scheirer MA. Program theory and implementation theory: implications for evaluators. New Direct Prog Eval. 1987;(33):59-76. https://doi.org/10.1002/ev.1446
13. Hunger R. Inclusão produtiva com segurança sanitária de pequenos produtores na área de alimentos: um olhar a partir do Sistema Nacional de Vigilância Sanitária [dissertação]. Rio de Janeiro: Fundação Oswaldo Cruz; 2018.
14. Magalhães R. Implementação de programas multiestratégicos: uma proposta de matriz avaliativa. Cienc Saúde Colet. 2014;19(7):2115-23. https://doi.org/10.1590/1413-81232014197.08482013
15. Ministério da Saúde (BR). Resolução Nº 466, de 12 de dezembro de 2012. Aprova novas diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial União. 13 jun 2013.
16. Ministério da Saúde (BR). Resolução Nº 510, de 7 de abril de 2016. Trata sobre as diretrizes e normas regulamentadoras de pesquisa em ciências humanas e sociais. Diário Oficial União. 4 maio 2016.
17. Agência Nacional de Vigilância Sanitária – Anvisa. Cartilha inclusão produtiva com segurança sanitária: RDC Nº 49/2013 norma comentada. Brasília: Agência Nacional de Vigilância Sanitária; 2014.
18. Resende AJC. O princípio da razoabilidade dos atos do poder público. Rev Legisl. 1999;(26):55-8.
19. Instituto Brasileiro de Geografia e Estatística – IBGE. Cidades e estados. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2021[acesso 23 ago 2021]. Disponível em: https://cidades.ibge.gov.br

20. Instituto Brasileiro de Geografia e Estatística – IBGE. Regiões de influência das cidades (Regic): coordenação de geografia. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2018.

21. Instituto Brasileiro de Geografia e Estatística – IBGE. Pesquisa de informações básicas municipais (Munic). Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2017[acesso 1 dez 2021]. Disponível em: https://www.ibge.gov.br/estatisticas/sociais/saude/10586-pesquisa-de-informacoes-basicas-municipais.html

22. Instituto Brasileiro de Geografia e Estatística – IBGE. Censo agropecuário 2017: resultados definitivos. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística; 2020[acesso 15 jun 2020]. Disponível em: https://biblioteca.ibge.gov.br/visualizacao/periodicos/3096/agro_2017_resultados_definitivos.pdf

23. Secretaria Estadual de Saúde do Paraná. Manual de orientação: boas práticas de fabricação de alimentos processados pelo empreendimento familiar rural. Paraná: Secretaria Estadual de Saúde. Paraná; 2018.

24. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução Nº 275, 21 de outubro de 2002. Regulamento técnico sobre procedimentos operacionais padronizados aplicados aos estabelecimentos produtores/industrializadores de alimentos e a lista de verificação das boas práticas de fabricação em estabelecimentos produtores/ industrializadores de alimentos. Diário Oficial da União. 21 out 2002.

25. Eduardo MBP, Miranda ICS. Vigilância sanitária. São Paulo: Universidade de São Paulo; 1998.

26. Astbury B, Leeuw FL. Unpacking black boxes: mechanisms and theory building in evaluation. Am J Eval. 2010;31(3):363-81. https://doi.org/10.1177/1098214010371972

27. 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.

28. Niederle PA, Wesz Junior VJ. As novas ordens alimentares. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2018.

Acknowledgments

To the Coordination for the Improvement of Higher Education Personnel (Capes) of the Ministry of Education, for the scholarship awarded to the main author. To all the health surveillance agents from the Municipal Health Departments, the family farmers, and the researchers from the Federal University of Fronteira Sul (UFFS), who contributed to the field research.

Authors' Contribution

Hunger R - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Magalhães R, Costa MD – Writing of the work. All the authors approved the final version of the work.

Conflict of Interest

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