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Report Name: Brazilian Legislation for Biopesticides - On-farm Biopesticides Production

Country: Brazil

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Report Category: Agricultural Situation, Policy and Program Announcements, Sanitary/Phytosanitary/Food Safety, Agriculture in the Economy

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Report Highlights:

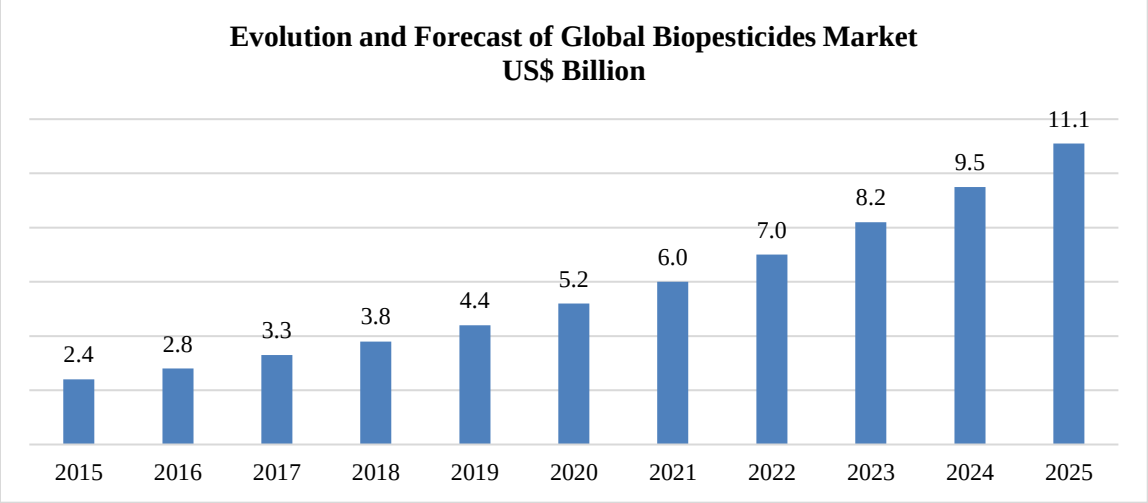
This report highlights the Brazilian biopesticides market and the current developments in the Brazilian legislation for biopesticides. The report focuses on the “on-farm” production of biopesticides, defined as the production of biopesticides at the farm level for non-commercial use. Government agencies and major stakeholders with a deep interest in the topic have listed several pros and cons relative to the matter. The topic has received a lot of attention at the Brazilian Congress. Further discussion is required before setting the regulatory framework for “on-farm” production and the registration of biopesticides by Brazilian authorities, given that the country would most likely be the first major agricultural economy to regulate the subject.

The Global Biopesticides Market

According to IHS Markit, biopesticides are widely used in various crops in Brazil and worldwide, with a global market estimated at US$ 5.2 billion in 2020. This figure accounts for eight percent of the worldwide chemical pesticides market (US$ 62 billion). The projected compound annual growth rate (CAGR) for the biopesticide market for the 2020-2025 and 2025-2030 periods are forecast at 16.4 and 10.4 percent, respectively.

The graph below shows the global biopesticide market's evolution and forecast until 2025. The biopesticide market is forecast at US$ 11.1 billion in 2025 and US$ 18.2 billion in 2030.

Graph 1.



Source: IHS Markit, 2021.

The following factors support the steady growth of the biopesticides industry:

- Political and social pressure for environmentally friendly and “low risk” crop protection technologies;
- Pressure from regulatory agencies, food companies, and consumers;
- An increasingly difficult regulatory climate for conventional chemical pesticides, including bans or restrictions on existing products;
- Increasing costs and time involved in registering new products and re-registering old ones;
- Technological innovations that provide better performance of biopesticides;
- Growing opportunities in the organic food sector.

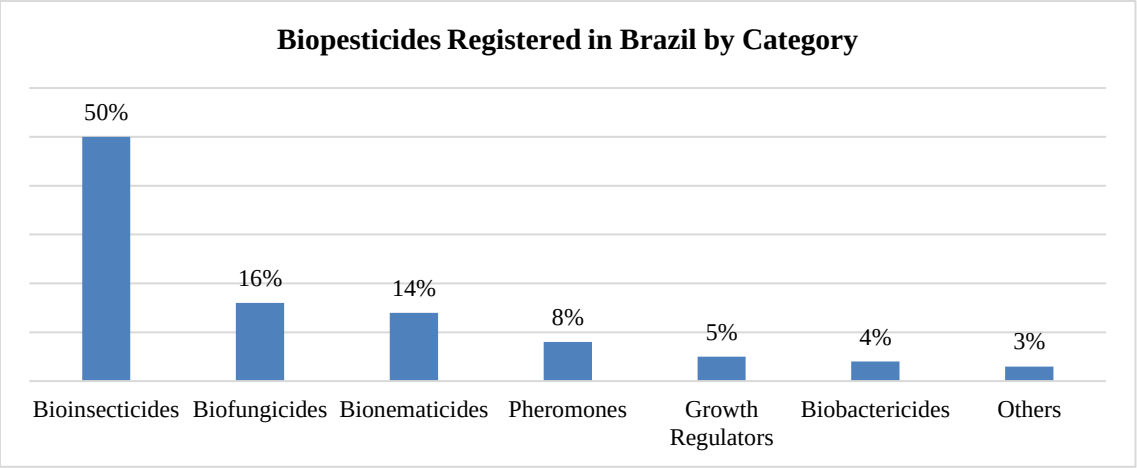
The Brazilian Biopesticides Market

According to industry sources, Brazil still has a small share in the global biopesticide market, roughly estimated at five percent. On the contrary, North America and the European Union (EU) account for 60 percent of the global biological control market. Although the Brazilian share is relatively small compared to the United States and the EU, Brazil stands out for its high growth in recent years.

The Brazilian compound annual growth rate (CAGR) between 2017 and 2020 was 42 percent, whereas the global CAGR for that same period was 16 percent. The biopesticide market revenue in Brazil was US$ 268 million in 2020, an increase of 35 percent compared to 2019. The industry expects growth rates to remain high over the following years. IHS Markit projects the CAGR for the 2020-2025 and 2025-2030 periods at 35 and 22 percent, respectively.

The increase in biopesticide registrations in Brazil is an important indicator of the high acceptance this category has received from farmers. According to IHS Market, currently, there are 433 biological control products registered with the Ministry of Agriculture, Livestock, and Supply (MAPA). In 2013, there were only 104 biopesticides registered with MAPA. Graph 2 below illustrates the distribution of biopesticides in Brazil by category.

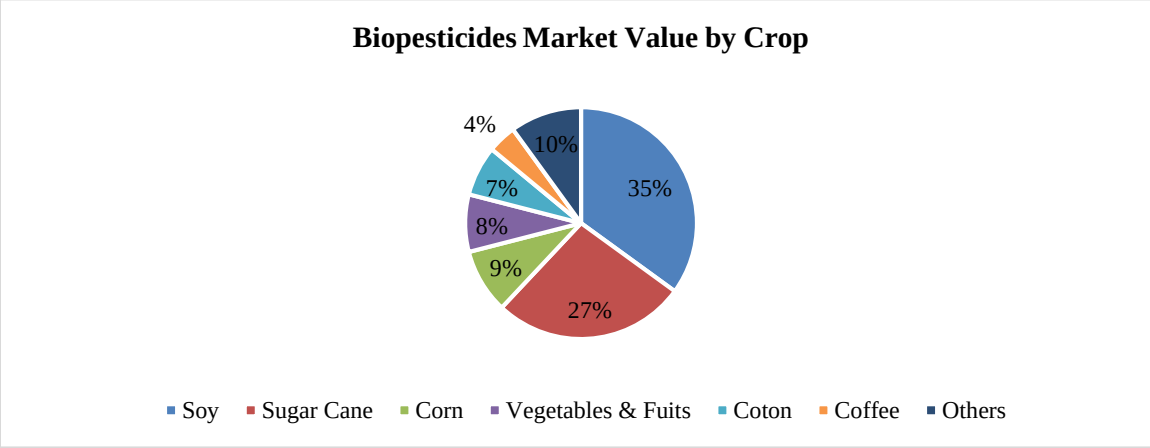
Graph 2.



Source: IHS Markit, 2021.

As reported by IHS Market, soybeans and sugarcane are the major crops using biological control products jointly, accounting for over 60 percent of the total market value for biopesticides.

Graph 3.



Source: IHS Markit, 2021.

Biopesticides Regulatory Framework in Brazil

Biopesticides are regulated by Bill #7,802 of July 11, 1989 ("*Lei dos Agrotoxicos*"), and by Decree #4,074 of January 4, 2002, as well as their amendments, following the same legislation as chemical pesticides. Bill #7,802 encompasses the entire production chain of pesticides, from scientific research to approval and registration of the active ingredient by the Brazilian authority, to the production, packaging, storage, labeling, and trade of commercial pesticides and biopesticides. Decree #4,074 regulates and provides specific tools and requirements to comply with Bill #7,802.

Companies interested in working with pesticides and biopesticides must carry out a rigorous registration process. The approval process takes approximately four years, and it involves the three Brazilian Ministries below:

1. Ministry of Agriculture, Livestock and Supply (MAPA) to assess agronomic efficiency;
2. Ministry of Health/National Health Surveillance Agency (ANVISA) to assess the risks to public health;
3. Ministry of Environment/ Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA) assesses environmental impacts.

Decree #4,074 exempts the registration of phytosanitary products commonly used to cultivate organic products. However, there is no mention under Decree #4,074 about production of biopesticides "on farm", defined as the production of biopesticides at the farm level for non-commercial use.

More recently, Decree #10,375 of May 2020 created the National Bio-inputs Program to expand and strengthen bio-inputs' use and promote the sustainable development of Brazilian agriculture. Bio-inputs include biopesticides, inoculants, and biofertilizers. The analysis of current legislation on bio-inputs, the release of "good practice" manuals for bio-inputs production, and providing incentives for scientific research and credit lines to encourage bio-inputs production are some of the initiatives under the aforementioned decree. It also created a strategic council to discuss the possibility of removing bio-inputs from Bill #7,082 ("*Lei dos Agrotoxicos*")

As opposed to Brazil, the United States has a very specific regulatory system for biopesticides which is dependent on a single regulatory agency, the Environmental Protection Agency (EPA). The registration process for a new biopesticide takes an average of 19 months. In the European Union (EU), the process is divided into two steps: the active ingredient is regulated at the EU bloc level, whereas the formulated products are reviewed at the country level. Registering a new biopesticide takes an average of three to five years. According to Post contacts, there is no specific regulatory framework for "on-farm" production in the United States and the EU legislation for biopesticides.

Proposed Changes in the Brazilian Regulatory Framework for Biopesticides

There are several Bill proposals at the Brazilian Congress to update the current legislation on biopesticides to simplify the registration process and to create the regulatory framework for "on-farm" biopesticides production (as opposed to traditional industrial plants). The main proposals are listed below:

1. *PL 658/2021*. The proposal unifies and simplifies the regulators of the different bio-inputs (biopesticides and biostimulants) and regulates the "on-farm" production of biopesticides. The assessment and registration of all types of commercial biopesticide products would be carried out by MAPA only. At the same time, ANVISA and IBAMA would participate in the product assessment restricted to cases of pesticides with microorganisms not yet registered in Brazil. Bill Proposal # 658/2021 defines "on-farm" biopesticides production as low or irrelevant risk, being exempt from environmental licensing and the rigorous product registration set in Bill #7,082. Farmers would only be required to keep a simple record of production batches, stocks, etc. The production of biopesticides on the farm would be authorized only for microorganisms already registered in Brazil or native to Brazil, and it would be exempted from the Brazilian genetic heritage laws (Brazilian Access and Benefit Sharing laws). The transportation of biopesticides produced "on-farm" would be allowed strictly for non-profit purposes. The link below shows the current status of PL 658/2021: https://www.camara.leg.br/propostas-legislativas/2271161

2. *PL 3,668/2021*. Proposes to regulate the entire production cycle of bio-inputs for commercial and non-commercial use ("on-farm" production) and adopts a series of measures to encourage the use of these technologies in agriculture. Like Bill proposal # 658/2021, ANVISA and IBAMA would assess product registration only for new microbiological active ingredients. "On-farm" production containing active microbiological ingredients classified as Risk Class 1 would be exempt from registration. Farmers would only have to self-declare the origin of the microorganism, the strain, and quality control standard, being exempted from the rigorous product registration set in Bill #7,082. The link below shows the current status of PL 3668/2021: https://www25.senado.leg.br/web/atividade/materias/-/materia/150351

3. *PL 6299/2002*. Proposes to change the registration system for pesticides (chemical and biological) and their components. In 2022, members from the Senate, proposed the production of "on-farm" biopesticides to be exempted from all the safety requirements imposed upon biopesticides commercial products. The link below shows the current status of PL 6299/2002: https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=46249

4. *PL 1293/2021*. Proposes to regulate the replacement of agricultural inspection by self-control programs by farmers and industry and encourage online control. The project also changes sanitary control rules and exempts non-commercial pesticide products (on-farm) from the rigorous product registration set in Bill #7,082. The link below shows the current status of PL 1293/2021: https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=2277190

Institutional Position from Brazilian Government Agencies

EMBRAPA: The Brazilian Enterprise for Agricultural Research recognizes the potential for bio-inputs in agriculture, including "on-farm" production. However, EMBRAPA highlights that improper "on-farm" biopesticide production could bring environmental and safety risks to producers and consumers. Within this context, the "on-farm" production of bio-inputs must be regulated according to the following premises: (1) to allow the multiplication of microorganisms that are listed at MAPA and/or referenced by accredited research organization and/or acquired at official germplasm banks recognized by MAPA;

(2) All establishments producing "on farm" biopesticides must be registered at MAPA; (3) "on farm" production supervised by a qualified professional. *Source: Official Declaration published at EMBRAPA's website* - see hyperlink below: Embrapa's position.

MAPA: The institution supports "on-farm" production and claims that providing a regulatory framework for producers to work with the technology is necessary. MAPA argues that although most microbiological control agents are safe and risk-free, certain microorganisms can pose a risk to human health and the environment. MAPA recommends the classification of microorganisms into different risk bands and the adoption of other regulatory criteria for each one. *Source: "On-farm" Production of Bioinputs Seminar: efficiency, safety, and regulation (CNA) held on 11/17/2020* - see hyperlink below: MAPA's position.

ANVISA: The agency recognizes the importance of bio-inputs for Brazilian agriculture. Anvisa alerts that the production process of bio-inputs, especially regarding the multiplication of isolated microorganism strains, must have clear technical criteria and control methods. ANVISA also expresses concern about possible loopholes in the regulations that would allow the commercialization of "on-farm" bio-input production. Moreover, an important objective of the agency within this process is to demystify the concept that if a product is natural, there is no risk of contamination to human health. According to ANVISA, the academic community already has evidence that inappropriate "on-farm production" of bio-inputs does lead to the proliferation of microorganisms that are dangerous to human health. In addition, there is an example of bio-products that are not dangerous themselves; however, their production process does bring health risks. Therefore the production process must be clearly regulated. The same goes for biochemical products where each molecule has its route of synthesis, such as plant extracts and semiochemicals. Such situations must be evaluated individually because these concentrated products are dangerous and must have a regulated production system. *Source: Interview conducted by USDA/FAS/Brazil.*

IBAMA: The institute highlights bio-inputs' importance for Brazilian agriculture and overall environmental preservation. However, IBAMA emphasizes that the institute should be part of the regulatory process for "on farm" bio-inputs production with regard to the potential (1) pathogenicity of the microorganism being multiplicated, (2) soil contamination, (3) introduction of exotic microbiological species into the environment; (4) risks during transportation. IBAMA should also support the legislation regarding inspection, genetic heritage, environmental licensing, and waste management. *Source: Joint Public Hearing (CAPADR / CMADS) held on 10/7/2021* - see hyperlink below: IBAMA's position.

Institutional Position from Brazilian Private Sector

ABRAPA: According to the Brazilian Association of Cotton Producers, farmers must have the right to produce their bio-input as long as they follow good health, safety, and environmental practices. "On-farm" producers must have civil and criminal liability for their production. The association recommends a qualified expert must oversee the production plant. ABRAPA advocates that the need for an environmental license should be mandatory only when the handling of bio-products is considered to be at high risk. The entity claims that the product registration should be simplified and conducted by MAPA and that the transportation of bio-inputs among farms owned by the same producers and/or

company should be allowed. ABRAPA is against the commercialization of "on-farm" produced bio-inputs. *Source: Interview conducted by USDA/FAS/Brazil.*

ABRAFRUTAS: The Brazilian Association of Fruit Exporters supports "on-farm" production of bio-inputs, as long as clear rules on production quality, employee safety, consumer health, and environmental preservation plans are set and followed. Like ABRAPA, the institution also advocates that the presence of a qualified technician at the bio-input plant is mandatory. They emphasize that any intellectual property related to the product and/or production process must be respected. *Source: Interview conducted by USDA/FAS/Brazil.*

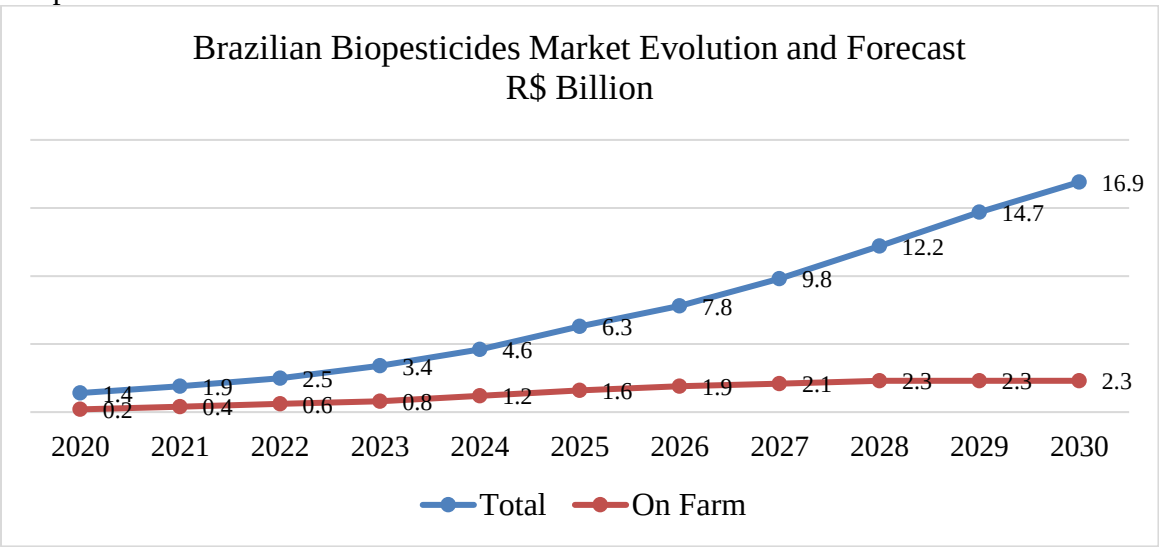
APROSOJA: The Soybeans Producers' Association has a favorable position to change current legislation to allow "on-farm" production of biopesticides. They argue that "on-farm" production of bio-inputs would be similar to those traditionally produced for organic agriculture without any harmful consequences for the environment and consumers. According to the entity, biopesticides are safe products that do not pose risks to the environment and/or consumers. They should receive different treatment in relation to chemical pesticides. The entity also favors a simplified product registration and environmental licensing regime, and they are strictly against commercializing biopesticides produced on the farm. *Source: Interview conducted by USDA/FAS/Brazil.*

CROPLIFE BRAZIL: The institution understands that the research, development, and technologies used in producing biological products for pests control must prioritize the safety of farmers, the environment, food, and consumers. Therefore, scientific rigor must be applied to the risk evaluation of production and microbial strains to control pests and diseases, following international safety standards. The institution argues that the risks of the microbial output are inherent to the activity and are not reduced according to the purpose (commercial or not) and plant location ("on-farm" – or traditional industry plants). Therefore, when a biopesticide is intended for agricultural use, it should not be exempted from a careful risk assessment. It could potentially put the environment, animals, and humans at risk. *Source: Interview conducted by USDA/FAS/Brazil.*

Possible Market Impacts of Potential "On-Farm Production of Biopesticides

From an economic standpoint, Graph 4 below illustrates that the overall Brazilian biopesticide control market has an exponential potential for growth, reaching R$ 16.9 billion in 2030. On the other hand, the growth potential for "on-farm" production is expected to be very limited over time, virtually stabilizing at R$ 2.0 – 2.3 billion as of 2026.

Graph 4.



Source: IHS Markit, 2021.

According to IHS Market, the expected limited growth for "on-farm" bio-input production is related to the complexity and high investments required to obtain a good quality product. Although there is a current interest in "on-farm" production, it is expected that this production model should not be sustained due to the overall low-quality products produced by rural producers. There are several reports of biopesticides produced on-farm showing contamination issues, which reduces or completely ceases their agronomic effectiveness. It is expected that only large economic groups will be able to build bio plants with adequate infrastructure and qualified labor to produce effective microbiological control assets. In the medium term, small and medium producers will likely realize that resources directed to producing biopesticides will be of better use if acquired from specialized pesticide companies.

Conclusion

This report focuses on the current developments in the Brazilian legislation for biopesticides, specifically for "on-farm" production of biopesticides, defined as the production of biopesticides at the farm level for non-commercial use. The topic has received much attention at the Brazilian Congress and academia. Government agencies and major stakeholders with a deep interest in the topic have listed several pros and cons relative to the matter.

They all agree that updating the current legislation is necessary but differ on how strict or not the regulatory framework should be in relation to production aspects, registration, environmental licenses, and risk assessment for human health and the environment. However, further discussion is required prior to setting the regulatory framework for "on-farm" production and the registration of biopesticides by Brazilian authorities given that the country would most likely be the first major agricultural economy to regulate the subject.

Table 1 below illustrates several pros and cons of "on-farm" production of biopesticides, including those reported by the different stakeholders.

Table 1.

Pros and Cons of "on-farm" Production of Biopesticides	
PROS	CONS
● Reduction of agricultural production costs ● Reduction of environmental impacts ● Reduction of food chemical residues ● Reduction of safety risks to rural workers ● Increased use of bioproducts could improve the Brazilian image abroad	● Risks to workers working in inappropriate bio plants ● Agronomic dangers due to the use of products with low efficacy ● Disrespect for intellectual property and reduced investment in R&D ● Risk of damage to the Brazilian image abroad if contaminated food is exported ● Possibility of food contamination with microorganisms such as E. Coli, Salmonella, etc. ● Possibility of environmental contamination through accidents

Attachments:

No Attachments.