AGRICULTURAL POLICIES IN DEBATE

Bioinputs in Brazil

Market and Compliance

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With support from

Federal Ministry of Food and Agriculture

by decision of the German Bundestag

MINISTRY OF AGRICULTURE AND LIVESTOCK

BRAZILIAN GOVERNMENT
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Implemented by

GFA CONSULTING GROUP
General Agent BMEL Berlin Office

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FGV EESP ESCOLA DE ECONOMIA DE SÃO PAULO

OBSERVATÓRIO DE BIOECONOMIA

São Paulo, October 2023.

ABOUT THIS STUDY

This study is used as a reference document for the APD | AGRICULTURAL POLICY DIALOGUE BRAZIL - GERMANY. The content of this study is the sole responsibility of the authors, and any opinions expressed herein are not necessarily representative or endorsed by APD.

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1. Introduction

Bioinputs have gained increasing attention and relevance in Brazil. The development of new bio-based products is a growing trend in the Brazilian market. Brazil is a global leader in the employment of bioinputs in agriculture. With the advancement of production and incorporation of bioinputs into agriculture, Brazil tends to benefit economically and environmentally.

At the same time, the widespread use of bioinputs brings involves particular concerns. On the one hand, bioinputs are, very often, prepared directly on the farm by producers. The free handling of bio-based products, without clear safety and quality parameters, has sparked off debates about contamination risks, health and market credibility.

On the other hand, the mere application of the current laws to regulate chemical products risks hindering the innovation and use of products which are generally more beneficial to the health and the environment. To respond to these concerns, Brazil has been, step by step, developing a regulatory framework for bioinputs. Today, two bills on bioinputs are pending vote in the Brazilian Congress: one in the House of Representatives and the other in the Federal Senate.

The purpose of this study is to describe the general status of bioinputs in Brazil. This study is divided into two main sections.

The first one is economic. The objective of this section is to understand the advancement of the "bioinputs market" in Brazil, based on two complementary analyses. The "macro" analysis presents general data on the bioinputs market and the employment of bioinputs in Brazil. The micro analysis focuses on an exemplary case of bioinputs: nitrogen fixation in corn farming.

The second section is regulatory. It provides an overview of the regulatory framework for bioinputs in Brazil. Firstly, it describes how Brazilian legislation has advanced, step by step, over the last 20 years, in terms of Brazilian bioinputs. Secondly, it analyzes the regulatory debate underway in Brazil, especially based on bills of law pending vote in the National Congress.

2. The market of bio-based inputs

The term "bioinput" is commonly used in Brazil as a synonym for bio-based product in agriculture and livestock farming. This term is generally used for bioinsecticides, biofertilizers and inoculants, for example. However, it has a much broader potential for application, covering not only agricultural systems, but also animal production and the processing of plant - and animal - based products (VIDAL et al., 2020).

On the international scene, initiatives seek to coordinate actions and understand the current state of this topic in different nations. Attempts to align concepts, establish essential tests for registration, promote new registration procedures that consider the multiple functionalities of bioinputs, adjust regulations and standards, create lines of support for the progress of bioinputs are some of the ongoing discussions in international forums (VIDAL et al., 2020).

Upon the release of the National Bioinputs Program, approved by Decree No. 10375 of 2020, the Ministry of Agriculture and Livestock (MAPA) adopted a comprehensive definition of bioinputs in Brazil. Bioinputs are, as defined by MAPA (2023), products, technologies or processes of plant, animal or microbial origin that are used in agriculture, livestock farming and in other activities related to the environment.

These inputs are derived from living organisms or their residues, such as bacteria, fungi, algae, plants and animals, and are intended to improve agricultural activity, serving as active ingredients aimed at plant nutrition, plant growth promoters, mitigators of biotic and abiotic stresses and antibiotic substitutes.

2.1. Macroanalysis

Bioinputs can be classified according to their purpose, namely: (i) **biological control inputs**, subdivided into macrobiological inputs (e.g., insects, mites and nematodes), microbiological inputs (e.g., bacteria, fungi and viruses) and biochemical and semiochemical inputs (e.g., plant strata, pheromones, enzymes and peptides); (ii) **growth promoters** (e.g., inoculants, biostimulants and biofertilizers); (iii) **products for veterinary use** (e.g., microorganisms and vaccines).

Biological control

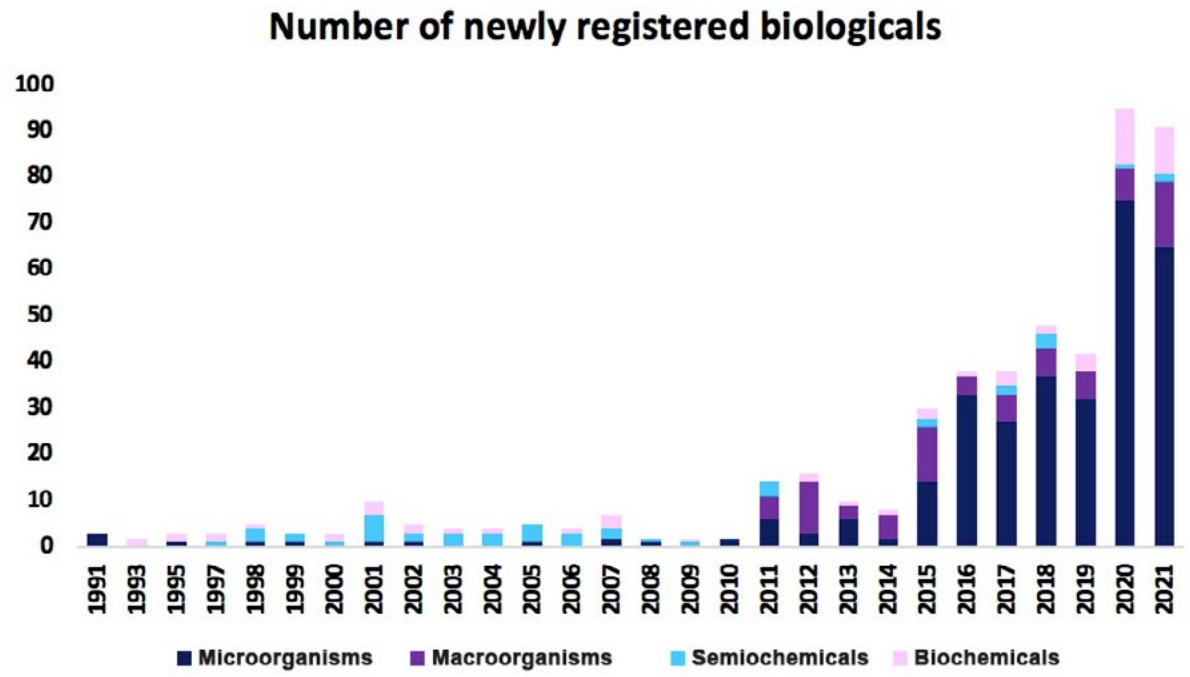
Biological control can be considered the use of some organism to reduce the population density of another, thus controlling diseases, pests, and invasive plants in agriculture and veterinary public health (Bettiol, 2022). In Brazil, the biological control inputs saw a turning point from 2005 and 2014, with important changes in the registration of biological control products, which resulted in an increase in registered products, as well as in the creation of new companies in the segment. Additionally, the foundation of the Brazilian Association of Biological Control Companies (ABCBio) marked the establishment of biological control in the country (Bettiol, 2022).

According to data from CropLife (2021a), by the end of 2021, 497 biological control products were registered in Brazil, for action on more than 200 biological targets. Among the registered products, 63% are classified as microbiological agents, approximately 16% are macrobiological agents, 12% are biochemical agents and approximately 9% are semiochemical agents. It is worth noting that biological ingredients of animal, plant, microbial origin or those resulting from technological processes that make them identical or structurally similar to these are classified as biochemical or semiochemical agents. Microbiological agents are living or inactivated unicellular organisms naturally occurring or obtained through genetic manipulation. Finally, products from living macroorganisms, naturally occurring or resulting from genetic manipulation, are classified as macrobiological agents (BORSARI E VIEIRA, 2022).

In fact, an exponential increase in the number of new biological control products registered in Brazil is seen in the 2010s, which can be explained by the outbreak of the *Helicoverpa armigera* caterpillar that affected important soybean areas in Brazil in 2013.

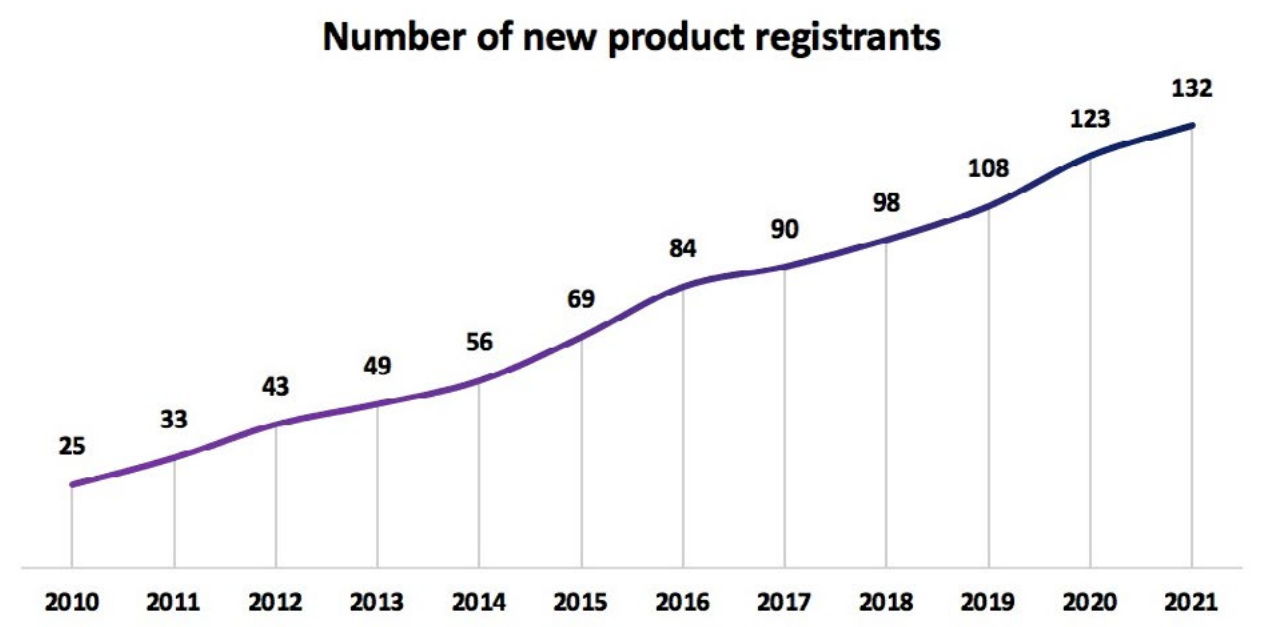
At the time, bioinsecticides demonstrated efficiency in control, resulting in intensification of investments in research and development, consequently generating an increase in technological innovation and launches of new products (BORSARI E VIEIRA, 2022).

Figure 1 – Number of new bioinputs registered in Brazil.



Source: MAPA.

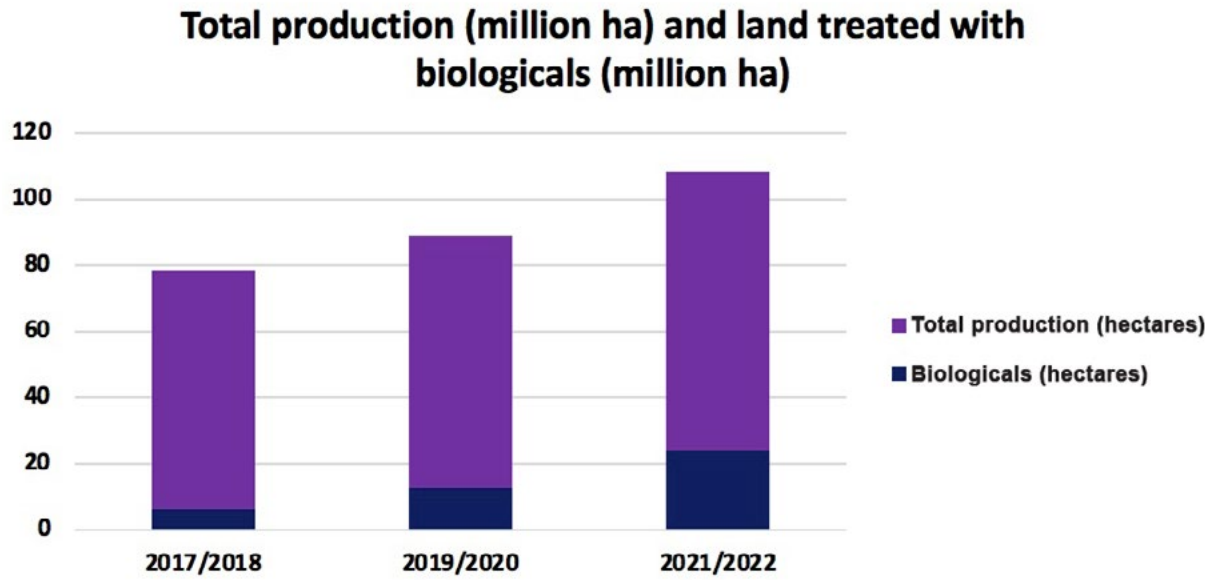
Figure 2 – Number of companies registering new biocontrol products in Brazil.



Source: MAPA.

The dissemination of biologicals in Brazil can also be seen in the growing increase in the land treated with this class of biological input. In 2017/2018, the land treated with biologicals covered around 9% of the total production of grains, sugar cane and coffee. In the following period, in 2019/2020, the use of biologicals was present in more than 17% of total production. More recently, in the 2021/2022 harvest, the use of biologicals covered around 28% of total production, accounting for more than 24 million hectares.

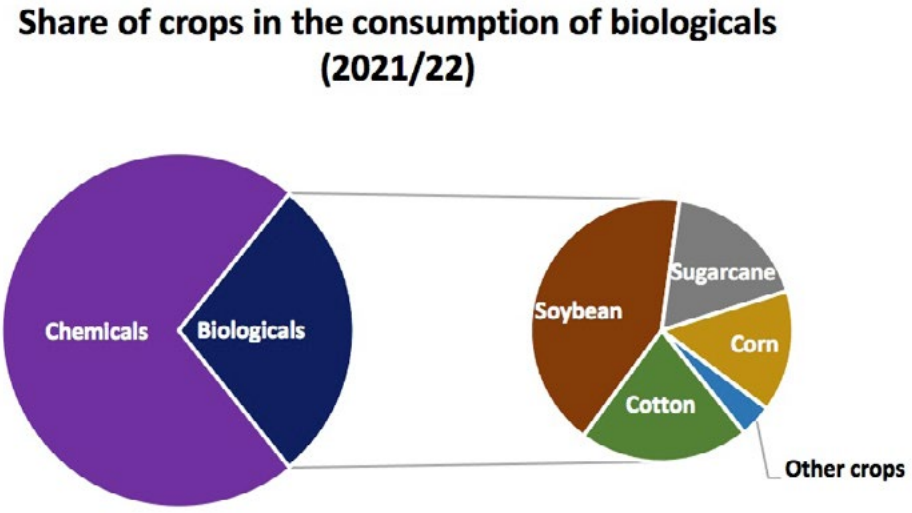
Figure 3 – Total production (in millions of hectares) and land treated with biologicals (in millions of hectares).



Source: prepared by the author based on CropLife (2021b) and CONAB.

Considering the share of biopesticides in the total production of grains, sugar cane and coffee in the 2021/22 harvest, soybeans are the crop in which biologicals are most present - accounting for around 42% of what is used in the Country - followed by cotton (21%), sugar cane (18%) and corn (15%). The other crops account for 4% of biologicals used in Brazil, according to data from CropLife (2021b).

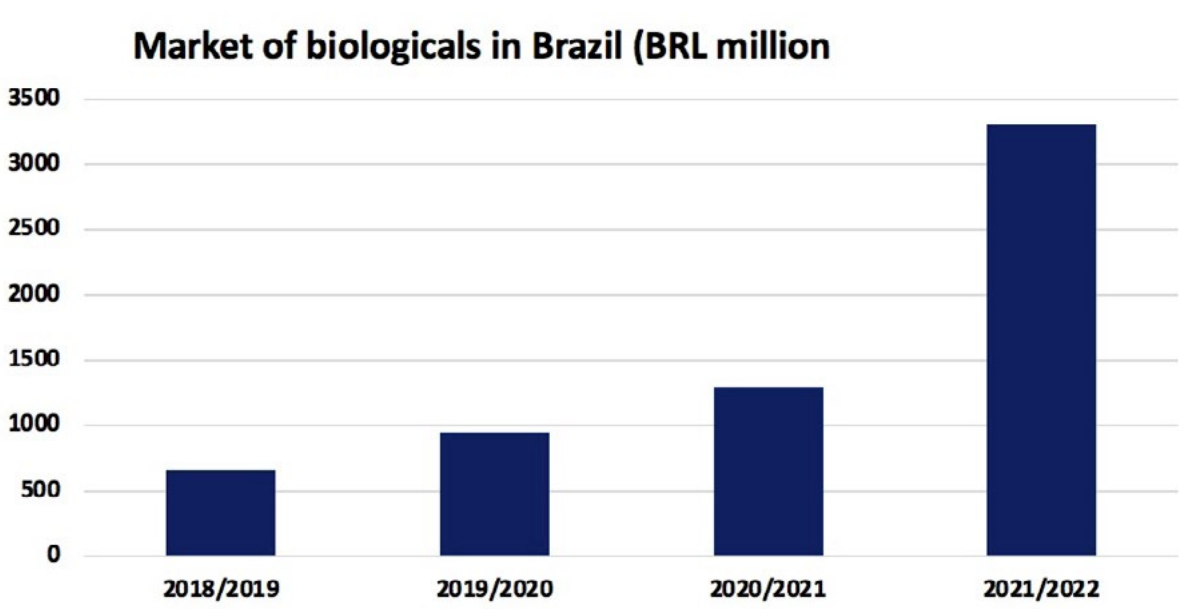
Figure 4 – Share of crops in the consumption of biologicals in the 2021/22 harvest.



Source: CropLife, 2021b.

Biologicals drive a market that has grown significantly over the past years. According to Borsari and Vieira (2022), in 2020/2021, the market of biologicals totaled BRL 1.3 billion, up more than 37% compared to 2019/20. Impressively, a recent study carried out by CropLife with S&P Global has found that the value of the Brazilian biologicals market was estimated at around BRL 3.3 billion for 2021/2022, up 219% compared to the previous harvest (CROPLIFE, 2022).

Figure 5 – Biologicals market in Brazil (in millions of BRL).



Source: Borsari and Vieira, 2022.

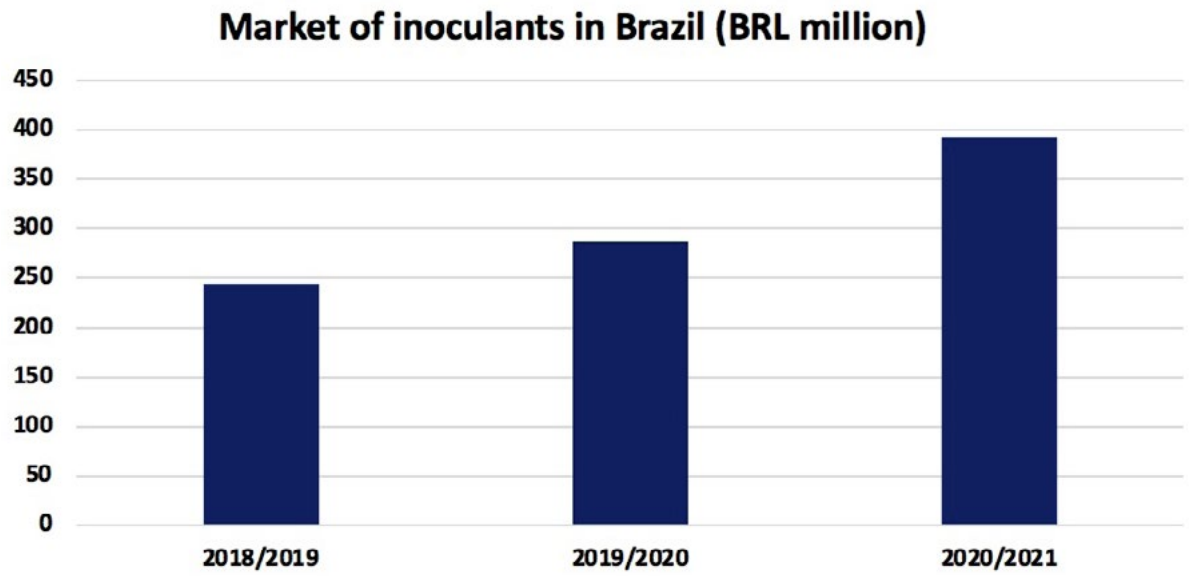
This market is expected to grow in Brazil, because the rate of bioinputs used by Brazilian farmers is around 28%,[1] which makes its expansion possible. Also, from the farmers' point of view, 58% of them believe that this market should advance in the coming years.[2]

Growth promoters

Growth promoters - such as inoculants, biostimulants and biofertilizers - are responsible for stimulating the development and healthy growth of plants by improving nutrient absorption, stimulating root growth, strengthening the immune system against pathogens, increasing resistance to environmental stress and promoting the production of plant hormones that influence plant growth and development.

The Brazilian inoculants market - dominated by nitrogen fixers, which represent 80% of this market - exceeded BRL 280 million in the 2019/2020 harvest, up 17% compared to the previous period. In 2020/21, the growth rate jumped to almost 37%, totaling BRL 393 million (BORSARI and VIEIRA, 2022).

Figure 6 – Inoculants market in Brazil (in millions of BRL).



Source: Borsari and Vieira, 2022.

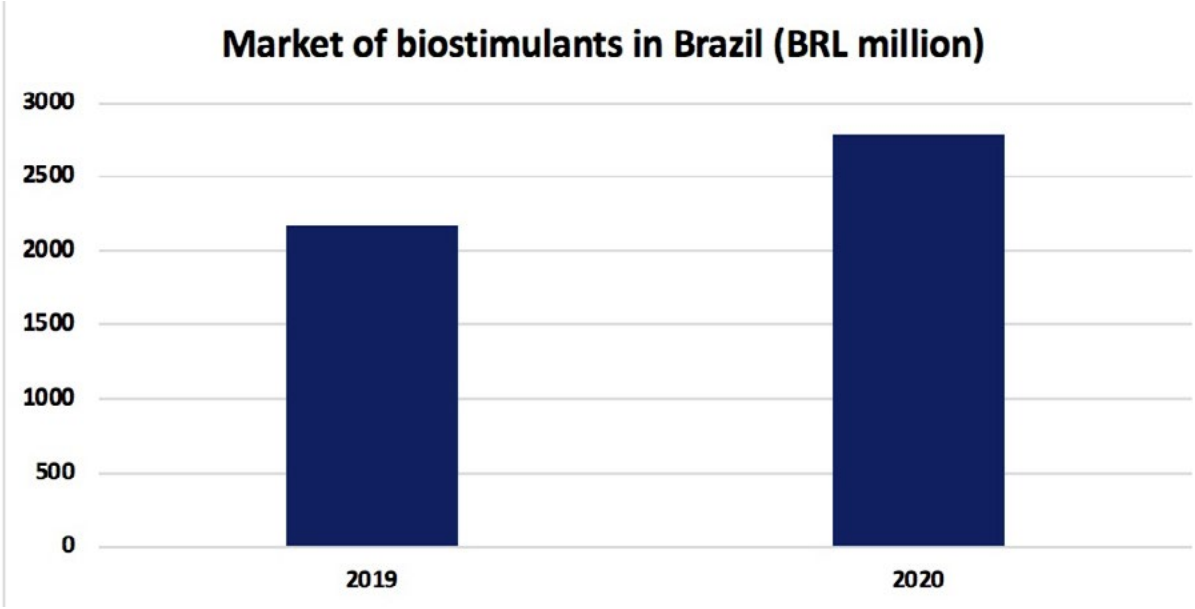
1 See: https://globorural-globo-com.cdn.ampproject.org/c/s/globorural.globo.com/google/amp/opiniao/vozes-do-agro/noticia/2023/05/bioinsumos-mercado-de-r-17-bilhoes-ate-2030.ghtml.

2 See: https://croplifebrasil.org/noticias/biodefensivos-cada-vez-mais-presentes-no-campo/.

The classification of "biostimulant" is not recognized by the Brazilian legislation, lacking clear indications of the necessary requirements and an authority in charge. However, this terminology has gained popularity over the recent decades, in reference to substances present in foliar fertilizers that aim to provide improvements not connected to nutrition, such as tolerance to abiotic stresses, increased crop quality and efficiency gains in nutrient absorption. As a consequence of the lack of legislation for this terminology, from a technical point of view, the outcome of this is an inconsistency, since there are other growth promoters that also have "stimulating" effects (BORSARI and VIEIRA, 2022).

This confusion creates difficulties in measuring the biostimulants market in Brazil. However, the Brazilian Association of Plant Nutrition Technology Organizations estimates that the market for foliar fertilizers containing biostimulant substances reached a value of BRL 2.7 billion in 2020, 28% higher than the previous year.

Figure 7 – Biostimulants market in Brazil (in millions of BRL).



Source: Borsari and Vieira, 2022.

Veterinary products

The term "bioinput" is mostly associated with agricultural systems, hiding its great potential for application in animal farming, for example. Some veterinary products are also considered bioinputs, such as inputs for the prevention, diagnosis and treatment of animal diseases (e.g., vaccines, medicines and antiseptics), products for animal

beautification and food products from plant, animal or microbial materials that comply with organic and sustainable production legislation (CROPLIFE, 2021c). However, regarding veterinary products, the main challenge lies in understanding the category, as it is still difficult to find data about the bioinputs used in this sector.

2.2. Microanalysis: a case study

Microorganisms of the genus *Azospirillum* are known to promote benefits for agricultural crops through their biological nitrogen fixation (BNF) capacity. With BNF, nitrogen (N) - an essential macronutrient for plant growth - is captured from the air and fixed in the plant through biological processes.

In the case of legumes, such as soybeans and beans, for example, BNF is a natural process of plant-bacteria interaction, in which root structures – nodules – are formed and where fixation occurs. Recent studies have shown the economic and environmental potential associated with BNF in soybean production in Brazil. Telles et al. (2023) estimate that the cost avoided by replacing chemical fertilizer (urea) with BNF in 2019/2020 soybean production is around 15.2 billion dollars. Additionally, the replacement of urea by BNF mitigated 183 million Mg of carbon dioxide equivalent (CO_2eq) in the same period, which, converted into carbon credits, corresponds to approximately 5 billion euros.

On the other hand, in gramineous plants, such as corn and rice, BNF occurs through bacteria that live close to the roots or inside the plant's tissues, which implies a smaller amount of nitrogen available to the crops, which is not enough to supply the plant's needs. However, recent research has shown promising results in inoculating bacteria into gramineous plants in order to capture nitrogen from the air in non-legume plants. A recent study conducted by the Brazilian Agricultural Research Corporation (Embrapa) has found, through experiments carried out over 10 years, that the inoculation of the bacterium *Azospirillium brasiliense* in corn seeds allows the reduction of nitrogen top-dressing (HUNGRIA et al., 2022).

Unlike soybeans, in which BNF is capable of supplying 100% of the nitrogen required for grain production, in the case of corn, fixation partially meets the plant's demand for nitrogen, and supplementation with nitrogen top-dressing is still required. In particular, the study findings suggest that 25% of nitrogen requirements in corn production can

be supplied by BNF, reducing the costs of nitrogen top-dressing, the environmental impacts of chemical fertilizers and increasing the efficiency of corn nitrogen fertilizer.

In view of the above and based on the findings provided by Hungary et al. (2022) and on the models proposed by Telles et al. (2023), this case study estimates the potential economic and environmental benefits of BNF in corn production in Brazil.

Data

In order to establish the potential for avoided costs through the value of ecosystem services provided by BNF in corn farming in Brazil, farmed land and corn productivity data (1st, 2nd and 3rd harvests) and prices paid for nitrogen fertilizers[3] were analyzed between 2009/2010 and 2019/2020 for 19 Brazilian states (Roraima, Rondônia, Acre, Amazonas, Amapá, Pará, Tocantins, Maranhão, Piauí, Alagoas, Bahia, Mato Grosso, Mato Grosso do Sul, Goiás, Minas Gerais, São Paulo, Paraná, Santa Catarina and Rio Grande do Sul) and the Federal District. The fertilizer adopted in this analysis was urea, which, containing 46% N, was assumed to be the fertilizer most used by farmers. The data was sourced from Companhia Nacional de Abastecimento (CONAB), which is responsible for monitoring and evaluating Brazilian harvests of grains, fibers, coffee and sugar cane.

Methodology

Based on our objective, the estimates made here are restricted to the benefit of BNF against the avoided costs generated by urea replacement, that is, the theoretical amount of urea necessary for corn production in the complete absence of BNF was considered. In particular, it is known that BNF is capable of reducing 25% of the nitrogen used in corn top-dressing, therefore the costs of supplying 75% and 100% of N top-dressing will be compared, with 100% corresponding to 30 kg of N for every 1000 kg of grain.[4]

3 Amounts converted into dollars, assuming that BRL 5.00 = USD 1, following Telles et al. (2023)

4 The theoretical amount of N required for corn production was considered to be 90 kg of N per hectare (HUNGRIA et al., 2022), and an average yield of 3000 kg/ha.

Importantly, the efficiency of N fertilizers varies from 30 to 50%, depending on factors such as cultivation, climate, soil and management practices. In this study, in particular, the efficiency of nitrogen fertilizer was set at 50% (TELLES et al., 2023).

Regarding secondary sources of nitrogen, it is known that, on average, Brazilian soils are poor in N, providing around 10 to 30 kg/ha. Considering this average amount of N supplied by soils and the use of monoammonium phosphate (MAP) and diammonium phosphate (DAP) fertilizers, it is assumed that 30 kg/ha of N are supplied through external sources. This amount is considered in the estimates of value saved by the use of BNF (TELLES et al., 2023).

The mathematical model to estimate the economic benefit provided by BNF in Brazilian corn is based on Telles et al. (2023), who proposes that the economic equivalence of N fixed by urea, which would be necessary in the complete absence of BNF, can be estimated by the following equation:

$$y = \sum_{\{i=1\}}^{I} \sum_{\{j=1\}}^{J} \{[(m_{ij} \cdot e) - s] \cdot d \cdot a_{ij} \cdot p_{ij}\}$$

where *y* is the economic benefit (in dollars) generated by BNF; *m* indicates corn production (kg/ha) in the i-th harvest and in the j-th region; *e* is the amount of N needed for each kilogram of corn (1/kg); *s* is the amount of N supplied by external sources (kg/ha); *d* is the efficiency of N application according to the percentage of losses; *a* represents the corn farmed land (ha) in the i-th harvest and in the j-th region; and *p* is the price of N offered by urea (in dollars per kg of N) in the i-th harvest and in the j-th region.

Additionally, it is possible to establish the mitigation, in CO_2eq, promoted by BNF based on the equivalent amount of urea necessary for corn production in the absence of BNF. Considering the synthesis and transport of N-fertilizer, it is estimated that the CO_2eq emission associated with the use of this input is 10 kg of CO_2eq per kg of N (IPCC, 2006). To account for the emissions avoided by BNF, the following equation was adopted:

$$z = \sum_{\{i=1\}}^{I} \sum_{\{j=1\}}^{J} \{[(m_{ij} \cdot e) - s] \cdot d \cdot a_{ij} \cdot c\}$$

where *z* represents the mitigation of CO_2eq generated by BNF (in kg); *m* indicates corn production (kg/ha) in the i-th harvest and in the j-th region; *e* is the amount of N needed for each kilogram of corn (1/kg); *s* is the amount of N supplied through external sources (kg/ha); *d* is the efficiency of N application according to the percentage of losses; *a* represents the corn farmed land (ha) in the i-th harvest and in the j-th region; *c* is the parameter that represents CO_2eq emissions (in kg of CO_2eq per kg of N).

Results

Based on the required N amounts, efficiency of fertilizer application in corn production and N supply from external sources, it was estimated that the association of 25% of BNF with chemical fertilization would result in an economic benefit close to US$ 1.4 million in 2019/2020, considering production in the 19 Brazilian states analyzed and in the Federal District.

At the state level, the potential economic benefit for the 2019/20 harvest lies in the leading corn producers: Mato Grosso (US$ 0.51 million), Paraná (US$ 0.19 million) and Goiás (US$ 0.17 million).

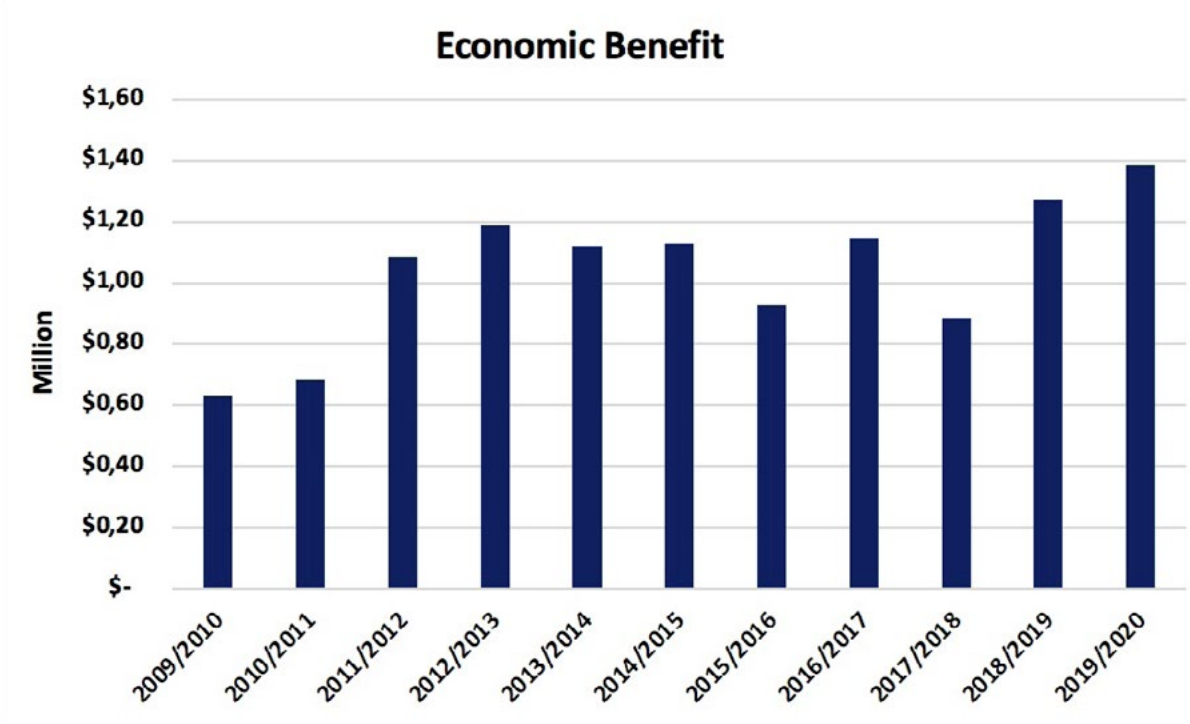
Considering the entire period under analysis (2009/2010 to 2019/2020), the potential economic benefit of 25% of BNF associated with crop fertilization in corn farming in Brazil could reach more than US$ 11.4 million.

Table 1 – Potential economic benefit of BNF against avoided costs generated by replacing 25% of urea top-dressing in corn farming by Brazilian state, considering the harvests of 2009/10 to 2019/20.

State	USD (million)										
	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20
RR	0,0001	0,0002	0,0002	0,0002	0,0001	0,0002	0,0002	0,0006	0,0006	0,0010	0,0013
RO	0,0042	0,0046	0,0070	0,0075	0,0065	0,0093	0,0100	0,0095	0,0086	0,0134	0,0147
AC	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0010	0,0011	0,0012
AM	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0002	0,0004	0,0004
AP	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000
PA	0,0062	0,0069	0,0086	0,0079	0,0076	0,0105	0,0101	0,0110	0,0094	0,0102	0,0122
TO	0,0030	0,0049	0,0064	0,0062	0,0097	0,0156	0,0081	0,0118	0,0089	0,0159	0,0217
MA	0,0068	0,0113	0,0090	0,0155	0,0223	0,0191	0,0118	0,0233	0,0208	0,0237	0,0286
PI	0,0040	0,0089	0,0108	0,0072	0,0141	0,0132	0,0100	0,0166	0,0155	0,0247	0,0307
AL	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0000	0,0003	0,0006	0,0008
BA	0,0241	0,0286	0,0328	0,0281	0,0461	0,0330	0,0197	0,0236	0,0226	0,0180	0,0295
MT	0,0911	0,1004	0,2394	0,2992	0,2578	0,2972	0,2325	0,3458	0,3076	0,4508	0,5113
MS	0,0430	0,0435	0,0982	0,1139	0,1269	0,1200	0,0824	0,1105	0,0594	0,0984	0,1060
GO	0,0566	0,0737	0,1245	0,1084	0,1194	0,1267	0,0898	0,1193	0,0972	0,1380	0,1749
DF	0,0029	0,0033	0,0053	0,0073	0,0123	0,0077	0,0043	0,0057	0,0071	0,0096	0,0065
MG	0,0745	0,0811	0,1171	0,1140	0,1028	0,0944	0,0788	0,0931	0,0805	0,0945	0,1070
SP	0,0578	0,0572	0,0713	0,0795	0,0583	0,0571	0,0594	0,0753	0,0395	0,0617	0,0581
PR	0,1505	0,1509	0,2629	0,2642	0,2146	0,2092	0,1976	0,2023	0,1271	0,1991	0,1937
SC	0,0414	0,0425	0,0435	0,0500	0,0466	0,0410	0,0351	0,0329	0,0285	0,0399	0,0364
RS	0,0613	0,0643	0,0465	0,0768	0,0738	0,0741	0,0762	0,0598	0,0484	0,0671	0,0472

Source: prepared by the authors.

Figure 8 – Potential economic benefit of BNF regarding the avoided costs generated by replacing 25% of urea top-dressing in corn production in Brazil, considering the harvests from 2009/10 to 2019/20.

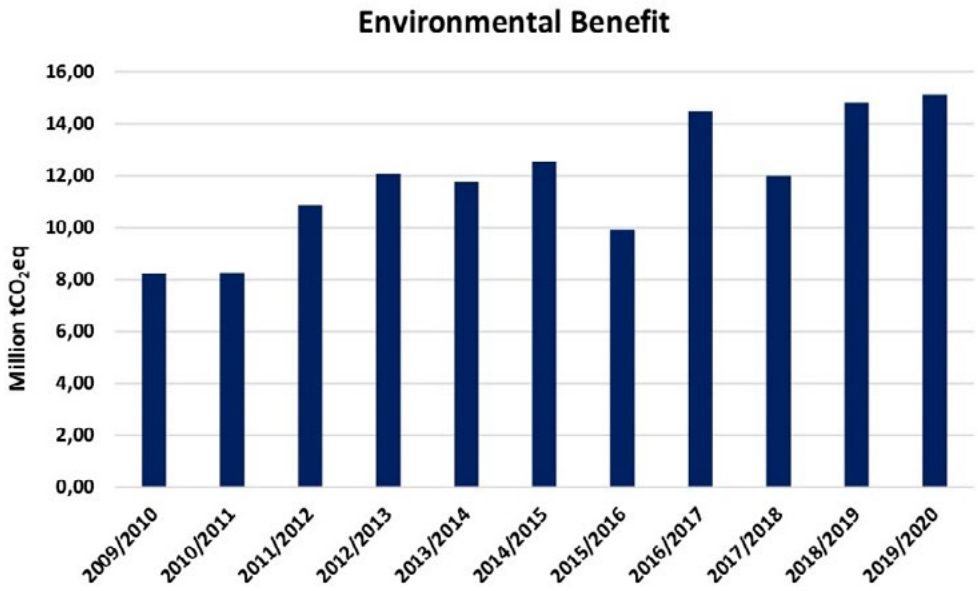


Source: prepared by the authors.

From an environmental point of view, mitigation estimates resulting from the replacement of 25% of N-fertilizers by BNF in corn production in Brazil can potentially cut 129 million tons of CO_2eq emissions, considering data from 2009/10 to 2019/20.

Considering that one ton of CO_2eq is equivalent to one carbon credit and that, on average, in the voluntary carbon market, one carbon credit is sold for around US$ 10 dollars, this means that BNF in corn farming in Brazil would have the potential to generate, in the last 10 years, a financial return of US$ 1.2 billion.

Figure 9 – Potential environmental benefit of BNF for avoided greenhouse gas emissions generated by replacing 25% of urea top-dressing in corn production in Brazil, considering the harvests from 2009/10 to 2019/20.



Source: prepared by the authors.

3. Regulation of biological inputs

The regulatory structure for bioinputs in Brazil has particular characteristics concerning the compared regime. The main one is "regulatory dualism." On the one hand, Brazilian regulation of bioinputs has advanced, like in Europe and in the United States, with the objective of setting limits to the market. In other words: establishing conditions and barriers for innovation and use of inputs in food production, compared to the regime that applies to chemical products.

On the other hand, national regulation on the use of bioinputs in food production has also advanced towards "flexibility" in the general regime, stimulating innovation, incorporation and dissemination of innovations, new inputs and new sustainable farming practices.

The national debate on the regulation of bioinputs in Brazil moves back and forth between two extremes: promoting the development and innovation of bioinputs as a relatively more sustainable production alternative to chemical products, or regulating and limiting the adoption of new biobased inputs, using pre-established market compliance rules and criteria.

To understand this dualism of the Brazilian model - and also how it has developed in recent years - it is important to investigate and reconstruct, step by step, the legislative structure on the use of inputs and food production in Brazil. Then, the closing section of this study focuses on the legislative debate taking place in Brazil on the new regulatory regime for bioinputs.

3.1. Pesticides Law: risk and restriction

The basic legislation on the production and sale of inputs in food production in Brazil dates back to the end of the 1980s, when Brazil passed the pesticides law (Law nº 7802/1989). Today, this is the statute that establishes the rules of control and inspection of pesticides, including, to a large extent, registration of bioinputs.

To understand this statute, it is important to observe four of its basic elements. The first one: its *subject matter* - the definition of pesticides. The second one: its *scope* - the regulated activities. The third one: the basic criterion of market *regulation* - risk management. The fourth one: *control* over potential failures.

Subject matter. The pesticide law adopts a comprehensive concept of pesticides. It regulates "pesticides and the like," as well as their "components." Each of these terms is defined literally in article 2 of this Law:

> I - pesticides and the like:
>
> a) products and agents of physical, chemical or biological processes, intended for use in production sectors, for storing and processing agricultural products, for pastures, for protection of native or established forests, and other ecosystems, and urban, aquatic and industrial environments, the purpose of which is to change the composition of flora or fauna in order to preserve them from the damaging action of harmful living beings;
>
> b) substances and products used as defoliants, desiccants, growth stimulators and inhibitors;
>
> II - components: active ingredients, technical products, their raw materials, inert ingredients and additives used in the manufacture of pesticides and the like.

Scope. The statute imposes far-reaching restrictions on the use of pesticides and the like. Practically any operation involving pesticides and their components is regulated by the statute. The list of actions that must be subject to legal rigor is broad and is set out in the introductory article of the statute. See below:

> Article 1 Research, experimentation, production, packaging and labeling, transport, storage, marketing, commercial advertising, use, import, export, final destination of waste and packaging, registration, classification, control, inspection and law enforcement over pesticides, their components and the like, will be governed by this Law.

Risk criterion. Then, it establishes the substance of regulation, how exactly to deal with the risk of "pesticides" on the market. The criterion used by the lawmaker can be characterized as "presumption of damage," which means that any market operation involving "pesticides" causes, in principle, damage to society, *until the opposite is proven.*

To organize the regime, the law then creates a set of pre-licensing criteria. State control, in this authorization process, is a way of protecting - or minimizing the chances of damage - to society. In other words, to prevent pesticides from "causing damage" to society, nature and the market itself, it is important to carry out prior inspection and control.

The specific criteria for this prior control are clarified by the statute.

> Article 3. Pesticides, their components and the like, as defined in article 2 of this Law, may only be produced, exported, imported, sold and used, if previously registered with a federal authority, according to the guidelines and requirements of the federal authorities responsible for the health, environment and agriculture sectors.

The law is highly strict. In practice, no goods can be produced, sold, imported, exported or used without State control and authorization (article 3, paragraph 1). At the same time, product registrants must inform, at an official register, the use of products on the market (article 3, paragraph 4). And any authorization to register new products is conditional on a proven reduction in the level of environmental or human toxicity of new products (article 3, paragraph 5).

Furthermore, the statute also conditions product licensing to a "containment plan." New products can only be authorized if the country has "methods for deactivating their components in order to prevent their remaining residues from causing risks to the environment and public health" (article 6, a), or an "effective antidote or treatment in place in Brazil" (article 6, b).

Control. Finally, the pesticides law creates an open and rigorous control regime over the adoption and use of pesticides in the country.

To this end, it defines a set of agents "empowered" to challenge any potential authorizations of pesticides in the country. These empowered agents include "organizations representing professions related to agriculture," "political parties represented in the National Congress" and "entities legally organized to advocate common interests related to consumer protection, the environment and natural resources" (article 5).

Finally, it creates a punishment regime for anyone failing to comply with it. Much more than a statute that guides and monitors the market, as it is customary in the public ordering of production activities, it goes further and specifies a comprehensive range of civil, administrative and criminal punishments.

Who exactly is to be punished? The penalties apply to failures of different agents in the regime: those prescribing the use of pesticides, going through the trader, registrant, producer, including the employer (who must ensure the safety of workers), including "users or contractors infringing the prescription" (article 14), "or recommendations from the manufacturer and registration and sanitary-environmental authorities" (in a criterion added by Law no. 9974, of 2000).

The penalties for failure to comply with the regulatory provisions, as provided by the statute, are relatively high. The penalties include, in addition to administrative restrictions (the right to carry out activities) and liabilities (the duty to compensate for damages), the restriction of freedom itself - *arrest*. See articles 15 and 16 of the Pesticides Law:

> Article 15. Anyone who produces, sells, transports, applies, services, disposes of waste and empty packaging of pesticides, their components and the like, in violation of the requirements established in the relevant legislation, will be subject to a ***prison sentence of two to four years***, and a fine.
>
> Article 16. Any employers, professionals or contractors failing to take any actions to protect the health and the environment will be subject to a *prison sentence of two (2) to four (4) years*, in addition to a fine of one hundred (100) to one thousand (1,000) MVR. If found guilty, they will be punished with a ***prison sentence of one (1) to three (3) years***, in addition to a fine of fifty (50) to five hundred (500) MVR.

In summary, the statute is highly strict. The State must strictly control each step of "pesticides and similar products" on the market, from experimentation to use,

including retail and advertising. Furthermore, it conditions practically any action involving pesticides to inspection and prior authorization from public authorities. To ensure that the law be complied with, it authorizes a group of entities, with high political power and economic representation, to step in and challenge the process. And it provides relatively high penalties, including imprisonment for non-compliance with legal provisions.

The intuition underlying the statute seems to be the following: pesticides are highly hazardous with potential for harm to humans, the environment, animals and the market. For this reason, its use must be "exceptional" and subject to maximum control and care in the country, under the watchful eye of national leaders, including political parties. Moreover, any failures in the high security regime established by this law must be punished, including the arrest of detractors.

3.2. Bioinputs: market & innovation

The growing popularity of bioinputs - and, in particular, organic and ecological agriculture - in Brazil, over the last 20 years, has given rise to another regulatory structure in the Brazilian food market. Instead of focusing on restricting (to neutralize the risk), enforcing the law (to ensure compliance) and punishing (to coerce detractors), multiple regulatory measures and public policies have promoted, in Brazil, a new organization and functioning of the food production industry.

The legal basis of this regime dates back to the early 2000s. In the following years, it was further detailed and regulated, while it gained representation in new political and social agents, in new forms of arrangement between public and social power. The combined effect, over time, was the ripening of a second agricultural project in Brazil, sometimes identified as family-based, agroecological or sustainable agriculture.

Organic and Agroecological Agriculture

The legal framework for organic and agroecological agriculture in the country was sanctioned in 2003. Law no. 10831, of 2003, is normally characterized as the result of demands from social movements associated with new political leaders in the country, who advocated a new role for the countryside and food production in the country.

This law established the so-called "organic system of agricultural production" characterized by the adoption of specific production techniques "aiming at economic and ecological sustainability... employing, whenever possible, cultural, biological and mechanical methods, as opposed to synthetic materials, at any stage of the production, processing, storage, distribution and sale process, and the protection of the environment" (article 1).

In practice, it "distinguished," among Brazilian production processes, those that should be specifically defined as organic or agroecological. Among other purposes, the differentiation had two main ones. The first one was to promote a *second* type of agriculture in Brazil, theoretically *better*, *healthier*, more *sustainable*, *economically fair* and more *biological* than commodity production.

Below are some of the reasons expressed in article 1, paragraph 1, of the Law:

> III – increasing the biological activity of the soil;
>
> IV – promoting the healthy use of soil, water and air, and reduce to a minimum all forms of contamination of any elements that may result from agricultural practices;
>
> V – maintaining or increasing soil fertility in the long term;
>
> VII – being based on renewable resources and locally organized agricultural systems;
>
> IX – manipulating agricultural products based on careful preparation methods, with the purpose of maintaining the organic integrity and vital qualities of the product at all stages.

The second objective was to organize, around this new "special food production regime", a range of special rules and policies that would encourage the advancement of *healthier*, *more sustainable and fairer* food production in the country. The limits of the new agriculture, in other words, should also be the focus of new state policies and actions, including targeted support programs and new market organization rules.

As a whole, the new "organic system of agricultural production" intended to set limits, restrict, hinder practices and inputs used in "traditional" food production in the country, as the Pesticides Law did. Moreover, it was intended to take a step forward and lay the foundations for supporting and opening up a new path towards producing "healthier," "more sustainable" and "fairer" food in the country. The law focused on digging up a new path.

For this reason, it lays down guidelines and open commands for "institutional and political construction" spearheaded by the State. It also determines the creation of a special registration regime for the use of inputs in organic and agroecological food production (article 9) - a way out of the high restrictions placed by the Pesticides Law.

How to justify this alternative path?

The new regime established by this law overturns the guidelines of the Pesticides Law. What is at stake, now, is no longer the presumed risk, the potentially disastrous threat to health, nature and the market - which, for this very reason, must be rigorously controlled preventatively and rigorously punished. On the contrary, the new law sets conditions under which the sustainability of food production can be assumed, with some certainty.

See the provisions of article 1:

> Article 1 An organic agricultural production system is considered to be any system in which specific techniques are adopted through the optimization of natural and socioeconomic resources available and respect for the cultural integrity of rural communities with the objective of economic and ecological sustainability, maximization of social benefits, minimizing dependence on non-renewable energy, employing, whenever possible, cultural, biological and mechanical methods, as opposed to synthetic materials, eliminating the use of genetically modified organisms and ionizing radiation, at any stage of the production, processing, storage, distribution and sale process, and the protection of the environment.

To demonstrate the "sustainability" of the agroecological and organic production regime, the law creates a *private regulatory regime* - based on certification - whose operating criteria would be established by the law itself. The key to the "private regulation" regime is to invite a group of agents to certify the products on sale. These agents, in turn, should operate according to some regulatory criteria.

The "quality assurance" of products, in the new law, is assumed - and responsibility for the result attributed to "producers, distributors, retailers and certifying authorities, according to the level of participation of each one." (article 4). The specific inspection criteria for compliance with quality standards, according to the law, must be established in Executive Branch regulations. See below:

> Article 5 The procedures relating to the inspection of production, circulation, storage, sale and certification of national and foreign organic products will be subject to regulation by the Executive Branch.
>
> § 1 The regulation must define and assign responsibilities for the implementation of this Law by the Federal Government.

The regulation must, among other topics, provide for technical standards for organic production and its governance within the federal and state government (article 11). Regulation must also involve "the participation of representatives from the agricultural sector and civil society, with recognized action at some stage of the organic production chain." (paragraph one).

The law, in short, adjusts the concept of food "quality" in two directions. On the one hand, it assumes this quality - as long as the production process follows a particular profile, certified by a third party. On the other hand, it also assumes quality, in the case of family farmers, as long as it is possible, at any time, to trace the product back.

In other words, it makes exceptions to the certification of family farmers, as long as "consumers and the supervisory authorities are assured of product traceability and free access to production or processing sites" (article 3, par. 1).

Regulation of Organic and Agroecological Agriculture

Regulation of the new production regime, organized by the Organic and Agroecological Agriculture Law, took place in 2007, with the approval of Decree 6323, of 2007.

The decree discriminates and details the characteristics of the organic agriculture system and each of its market stages: production, sale, import and export, quality information, advertising. It also establishes a control system over the quality of organic products and establishes liability for any breaches.

Definition of the "organic system" combines very diverse attributes - which include environmental, agronomic, social, economic, technical, political, and moral issues. See the provisions of article 3 of Decree 6323 of 2007:

Article 3 The guidelines of organic agriculture are:

I - contribution of organic production to local, social and economic sustainable development;

II - continual efforts by the organic production chain to comply with environmental and labor laws at all production sites;

III - development of locally organized agricultural systems based on renewable resources;

IV - encouraging the integration of organic production and regionalization of production and sale of products, stimulating the direct relationship between the producer and the final consumer;

V - inclusion of sustainable practices throughout its process, from choosing the product to be farmed to placing it on the market, including the management of production systems and waste generated;

VI - preserving the biological diversity of natural ecosystems and reinstating or increasing the biological diversity of the modified ecosystems where the production system is based, with special attention to species threatened with extinction;

VII - labor relations based on justice, dignity and equity, regardless of the employment contract;

VIII - responsible consumption, fair and supportive retail based on ethical procedures;

IX - offering healthy contaminant-free products resulting from the intentional use of products and processes that can generate them and that do not put the environment and the health of producers, workers or consumers at risk;

X - good handling and processing practices with the purpose of maintaining the organic integrity and vital qualities of the product at all stages;

XI - at the production site, adoption of practices that consider the healthy use of soil, water and air, in order to reduce all forms of contamination and waste to a minimum;

XII - use of production management practices that preserve animal welfare conditions;

XIII - increase in the resources necessary for the development and balance of the soil's biological activity;

XIV - use of products and processes that maintain or increase soil fertility in the long term;

XV - recycling of waste of organic origin, reducing the use of non-renewable resources to a minimum; and

XVI - progressive conversion of the entire production unit to the organic system.

The precise qualification of each of the "organic production" criteria tends to require better detailing and characterization. Regarding the "inputs" used in organic agriculture, the Decree qualifies the legal determination, to require priority and simplified mechanisms for registering inputs approved for use in organic agriculture (article 24). It further adds that, if the registration involves different authorities, the registration mechanisms must be established jointly (paragraph one).

Making sense of the regulatory standard - and the precise differentiation between production systems and, above all, between the inputs used by each one - advances, in stages, with the development of new policies to promote organic production and agroecology in the following years.

National Agroecology and Organic Production Policy

The new regulatory structure for organic agriculture opened space for the development of public policies to promote the sector. Under the impetus of social movements and national conferences, the Brazilian government makes a National Policy on Agroecology and Organic Production ("PNAPO"). The policy was finally approved in 2012, under Decree 7794, dated August 20, 2012.

It takes three steps to promote agroecology and organic production. Firstly, it establishes a *national policy* - a direction and a message for the development of production activities. The national policy is defined in the introductory article of the policy, in the following terms:

> Article 1 The National Policy on Agroecology and Organic Production - PNAPO is hereby established. It is intended to integrate, articulate and adjust policies, programs and actions that induce agroecological transition and organic and agroecological-based production, supporting the sustainable development and the quality of life of the population through the sustainable use of natural resources and the supply and consumption of healthy foods.

Secondly, it organizes *criteria* for a national plan created in a participatory manner with society, to guide paths toward implementing the policy. The plan is officially titled the National Plan on Agroecology and Organic Production – PLANAPO" (article 4, I).

Thirdly, it determines that this Plan should be managed by a "National Commission on Agroecology and Organic Production – CNAPO" composed of representatives from different government authorities and society. The Commission's tasks included:

Article 7 CNAPO is in charge of:

> I - promoting society's participation in the preparation and monitoring of PNAPO and PLANAPO;
>
> II - setting up thematic subcommittees that will bring together government officials and society representatives to propose and support decision-making on specific topics within PNAPO;
>
> III - proposing PLANAPO guidelines, objectives, instruments and priorities to the federal Executive Branch;
>
> IV - keeping track and monitoring the programs and actions that are part of PLANAPO, and proposing changes to improve the achievement of its objectives; and
>
> V - promoting a dialogue between governmental and non-governmental authorities related to agroecology and organic production, at national, state and district levels, for the implementation of PNAPO and PLANAPO.

The promotion of organic production and agroecology is seen, to a large extent, as a complement to a social movement agenda. The Plan does not include the concept or details of the new food production regime. Instead, it encourages the creation of regulatory spaces for participation and deliberation on the topic. At this point, the first duty of the Commission (CNAPO) is to *"promote the participation of society in the development and stewardship of PNAPO and PLANAPO."*

New agroecology and organic agriculture policies should respond to social guidelines and expectations. The legal command was finally implemented with the approval of the first National Plan (PLANAPO), for the years 2013–2015. Then, with the release of the second plan, for the years 2016–2019, approved by Joint Administrative Order MDA-SEGOV-PR no. 1 of May 3, 2016.

The document contains a comprehensive list of 185 initiatives, 29 goals and 6 strategies: production; use and conservation of natural resources; knowledge; sale and consumption; land and territory; and sociobiodiversity. Goal number 6 deserves special attention: *"creating and implementing a national input program for organic and agroecological-based production (Bioinputs Program)."* The fulfillment of this objective, in turn, is broken down into a range of commitments-activities. These commitments-activities included "creating a WG to prepare the proposal for the *Bioinputs Program* within 6 months."

The evolution of organic production and agroecology seemed to rely continuously on the advancement of "bioinputs." This advance meant, on the one hand, stimulating and supporting the development of new products and techniques that would help eliminate, or significantly reduce, the dependence of agroecological and organic agriculture on chemical inputs. This also meant avoiding the application of the strictest risk criteria, established by the Pesticides Law, for the "regulation" of new bio-based inputs.

In summary, PLANAPO helped to strengthen organic production movements and to further develop the sale regime. Associations of organic producers have gained relevance and political presence in different parts of the country. Public policies made by different ministries focused their efforts on small farmers or family farmers engaged in organic production.

In particular, PLANAPO oriented initiatives and actions at promoting "bioinputs" in the country. Research and scientific investigations have advanced, especially at Embrapa,

towards the development of new bio-inputs in the country. Scientific research initiatives have turned "bioinputs" into a promising frontier in the agribusiness economy - and in the advancement of scientific knowledge itself.

New "bioinputs" were then gradually and quickly assimilated by the Brazilian market. But now, with a particularity. Bioinputs have penetrated not only organic production and family-based activities, but also large commodity producers in the country. Scientific progress, in fact, opened the doors to the incorporation of biobased products across national production.

In the public debate, bioinputs are no longer seen and treated as a particularity of an organic and agroecological agricultural model; rather, they are now perceived as a raw material essential to the productivity and sustainability of Brazilian agriculture. At the source, the distinction between inputs and production processes, although existing in form, is diluted, to a large extent, in practice.

This dilution creates a fertile space for, in 2020, the Brazilian government to resume PLANAPO's "Goal 6" and implement the regulation of the sector with the launch, in Brazil, of a National Bioinputs Program aimed at promoting innovation and adoption of bioinputs in Brazil. In doing so, the proposal also meant opening a new route for the adoption of new inputs without going through the restrictive loopholes of traditional regulation.

3.3. National Bioinputs Program

Decree 9784 of 2019 created the National Bioinputs Program. This program is characterized by three unique attributes.

Firstly, it creates a common regime for Brazilian agriculture. The program dilutes the historical contrast between large-scale agriculture and family farming. The regulatory and organizational dichotomy between sectors is replaced by a single, shared regime. Instead of taking two routes toward agricultural progress, with two notions of risk or quality, this program creates a common regime applicable to everyone. Bioinputs, in this view, are not a particularity or a privilege of a type of agriculture or a type of production scale, but a valuable resource for the production of relatively more sustainable foods in the country.

Secondly, the National Bioinputs Program focuses on innovation. Instead of restricting and taming market advancement, the program embraces and supports a process of local experimentation, under the leadership of market - and state-level initiatives as a way of pushing back the frontier of innovation in bioinputs in the country. In practice, this was already an ongoing process in the Brazilian reality, spearheaded by the Brazilian states, such as Goiás, which the Program recognizes and appreciates. The target, in any case, is the recognition of innovation at the edge, by the producers themselves, in the development and preparation of their own inputs.

Thirdly, the National Program consists of a particular governance regime. This regime organizes a "system," which (i) releases and supports innovation at the edge, (ii) identifies and disseminates good practices at the bottom.

Innovation at the edge comes with the production and adoption of bioinputs on the farm. In practice, the so-called on-farm production, led by "biofactories," is becoming popular in the country (article 3, V, Decree 10375, of 2020). As in organic agriculture, medium and large Brazilian farms continually embrace the technique of preparing their own bioinputs, in order to save costs and improve quality.

The role of centralized governance is to gather and catalog innovations in products and techniques for using bioinputs, into a national list, provided on a public network (article 3, III and IV, Decree 10375, of 2020). Publicizing the information would serve to guide and streamline the market, provide easier identification and choice of inputs for application at the end.

The middle ground between innovation and dissemination of information is mediated by a Strategic Council under the National Bioinputs Program. Council members would come from different parts of the government, market and society. Its role would include monitoring market progress and "proposing the improvement of legislation to cover bioinput actions" (article 6, III, of Decree 10375, of 2020).

The National Bioinputs Program takes a step towards organizing a shared governance regime for bioinputs in Brazil. This shared regime, in turn, is not supposed to be connected to far-reaching abstract quality criteria or to group processes. Nor would it be limited to assuming the absolute risk of traditional pesticide control in the country.

With the spread of bioinputs in Brazil, however, a new concern arises: shouldn't "bioinputs", as well as chemical inputs, also be controlled and supervised by the State?

Alerts about on-farm "biofactories," in which producers prepare the product for use, not always with expected strictness or care, raise awareness about the potential risk of contamination from the mobilization of bio-inputs, thus producing undesirable and potentially serious consequences for the image of the industry and for the safety of food production in the country (Technical Note no. 12/2020/SEI/GEAST/GGTOX/DIRE3/ANVISA, Anvisa).

Public Note released by Embrapa researchers, on November 17, 2021, supports the need to regulate the production of bioinputs in Brazil. The Note, among other topics, presents two essential points for regulation. The first one: "only allowing the multiplication of microorganisms with an approved reference specification acquired from germplasm banks accredited by the Brazilian Ministry of Agriculture." The second one: "appointing a qualified technician."[5]

In summary: bioinputs, initially perceived as an agroecological demand, become an opportunity for Brazilian agriculture as a whole. Industry innovation respond to the growing demand for new bio-based products while stirring up the interest of different classes of producers. At the same time, however, concerns about the indiscriminate manufacture and use of bioinputs, especially those involving microorganisms as active ingredients, renew the demand for regulation of this sector.

Regulation of bioinputs

The debate on the regulation of bioinputs gains ground in the National Congress, in two bills that propose the regulation of bioinputs in Brazil. The first, bill of law no. 658/2021, by Representative Paulo Bengston (PTB-PA), is pending vote in the House of Representatives. The second, bill of law no. 3668/2021, by Senator Jaques Wagner (PT-BA), is pending vote in the Federal Senate.

5 The two points are described in the Report by Senator Veneziano Vital do Rêgo, available at: https://legis.senado.leg.br/sdleg-getter/documento?dm=9178865&ts=1671822313672&disposition=inline (retrieved on 9.9.2023).

In the discussion of bill no. 658/2021 (House of Representatives), the recitals of a substitute report, by Representative Zé Vitor (PL-MG) provides:

> The country still lacks comprehensive national legislation regulating the matter, which provides legal security for investment, research and production of bioinputs. The proposal under discussion represents an undeniable step forward in this direction. It is our understanding, however, that we must expand its scope, regulating not only the production of bioinputs through on-farm biological management, but the production, import, export, sale and use of bioinputs in general. With this objective in mind, we are proposing a substitution for the project at hand.

The recitals of bill no. 3668/2021 (Federal Senate), by Senator Vital do Rêgo (MDB-PB), provides:

> The new legal framework for the production of bioinputs must regulate not only the production of bioinputs through biological management, but also its entire production cycle, which includes production, import, export, sale and use of bioinputs in national agricultural production. This is necessary to optimize the process of regulating the innovations required for the use of bioinputs in Brazil and to promote greater legal security for rural producers, investors and society as a whole. (...)

Unrestricted regulation of bioinputs, on the other hand, could imply limiting farmers committed to developing sustainable inputs. Regarding organic and agroecological agriculture, this could hinder the original momentum that drives the movement - the development of sustainable food-qualifying products and techniques.

The two bills suggest basic regulatory criteria to reconcile the demand for safety and quality with freedom of production and innovation on the farm. They do this by disciplining, among others, two central matters: (a) the "motive-site" of production (on-farm for local use, or commercial production), and (b) the control regime for bioinputs (self-control system).

On-farm vs. commercial production

Despite the different structures and specific variations, in their essence, the two bills follow similar guidelines.

Bill 658 of 2021 (House of Representatives). The bill establishes, as a general rule, the regulation of bioinputs produced for commercial purposes. At the same time, it waives registration of bioinputs for personal use.

See the wording of articles 3 and 4:

> Article 3 Any establishments that produce or import bioinputs for commercial purposes are required to register with the Ministry of Agriculture, Livestock and Supply.
>
> Paragraph One. The regulations of this Law will provide for the procedures for registering an establishment.
>
> Article 4 Bioinputs produced and imported for commercial purposes must be registered with the Ministry of Agriculture, Livestock and Supply.
>
> Paragraph 1 The following are exempt from registration:
>
> I - goods produced by farmers exclusively for their own use, and

The general rule, therefore, is registering, according to regulations to be approved by the Ministry of Agriculture, Livestock and Supply. The exception, which eliminates the need for registration, is where production is intended solely for self-consumption. This is what article 4 of the Bill of Law provides, once again:

> Article 9 Production of bioinputs in a rural establishment for their own use is authorized. This is considered a light-risk or irrelevant-risk activity, as set out in Law no. 13874, of September 20, 2019 and its regulations, in which case establishment and product registration are waived.

The bill gives special treatment, however, to bioinputs with *microorganisms as an active ingredient*.

In the case of *commercial production*, the bill requires, for registration, a set of specific information and studies, which include: "full description of the place of deposit and the reference of the isolate, strain or lineage deposited in the collection, for access to biodiversity by other stakeholders; agronomic efficiency; behavior of the microorganism in the environment; whether the microorganism could be toxic to the human species." (article 7, I).

Regarding production for *individual consumption*, in turn, the bill is more relaxed, but it also sets out conditions. Firstly, bioinputs with microorganisms as an active ingredient must be limited to "isolate, lineage or strain obtained directly from an official or private germplasm bank, companies registered for the production of bioinputs or from another source capable of guaranteeing their identity and origin" (article 11).

Furthermore, the production of bioinputs must follow a "Guidebook of Good Practices" to be prepared by the Ministry of Agriculture, Livestock and Supply within 180 days from approval of the bill (paragraph 2, art. 9 of the Bill of Law). Finally, producers must register "with the state or district agriculture authority to produce bioinputs that include microorganisms as active ingredients for their own use." (paragraph 3, article 9 of the Bill of Law). Except in the case of rural producers included in the National Register of Organic Producers" (para. 4, article 9 of the Bill of Law).

Bill No. 3668/2021 (Federal Senate). The bill makes a distinction between regulation of production for commercial purposes and for one's own use, and also makes exceptions for production for one's own purposes.

Biofactories with commercial purposes, according to the bill, must previously register their products with the competent government authority. Criteria for registration depend on a risk analysis of the product.

Article 14. Production and import of bioinputs or bioinput inoculums for commercial purposes depend on prior registration of the product with the federal authority responsible for agricultural matters, following the guidelines and requirements of the federal health and environment authorities, according to with the type of product and level of risk, as per regulations.

§ 1 The requirements and procedures for registration of bioinputs, as per the regulation should consider the risk assessment and management, product purpose and category, all in compliance with this Law.

§ 2 Semiochemical products with exclusively mechanical action, such as sheets and traps, and food attractants for monitoring insects in which the active ingredients come exclusively from biological fermentation and/or from foods and food residues are exempt from registration.

§ 3 The federal agricultural authority will publish, on its website, a list of species of organisms and products authorized for biological control, exempt from registration, pursuant to the regulation.

The application for registration of bioinputs must include:

I – full description of the place of deposit and the reference of the product, strain or lineage deposited in a public or private germplasm bank accredited with the federal agricultural authority, for macro or microorganisms;

II – agronomic efficiency;

III – product behavior in the environment; and

IV – whether the product has the potential to be toxic to humans, animals, plants, microorganisms and the environment.

Like Bill 658 of 2001, now pending vote in the House of Representatives, Federal Senate Bill 3668, of 2021, also exempts the production of bioinputs for personal use and without commercial purposes (article 18). Production for individual purposes, however, must follow some requirements that are also similar to those required in the bill of law proposed in the House of Representatives. The first one is to follow the good practice instructions provided by a competent authority. The second one is to use only classified organisms that are found on a positive list, and "available in a public or private germplasm bank accredited by the federal agricultural authority."

Finally, two particular requirements are made by the Senate bill: appointing a qualified technician with self-declaratory registration filed in a public agency.

> § 3 On-farm biofactories must engage a qualified technician accredited for this purpose by the federal agricultural authority, if required by a regulation, according to the scale of production and the conditions of use or production of biological agents.
>
> § 4 On-farm biofactories must carry out, as per the regulation, a simplified self-declaratory registration of an establishment producing bioinputs, which must include, at a minimum, production capacity, identification and origin of the classified organism, lineage or strain and quality control mechanisms. This information must be entered into a website informed by the federal agricultural authority.

Once registered, biofactories are authorized to produce bioinputs, regardless of product registration - and provided that it is only for their own use (article 18, paragraph 1). Another particularity of bill no. 3668-2001 is to exempt family farming from registration (article 19, paragraph 2).

Bill 3668-2001 was approved by the Senate and is now under consideration at the House of Representatives.

Self-control system

The two bills adopt the so-called "self-control system." They employ the concept of self-control without defining it in detail. In the literature, self-control is typically considered a collaborative regulatory regime based on risk management, in which the State requires

the provision of comprehensive information from the individual on the conduct of its production system and guides private agents on any potential correction of failures, without apply any immediate punishment, instead of assuming the "high risk of disastrous consequences" punished with extreme penalties, which include arrest - as established by the pesticide law. Or instead of assuming the "negligible risk" through private certification or depending on the nature of production (e.g.: agriculture), far from state inspection, as organic production does. The bill suggests public-private collaboration with flexible control.

The regime initially relies on trust and collaboration between public and private agents for the purposes of improving law enforcement and quality services. The "test" of good faith is the provision of information, by the private agent, about its production process and inputs used. This information must be registered on a public platform managed by the State. Any flaws, identified by public control, now equipped with comprehensive information, will be pointed out by the State. If immediately remedied by the private agent, the punishment may be avoided.

Bill 658 of 2021 (House of Representatives). Bill 658 of 2021 (House of Representatives) specifies general criteria for the self-control system provided in article 14. See below:

> Article 14. Establishments that produce or import bioinputs for commercial purposes must develop self-control programs for the purpose of guaranteeing the harmlessness, identity, quality and safety of their products.
>
> § 1 The establishments must make sure that the self-control programs described in the introductory clauses be implemented, maintained, monitored and checked.
>
> § 2 The self-control programs must contain:
>
> I - systematized and auditable records of the production process, from sourcing and receiving raw materials, ingredients and inputs to shipping the final product;
>
> II - recall arrangements for any flaws or non-conformities that may cause risks to consumer safety or animal and plant health; and
>
> III - description of self-correction procedures.

Bill 3668, 2021 (Federal Senate). Bill 3668 of 2021 (Federal Senate) is quite similar. The self-control criteria are provided in article 11:

Article 11. Commercial biofactories that produce or import bioinputs or bioinput inoculums for commercial purposes will develop self-control programs to ensure the identity, quality and safety of their products, as per applicable regulations, and must present:

I - auditable systematized records of the production process, from sourcing and receiving raw materials, ingredients and inputs to shipping the final product;

II - recall arrangements for any flaws or non-conformities that may cause risks to consumer safety or animal and plant health;

III - description of self-correction procedures; and

IV - participation in interlaboratory tests organized by an independent laboratory accredited by the Ministry of Agriculture and Livestock (MAPA), aiming to continuously improve the quality of bioinputs used in the country.

§ 1 The establishments must make sure that the self-control programs described in the introductory clauses be implemented, maintained, monitored and checked.

Defining a specific "control" regime for bioinputs is a controversial issue in Brazil. As the bioinput bills were pending in Congress, Brazil approved another bill of law (Bill No. 1293, of 2021), which provided for "self-control programs for private agents regulated by agricultural defense and over the organization and procedures applied by agricultural defense to agents in agricultural production chains."

The law, approved under number 14515, of 2022, creates, in short, a "self-control system" for enforcing the law in agricultural activities in general. Articles 23 and 24 of this law laid down simplified conditions for product registration. Article 23 determined that the Ministry of Agriculture and Livestock (MAPA) should approve risk classification. And article 24 explicitly exempted the production of inputs for individual use. Article 24, however, was vetoed by the President. Below is the content of article 24, *ipsis literis*:

> Article 24. Agricultural inputs produced or manufactured by rural producers for their own use are exempt from registration, and the sale of said inputs in any form is not allowed.

Today, the self-control law still lacks formal enactment. At the same time, it is not clear whether the regime established there should apply to bioinputs. The enforcement and control regime applicable to bioinputs is expected to be defined and detailed in the bill pending vote in the legislature.

4. Closing remarks

This study analyzed the status of bioinputs in Brazil, from two complementary perspectives. Firstly, it provided an economic assessment of the matter, which quantifies the expansion and advances in the sector in Brazil. An exemplary case - nitrogen fixation in the soil in corn crops - is detailed to make it easier to understand the importance and potential for farming innovations.

Secondly, the study focused on the regulatory status of bioinputs in Brazil. At the basis of the discussion is the debate on the food production model and risk management in Brazil. Over the last 30 years, the country has created two different regimes for organizing production and use of inputs.

The traditional regime presupposes a high risk of serious consequences, which need to be state-controlled with an iron fist under highly strict and punitive regulations. The "organic and agroecological" regime creates a more flexible path, in which the presumption of risk and damage is mitigated, under particular conditions, and the priority focus is the promotion and support of new producers.

The advancement of bioinputs suggests, at first, an effort to dilute this frontier - biobased innovations are recognized and assimilated by agriculture as a whole. At the same time, fears about the indiscriminate use of biobased products reopen the discussion about the need to organize the production and use of bioinputs in the country.

Bills currently pending in Congress suggest criteria for ordering the topic. The prevailing position, to date, is not based on "production models" or "property sizes", but on "functions" and "ingredients." Production for individual purposes would not require prior registration. Production for commercial purposes would. Bioinputs with microorganisms as active ingredients would have particular restrictions. A new flexible-control regime - self-control - would guide law enforcement and further development in the sector.

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Daniel Vargas, Fernanda Valente, Cícero Lima, Sabrina Matos

Graphic design
Contexto Gráfico

Front cover and text formattings
Scriptorium design, Kenia de Aguiar Ribeiro

Publisher
Agricultural Policy Dialogue Brazil-Germany (APD)

Editorial Coordination
Gleice Mere, Ingo Melchers and Carlos Alberto dos Santos

Cover Photo
rawpixel.com / Wan