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Profile of on-farm biofactories and survey of potential biological hazards in the production of bioinputs

Perfil das biofábricas *on farm* e levantamento dos perigos biológicos potenciais na produção de bioinsumos

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ABSTRACT

Introduction: To meet the growing productive sector and society's demand for bioinputs as alternatives in agricultural systems and for even more sustainable products, Decree No. 10,375 was published in May 2020, which created the National Program of Bioinputs. **Objective:** Considering the importance of the program's purpose, which is to expand and strengthen the use of bioinputs in the country to benefit the agricultural and livestock sectors, and since the program is an instrument of Brazilian Agricultural Policy, it is proposed to investigate the program implementation concerning one of its main tools, the biofactories. **Method:** Taking a sample, the investigation maps and traces a profile around the working conditions of some biofactories installed in properties that produce their own bioinputs (on farm system), through the use of a research survey, as a standardized technique for data collection. **Results:** Weaknesses were found in on farm manufacturing processes. The information generated, mainly regarding the potential dangers inherent in the manufacture of bioinputs and raised by this study, can be used for supporting decision making and program improvement. **Conclusions:** The results of this research intend to contribute to the improvement of the entire process, so that it works as a tool to guide and prioritize the actions to be carried out by the actors involved. Bioinputs must, in fact, be well managed in order to reflect their benefits with low risk.

KEYWORDS: Biofactories; Bioinputs; Biological Security; Health Risk; Public Policies

RESUMO

Introdução: A fim de atender à crescente demanda do setor produtivo e da sociedade em buscar alternativas de insumos de base biológica para os sistemas agropecuários e de produtos cada vez mais sustentáveis, em maio de 2020, foi publicado o Decreto no 10.375, de 26 de maio de 2020, que criou o Programa Nacional de Bioinsumos (PNB). **Objetivo:** Dada a importância da finalidade do programa, qual seja ampliar e fortalecer a utilização de bioinsumos no país para beneficiar o setor agropecuário e, uma vez que o referido programa é um instrumento da Política Agrícola Brasileira, propõe-se investigar a implementação do programa no que diz respeito a uma de suas principais ferramentas, as biofábricas. **Método:** A investigação mapeia e traça um perfil das condições de funcionamento de uma amostra de biofábricas instaladas em propriedades que produzem os seus próprios bioinsumos (sistema *on farm*), por meio do uso de um questionário, como técnica padronizada para coleta de dados. **Resultados:** Verificaram-se fragilidades nos processos produtivos dos bioinsumos fabricados em sistema *on farm*. As informações geradas, principalmente as referentes aos perigos potenciais inerentes à fabricação dos bioinsumos e levantadas por este estudo, podem ser usadas para subsidiar a tomada de decisões e o aprimoramento do programa. **Conclusões:** Os resultados desta pesquisa visam contribuir com a melhoria de todo o processo, de forma que sirva de ferramental aos atores envolvidos para guiar e priorizar as ações a serem conduzidas. Os bioinsumos devem, de fato, ser bem manejados a fim de refletir os seus benefícios com baixo risco.

PALAVRAS-CHAVE: Biofábricas; Bioinsumos; Segurança Biológica; Risco à Saúde Humana; Políticas Públicas

INTRODUCTION

Bioinputs, according to the definition provided by the National Bioinputs Program (PNB), are biologically-based products, processes, or technologies intended for use in the production, storage, and processing of agricultural products, aquatic production systems, or planted forests, which positively interfere with the growth, development, and response mechanism of animals, plants, microorganisms, and derived substances and which interact with physical-chemical and biological products and processes[1].

This program, created by Decree No. 10.375 of May 26, 2020, aims to expand and strengthen the use of bioinputs in Brazil[1] and, to this end, provides a strategic set of actions for the development of alternatives for agricultural production, considering the economic, social, productive, and environmental dimensions. One of the PNB's guidelines is to encourage the adoption of sustainable assets based on the use of technologies, products, and processes developed from renewable resources, through integrated action by the science, technology, and innovation sectors and the productive sector[2].

Another one of the PNB's guidelines is to value Brazilian biodiversity which, once it is known, has great potential to be exploited in a sustainable way[1], with the aim of controlling pests, improving soil conditions, and strengthening cultivated plants. Brazil's megabiodiversity can be considered an instrument with many possibilities for generating alternative solutions to be used in the field[3], such as biological control of pests and diseases, biostimulants, and biofertilizers.

Among these alternatives, the program encourages the implementation of biofactories, defined as bioinput production units, which are considered to be one of the program's main instruments. Albuquerque and Silva[3] stated that "exploiting the potential of Brazilian biodiversity, combined with the technologies and entrepreneurial vision of biofactories, is the basis for a new type of agribusiness".

For some time now, even before the existence of the PNB, family farmers have been producing bioinputs on their farms. The production of bioinputs for own use is carried out by the rural producer for use on the farm itself for the intended purpose, and the sale of bioinputs manufactured there is prohibited. In recent years, large commodity producers have also started producing bioinputs for their own use on their farms, given the high demand for this type of product[4]. Another factor that has encouraged on-farm production is the possibility of exempting the product from registration when the result of manufacture is exclusively for own use, without commercial purposes. This regulatory opening began in July 2009, with the publication of Decree No. 6.913, of July 23, 2009, which amended Decree No. 4.074, of January 4, 2002[5]. Paragraph 8 of Article 1 of Decree 6.913/2009 stipulated that phytosanitary products approved for use in organic farming and produced exclusively for their own use were exempt from registration. Since this Decree, there has been a significant increase in the production of products of microbiological origin on farms, also known as on-farm production[6].

With the advent of the PNB, regulations were proposed to exempt bioinputs manufactured for their own use from registration, even if they are for use in conventional agriculture. Thus, Decree No. 10.833, of October 7, 2021, which amended Decree No. 4.074/2002, established that phytosanitary products with approved use for organic farming produced exclusively for their own use in organic or conventional production systems are exempt from registration[7]. This clearly encourages this type of self-production on both organic and conventional properties.

Given that biofactories have been expanding rapidly[8], the strategy of mapping and monitoring them can be a good way of monitoring important aspects of the PNB, such as the pace of implementation and the achievement of certain intended results. Furthermore, biofactories should be monitored because of their productive nature and the potential risks they pose to public health, given that the current paradigm combines productivity with product quality and safety for humans and the environment. The object of this study was therefore biofactories and how they function in the context of the PNB. A mapping of the biofactories installed on rural properties that produce their own bioinputs, also known *as on-farm* production, was carried out to draw up a profile. In particular, we investigated the possible negative impacts on human health and the environment and their respective negative externalities in the case of the use of bioinputs that could escape quality control in terms of biological safety parameters, such as the occurrence of contaminants and human pathogens of public health importance.

This study also started from a gap in the existence of a database on biofactories in rural establishments that practice on-farm production.

METHOD

This is a descriptive study with a quantitative approach, as it was necessary to specify the attributes and characteristics of the object under study - biofactories - using standardized data collection techniques, such as questionnaires[9].

In order to collect data, a questionnaire designed and placed on a virtual platform (Microsoft Forms) was applied through the Associated Group for Sustainable Agriculture (GAAS - https://gaasbrasil.com.br/), a national association of farmers. This group has around 650 members, but the association does not have information on how many of these producers manufacture bioinputs on-farm.

The data collection tool was sent to the 650 members and was aimed exclusively at rural producers who manufacture their own bioinputs (on-farm). The questionnaire was made available for

one month (from February 14 to March 14, 2022) and 27 respondents returned it. Although it was not compulsory to fill in the form, the information collected was sufficient to draw important insights and developments.

It should be noted that, despite the 27 respondents, the total number of biofactories mapped corresponds to 30 biofactories, as one of the producers reported having four bioinput production units on farms located in different cities.

The questionnaire presented questions divided into sections to map the number of biofactories, where the farms that produce bioinputs on-farm are located, how this production takes place, and what the controls are in the process.

The following are the sections of the questionnaire that were explored in this article: 1 - Identification of the Rural Property and the Biofactory; 2 - Characterization of the Biofactory; 3 - Human Resources of the Biofactory; and 4 - Control of the Biofactory Processes.

The data was extracted from Microsoft Forms into a spreadsheet (.xls) so that it could be treated and analyzed using descriptive statistics. Frequencies in percentages and graphs were used to summarize the data.

In compliance with ethical precepts and in order to preserve the identity of the respondents, they were presented with an informed consent form to agree or not. Once they had accepted, the questionnaire was opened so that they could continue answering the questions.

This article is an excerpt from the dissertation[10] presented at the Professional Master's Program in Evaluation and Monitoring of Public Policies, at the National School of Public Administration (Enap), from 2020 to 2022.

RESULTS AND DISCUSSION

Of the 30 biofactories mapped, there was a concentration of them in the Southeast and Midwest regions, with more in some states of the federation, such as: Minas Gerais with six units, São Paulo with four, Goiás with four, and Mato Grosso do Sul with three. The map shows where these on-farm biofactories are located throughout Brazil (Figure 1).

Considering that one of the program's structuring actions is to encourage the implementation of bioinput factories throughout the country, especially in the North, Northeast, and Midwest regions[11], one would expect a real increase in the number of biofactories, especially in these regions which are even more in need of sustainable alternatives for agricultural production, given the deficit and vulnerability in terms of food security in some states. However, it can be seen from Figure 1 that the study showed that there is a gap in the North and Northeast regions.

Historically, there has been a socioeconomic disparity in the North and Northeast regions of the country, which deserve greater attention and monitoring during the implementation of this type of public policy because, as Vidal et al. have pointed out[1], it is well known that a large part of the production of bioinputs is currently concentrated in the south-southeast axis of Brazil.

It's worth noting that of the 27 respondents, the majority (19) are conventional farmers. As for the others, two are organic farmers and six said they were in transition. With this, it is possible to see and corroborate what the literature says about bioinputs actually being a reality in Brazil, beyond the organic farming sector which initiated this demand[12]. Sustainable agriculture has indeed been practiced by conventional farmers, with a clear demonstration of increased adoption.

Not only should the production system be taken into account in this analysis, but also the size of the properties and the cultivable area where bioinputs are applied. To this end, three questions were asked for characterization purposes, namely how many hectares the rural property has, how many hectares the cultivated area has, and how large is the area (in hectares) in which the bioinputs are applied.

When it comes to the size and classification of rural property in Brazil, it should be said that the characterization as small, medium, or large is defined by law and has some variables and parameters. There is a unit called a fiscal module and its concept was introduced by Law No. 6,746 of December 10, 1979. Law No. 8,629, of February 25, 1993, uses the fiscal module as a basis for determining that a small property has between one and four modules, a medium-sized property has between 4 and 15, and a large property has more than 15. Furthermore, the size of the fiscal module is variable and is defined for each municipality, depending on a series of factors[13].

Source: Prepared by the authors, 2023.

Figure 1. Distribution of the biofactories studied with on-farm production through Brazilian territory in 2022.

Based on the responses received, it can be said that the vast majority (74.0%) are large farms, 22.0% are medium-sized, and 3.7% are small. Thus, in addition to the prevalence of conventional farmers in this sample, most of them are also large properties. In addition, 18 (66.6%) of the 27 producers apply bioinputs in an area equivalent to the entire cultivated area reported. All of this indicates a trend toward the use of bioinputs by this group of producers.

An important interpretation can be made from question 6 of the questionnaire about when the biofactory started operating. It was found that 48.0% of on-farm biofactories were installed before the publication of Decree No. 10,375/2020. This result allows us to say that, even before the Decree, some producers were already betting on the use of bioinputs and implemented the manufacture of these on their properties, indicating that the movement towards more sustainable agriculture was already a trend.

Next, a question was asked about the purpose of using the bioinputs produced in the biofactory. The question had several options for marking the answer (more than one option could be chosen) - Biological control of pests and diseases, Biofertilizer, Bioinoculant, Growth promoter or regulator, Other (open).

All the producers use the bioinputs manufactured for the biological control of pests and diseases, which is historically the most common use. Furthermore, 74.0% of respondents use bioinputs for this type of control and for at least one other use.

According to Figure 2, biofertilizer is the second most used product, which is in line with the literature on its growing use[14].

There is a real interest in biofertilizers, as producers believe they can benefit from cost savings when compared to synthetic fertilizers, and consequently contribute to reducing negative environmental impacts[15].

Furthermore, the fact that producers use bioinputs for various functions, 70.0% of them for at least three of the options presented, confirms that their application in the field can be systemic and beneficial.

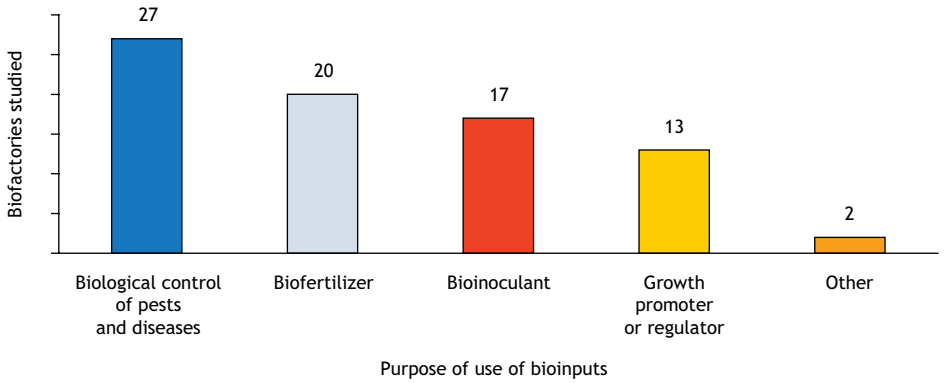
Another question asked of the producers was which species of organism(s) are used as the basis for the bioinputs produced. Regarding this question, it should be noted that production can take place by replicating commercial products purchased on the market, by multiplying microorganisms obtained from germplasm banks, or by means of pre-inocula prepared and sold by specialized companies[8].

It was found that all the producers who responded work with more than one microorganism in their own production. Among the responses, the use of bacteria of the genus *Bacillus* and the fungi *Beauveria bassiana* and *Metharizium anisopliae* prevailed, as well as those of the genus *Trichoderma*, organisms that have already been widely used in the field for some years. It is worth pointing out a concern about on-farm production with multiple microorganisms, which will be discussed further below when dealing with the necessary in-process controls.

The next question asked which agricultural crops the manufactured bioinputs are applied to. It was found that the crops most often mentioned by producers are corn and soybeans, as can be seen in Figure 3. In addition to these, there is a relatively wide range of applications, which can be seen from the column in the "other" category, which includes crops such as sesame, oats, carrots, tomatoes, rice, barley, among many others, mentioned at least once in the answers. Fruit trees include citrus, strawberries, and bananas. Others that were mentioned less often, but were mentioned significantly, were pastures, sugar cane, beans, wheat, sorghum, and coffee.

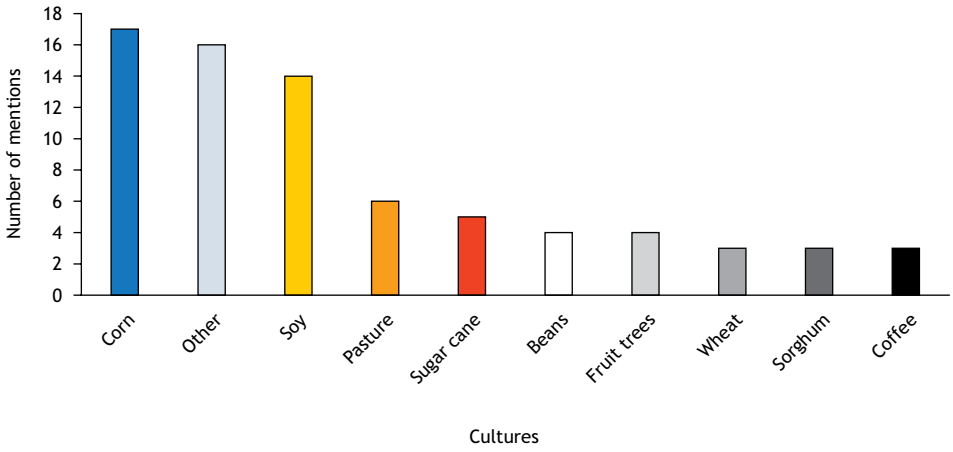
The third section of the questionnaire, relating to the human resources involved in biofactories, asked about the number of people involved in the production of bioinputs: 19 of the 27 respondents, or 70.0%, have only one or two employees involved in production. The rest of the answers varied between three, four, five, or seven people involved in the manufacture of bioinputs.

More than the quantity, it was also interesting to know about the training process of these employees, after all, the multiplication of organisms involves a series of technical skills so that



Source: Prepared by the authors, 2023.

Figure 2. Different uses of the bioinputs produced in the on-farm system by the biofactories studied in 2022.



Source: Prepared by the authors, 2023.

Figure 3. Crops mentioned by producers to which the bioinputs manufactured by the biofactories studied in 2022 are applied.

everything goes as expected. To this end, we asked about the training process for employees involved in the production of bioinputs. The majority indicated that they had received training from partners, such as the Brazilian Micro and Small Business Support Service (SEBRAE) or the Brazilian Agricultural Research Corporation (EMBRAPA), from consultants or specialized technical advisors, or from the company that supplies the equipment and inoculums. In other words, this result shows the concern to train the staff involved in on-farm bioinput factories with a minimum of technical support.

They were also asked about having a technical manager for the production of bioinputs, a principle already recommended by EMBRAPA[8] for this purpose. Twenty-one of the 27 respondents said they had a technical manager for the biofactory. Of the almost 80.0% of producers in our sample who said they had a technical manager, it was possible to find out a little about this professional's training based on the answer options presented in the next question. This revealed that 13 of them are agronomists, three are agricultural technicians, two are biologists, and another three indicated other backgrounds. In other words, in general, these answers indicate that there is a concern to entrust this responsibility to someone more specifically qualified, which is very important and demonstrates a practice to be followed.

The next section was related to the biofactory's in-process controls, with a focus on biological safety concerns. In order to map the existing controls during manufacturing, the question was asked about which parameters are monitored during the manufacturing process for the purposes of quality control of production at the biofactory, for which there were several possible options to be marked: temperature, pH, toxins, identification of the organism, concentration of the microorganism/type of active ingredient, determination of contaminants, and other (open field).

First of all, seven of the 27 responses indicated a warning. Two of the biofactories control temperature and pH, another two only temperature, one only does "visual control", another "color and odor", and finally there was one answer that indicated that no control was carried out. Of these, it stands out that the biofactory that only carries out visual control is multiplying organisms from the forest, i.e. it is not known exactly what is being multiplied. Multiplying organisms found in nature without proper characterization and knowledge of their virulence, the production of possible relevant toxins, and other characteristics can lead to threats to human health and the environment[16].

Another example was the producer of a biofactory who answered that they carry out controls based on the parameters of color and odor - this producer indicated earlier in the question about which organisms are the basis of the bioinputs that they use the genus *Bacillus*, which is quite broad, the genus of fungi *Trichoderma*, and specified others with the species *M. anisopliae* and *Beauveria bassiana*. Thus, the controls of this biofactory can be very superficial given the great diversity of microorganisms that are worked with in the facilities, leaving room for contamination, lack of product efficacy, among other shortcomings.

These difficulties in standardizing the production system and establishing quality control measures were exposed in the study by Valicente[17]. In it, the consequences of these weaknesses are presented and, as a result, in some samples collected from properties in the state of Mato Grosso, contamination by microorganisms of the *Microbacterium* genus was detected, some species of which are resistant to multiple antibiotics, and the prevalence of *Enterococcus casseliflavus* and *Enterococcus gallinarum*, which is alarming as they are associated with endocarditis and meningitis in humans.

Considering the need to maintain the quality of the organisms manipulated in a biofactory, so that they are identified and well preserved, we asked how the biological material that serves as a bank/working collection for the manufacture of bioinputs is maintained/preserved. Based on the answers, some producers seem to be unaware of the concept of a working collection or the importance of this type of maintenance. There were answers

such as “there is no standard” or “it is not done”. Several others replied that they only keep it in a cold room or refrigerated, whereas the care taken to maintain a working collection goes beyond that.

Furthermore, one of the concerns when working with products based on microorganisms is the possibility of biological contamination. We therefore asked what measures are in place to avoid biological contamination during the production process. As already explained in this study, if production is carried out under inadequate conditions, one of the most serious risks is the proliferation of contaminants and pathogens that are undesirable for the environment and human health. The vast majority of respondents described the care taken to clean and disinfect the environments and equipment used to ferment the organisms. Some also indicated that care was taken to use appropriate personal protective equipment (PPE), such as gloves and masks, as well as restricted entry to the manufacturing site.

Finally, the last question in this section asked about protocols to be followed if contamination is detected during or after the manufacture of the bioinput. The vast majority indicated that the procedure to be taken is disposal, however, no further details were provided about this destination, which could be a worrying point.

Only two of the 27 responses said that they carry out an analysis to check what caused the problem and proceed with the necessary corrections, as well as directing the contaminated residual in a different way if the contaminant is a pathogen. One respondent said there was no standard in the event of a contamination incident. One said there was no procedure for this, as the laboratory analysis always arrives after the bioinput has been used. In other words, if there is a contaminant, it would have already been released into the environment and possible negative impacts could be generated from this action.

This is a serious and important issue because, in this small sample space, there is generally no concern about what should be done in the event of contamination and the consequences of this possibly inappropriate disposal, without proper verification, investigation, and microbial inactivation where necessary.

In order to ratify the importance of these issues raised, Bocatti et al.[18] carried out analyses of inoculants based on *Bradyrhizobium spp*. and *Azospirillum brasilense* produced in an on-farm system which revealed a high contamination with non-target organisms. Eighteen samples were collected from farms in five different Brazilian states.

After due analysis, it was found that many of the bioinputs did not contain the organism of interest and, what is worse, contained species potentially pathogenic to humans, which were dominant during multiplication to the detriment of the target microorganism. The authors warned of the importance of ensuring minimum procedures during this type of microorganism multiplication so that the organism of interest prevails in the culture medium used[18].

The Decree establishing the program provides for the publication of a manual of good practices for bioinput production units - biofactories, to be promoted throughout the country[2]. Also among the structuring actions is the encouragement of the development of manuals of good practice in the production, use, and application of bioinputs in partnerships with public and private institutions[11].

In this sense, there is a regulatory gap, since this planned manual has not yet been released to technically subsidize the manufacture of bioinputs in biofactories. It is possible to find technical-theoretical material containing guidelines that apply to the manufacture of some types of bioinputs, such as the guide published by EMBRAPA on the production and quality control of biological products based on *Bacillus thuringiensis* for use in agriculture[19]. However, officially, during the implementation of the program and to date, there has been no publication to this effect covering other types of bioinputs.

It is worth mentioning a Technical Note issued by EMBRAPA[8], published on November 17, 2021, which sets out three basic principles to be observed when producing biological inputs by on-farm producers:

only use microorganisms that appear on the official lists of the Ministry of Agriculture, Livestock and Food Supply (MAPA), or with reference specifications, and that are acquired from germplasm banks recognized as official by the Ministry, in order to guarantee the reliability of origin and efficacy;

the existence of a register of establishments producing bioinputs with MAPA to enable traceability in the event of any problems arising from production;

the need for a qualified and properly trained technical manager on farms for the production of bioinputs.

Therefore, in addition to these recommendations and guidelines, a more complete manual containing the minimum standards for a biofactory is essential in order to manage the risks involved in public health, food safety, and environmental balance.

CONCLUSIONS

This research has promoted an unprecedented survey of on-farm biofactories, seen as a potential instrument for changing the key to agricultural practices. It is therefore necessary to know where the biofactories are, how they produce, to what extent they can benefit producers and consumers, among other aspects. Furthermore, this study also proposed an evaluation parameter for the PNB, since biofactories are one of its instruments.

Given the contributions of this research, it was found that there is an urgent need to spread the manufacture and use of bioinputs. However, caution is needed, as the lack of regulation for biofactories/on-farm production and parameterization of production processes can lead to a drop in the quality of bioinputs and the generation of negative effects on human health and the environment.

It is essential that better defined guidelines are made available so that producers can be confident when practicing the on-farm production of bioinputs, because what we see today is a low capacity for control.

The risks of manufacturing without proper quality control and monitoring are worrying. The motto of biodiversity for agriculture can turn from an opportunity into a problem, both for public health and for discrediting consolidated and promising technologies for the sustainability of agricultural systems.

The issue of biological safety has been a concern throughout this work. Even among the major producers, there were weaknesses in the production of bioinputs that call into question Brazil's potential to continue to lead the world in this area, even though the country has all the favorable conditions to do so.

Problems with contamination in products from crops where bioinputs produced without good practices are applied can, for example, have a negative impact on Brazilian exports as soon as they are tested and rejected according to the importing country's control parameters. Bioinputs must, in fact, be well managed in order to reflect their benefits at low risk.

For this type of production, suitable technical conditions and quality control must be in place to prevent the multiplication of species that are not effective for the proposed purpose or of species that are pathogenic and/or generate toxins that are relevant from the point of view of human health.

In order to make it possible to monitor biofactories regarding the aspects raised, there is an urgent need for a national register of producers who produce bioinputs on farm in order to track down non-compliances that could cause health, environmental, and/or occupational accidents.

Finally, given that MAPA, the program's coordinating body, is responsible for monitoring and following up on the results achieved and supporting the stages of reviewing and redirecting the program, this research can contribute to achieving this competence.

As for the factors that limited this research, the main one was the lack of a national register of on-farm bioinput producers. This gap made it difficult to locate the biofactories set up for the purpose intended in this study.

Regarding the sample, despite the novelty of the diagnosis carried out, it can also be said that it cannot be generalized, since we have no real idea of the sample universe to state its significance.

Access to the data of bioinput producers was also somewhat limited due to information protection issues and the internal policy of the association, which kindly made it possible to administer the questionnaire to its members.

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Authors' Contribution

Xavier VL - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the paper. Rodrigues RWS - Planning (study design) and writing the paper. All the authors approved the final version of the paper.

Conflict of Interest

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

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