



BIOINPUTS

REGULATIONS

DEMAREST

INTRODUCTION

Rich in biodiversity, Brazil is a worldwide leader in using and producing Bioinputs. According to the government-owned Brazilian Agricultural Research Corporation (Embrapa), the country can expand sustainable technology even further.

The Bioinputs market generates billions of reais each year. Bioinputs are a valuable, strategic replacement to traditional chemical products, especially during crises, e.g., when the dollar rises against local currencies or an agriculture shortage occurs.

However, Brazil has yet to regulate Bioinputs. The current scenario, without specific legislation, can result in legal uncertainty in the sector.

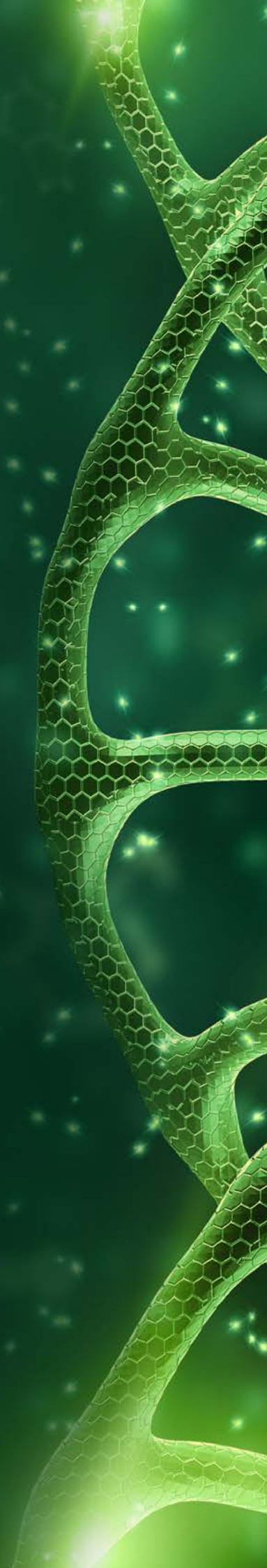
Currently, “biological inputs” are classified and regulated under different regulations according to their use, such as organic agriculture, biofertilizers, biological control, and veterinary biological products. In other words, the current regulations on Bioinputs

are too broad and generic. We believe that specific rules can stimulate business in Brazil.

To improve the Bioinputs legal framework, consolidate the regulation, and ensure legal certainty, two important bills seek to establish the Bioinputs Regulatory Framework in Brazil: [Bill No. 658/2021](#), currently in the House of Representatives, and [Bill No. 3,668/2021](#), currently in the Federal Senate.

Demarest’s Life Sciences team has created this Bioinputs regulation overview to assist our clients and business partners. This document provides an outlook of the main discussion points on these two bills.

Business players must clearly understand the current regulatory landscape and upcoming innovations to anticipate costs, obstacles, incentives, and opportunities. In the meantime, companies can participate in the discussion to develop the bills before the Congress votes on them.



WHY ARE BIOINPUTS TRENDING?

What is a bioinputs?

A **biological input** (or bioinputs) is a product, process, or technology of biological, plant, animal, or microbial origin to be used in agricultural products' production, storage, and processing.

ADVANTAGES



Low toxicity



Biodegradable



Low carbon footprint agriculture



Reduced environmental impact



Low reliance on imported inputs



Sustainable, biological, and regenerative agriculture









Lower production cost

CURRENT REGULATIONS

NATIONAL BIOINPUTS PROGRAM

[Decree No. 10,375, of May 26, 2020](#) established the NATIONAL BIOINPUTS PROGRAM (PNB) and created the Strategic Council of the National Bioinputs Program.





The PNB’s main goals and results are:

-  Consolidating the national bioinputss catalog
-  Reducing reliance on imported fertilizers – resulting in sustainability and bioeconomy
-  Supporting technological innovation – research
-  Boosting bioinputs use
-  Developing a regulatory framework and establishing good practices in bioinputss production
-  Offering biofactories financial, technical, and management support + credit lines and incentives

UNFOCUSED LEGISLATION

Because of the broad use of bioinputss broad use, such products can be classified under different regulations, such as:



- PLANT PROTECTION PRODUCTS**
-  Organic Agriculture
 -  Biofertilizers
 -  Biological Control (Agrochemicals Law)
 -  Animal (Veterinary Products)

BIOINPUTS MARKET IN BRAZIL



BRAZIL IS A WORLDWIDE LEADER IN BIOINPUTS PRODUCTION AND USE



BRL 3 BILLION

2021 bioinputs revenue



BRL 18.5 BILLION

Worldwide Bioinputs transactions forecast by 2026



BRL 340 BILLION

Total available rural credit: *Plano Safra 2022-2023* (Brazil's rural credit policy) with resources to finance biofactories and other expenses



74%

Sector's expected development by 2026



526 products aimed at pest control

555 inoculating agents*



BRL 165 MILLION

annual savings due to biological control products



* Latest Embrapa's "Bioinsumos" smartphone app update

Source: Market Research - Research and Markets, MAPA and EMBRAPA

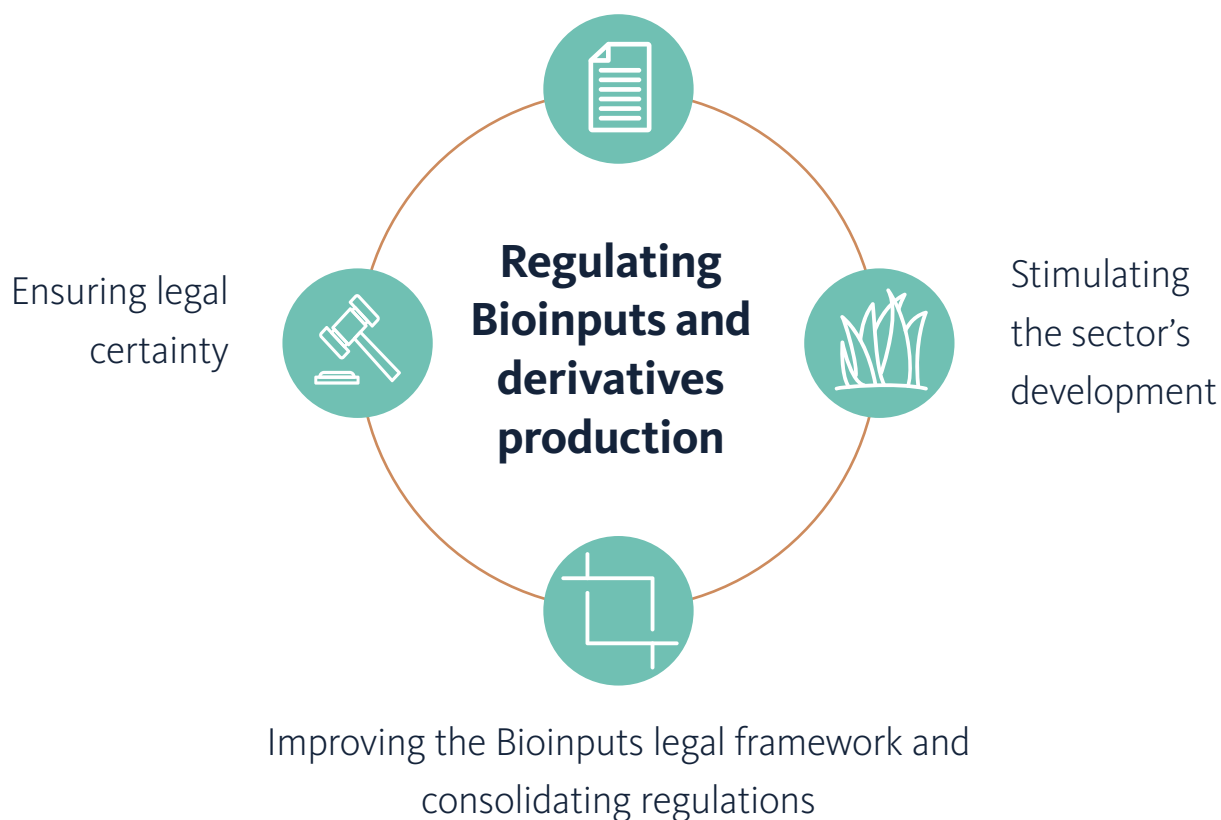


ONGOING BILLS AND RESPECTIVE IMPACT

MAIN GOALS OF THE BILLS

WHAT ARE THE GOALS?

Establishing modern, clear, and specific bioinputs production and trading rules within the Brazilian market



MAIN ONGOING BILLS

WHAT ARE THE BILLS? (AGROCHEMICALS)

[BILL NO. 6299/2002](#)

Submission Date: March 13, 2002

Amendments: 11 amendments

Author: Federal Senate - Blairo Maggi - SPART/MT

Regime: Fast-track (Art. 155, RICD)



Summary: Regulates research, testing, production, packaging, labeling, transport, storage, marketing, use, importing, exporting, waste and packaging disposal, registration, classification, control, inspection and control of pesticides, environmental control products, and the like; amends Law no. 8 issued on October 11, 1962; repeals Laws no. 7,802, issued on July 11, 1989, and 9,974, issued on June 6, 2000, repeals parts of annexes to Laws No. 6,938, issued on August 31, 1981, and No. 9,782, issued on January 26, 1999, and regulates provisions in Law no. 12,873, issued on October 24, 2013, among other provisions. (New Summary)

Status: Pending Federal Senate's approval

Regime: Fast-track (Art. 155, RICD)

*Last checked on April 24, 2023



Goal:

Known as the **“Pesticides Bill”** or **“Poison Package”** among opponents, Bill No. 6299/2022 modifies the agrochemicals registration system.



Continuity of production and adjustment term:

Phytosanitary products production and own use will continue, and after the law passes, the respective organizations must comply with the new provisions within 180 days.



Waiver of registration:

Companies are exempt from registering Bioinputs for **own use**, provided that:

- a. The plant (regardless of size) is registered with the agriculture agency, informing who is the Technician in charge (except: family farmers).
- b. Producers do not sell phytosanitary products for own use.
- c. The respective local authority authorizes the production of phytosanitary products for own use.
- d. The producer does not use products based on microbiological agents, exotic or unnaturally present in Brazil.



The concept of “phytosanitary product for own use”:

Organic pesticides produced by an individual or legal legal entity to use in own crops, in organic or conventional production systems.

MAIN ONGOING BILLS

WHAT ARE THE BILLS? BILL 658/2021 AND BILL 3,668/2021

BILL NO. 658/2021



Submission Date: March 02, 2021

Amendments: 29 amendments

Author: Representative Zé Vitor (PL-MG)

Regime: Ordinary Legislative Procedure (Art. 151, III, RICD). On June 02, 2022, a request for fast-tracking the Bill was submitted.

Summary: Regulates classification, treatment, and production of on-farm Bioinputs handling; the bill ratifies the National Bioinputs Program and establishes other measures.

Status: An appeal filed on February 03, 2023 is pending Congress approval. *

Next steps: If representatives reach an agreement, the Bill will move forward to the Senate. Otherwise, the full court of the House of Representatives must reassess the Bill.



MAIN ONGOING BILLS

BILL NO. 3668/2021



Submission Date: October 19, 2021

Amendments: 19 amendments

Author: Senator Jaques Wagner

Summary: Regulates production, registration, sale, use, waste and packaging disposal, inspection and control, research and testing, and incentives for agricultural bioinputs production, and provides other measures.

Status: Forwarded to Senator Veneziano Vital do Rêgo to issue a report. Currently with the Environmental Committee.*

Senator Jaques Wagner's Justification for presenting a new bill on the same subject in the Senate:

*"(...) We think we must broaden the debate here in the Federal Senate **to speed up the implementation of this legal framework to produce Bioinputs**. We believe that, above all, **expanding the scope of this noble legislative proposal** is necessary to regulate not only the production of on-farm Bioinputs handling, but also Bioinputs' entire production cycle, which includes producing, importing, exporting, selling, and using Bioinputs in domestic agricultural production. (...)"*

*Last checked on April 24, 2023

IMPORTANT TOPICS

DISCUSSION HIGHLIGHTS - BILL 658/2021 AND BILL 3,668/2021



**TECHNICIAN
IN CHARGE**



**BIOFACTORY
REQUIREMENTS**



**ON-FARM
BIOLOGICAL
HANDLING**



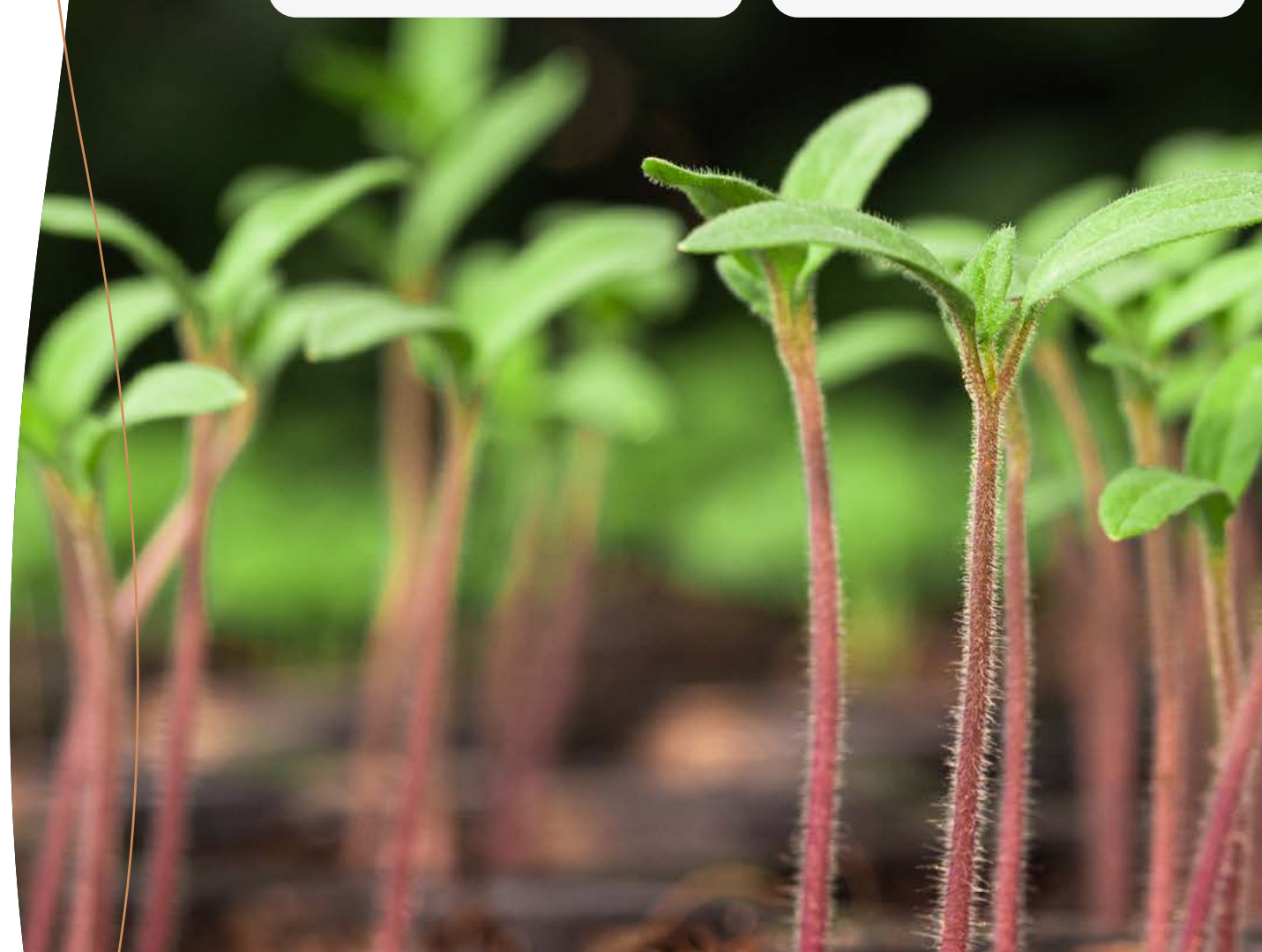
**ENVIRONMENTAL
AUTHORIZATION**



**BIOINPUTS
TRANSPORTATION**



**PRODUCT
REGISTRATION**



POTENTIAL IMPACT

MAIN TOPICS OF BILL 658/2021 AND BILL 3,668/2021



INCREASED COSTS



**INCREASED REGULATORY
AUTHORITIES' MONITORING
AND CONTROL**



INCREASED RED TAPE



**INCREASED LEGAL
CERTAINTY**

QUESTIONS? FEEL FREE TO CONTACT US!



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