

# BIOLOGICAL PRODUCTS REGISTRATION IN BRAZIL

AN OVERVIEW FROM INDUSTRY EXPERIENCE

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# BIOLOGICAL Products – Brazilian market

WHICH PRODUCTS ARE WE TALKING ABOUT?

**Mineral Fertilizers**

**Inoculants**

**PGR**

*(Plant Growth Regulators)*

**Biocontrol**

*(microbial pesticides)*

**Biostimulants**

**Biofertilizers**

**Organic-mineral  
Fertilizers**

**Organic Fertilizers**

# LEGISLATION STRUCTURE - Brazil

## OVERVIEW

Part I

Part II

Part III

- **Legislation goals**

- **Product definitions** (legal framework)

### Effect



### Cause

• Growth stimulation	Nutrients	Fertilizer
• Growth stimulation	Hormone	PGR
• Fungi control	Chem. molecule	Fungicide
• Fungi control	Microrganism	Microbial Fungicide
• Growth promoter	Metabolite	Biostimulant
• etc	etc	etc

Registration  
procedures and  
requirements

Administrative  
procedures  
(inspections, duties ,  
prohibitions, fines etc)

# Current Legal Basis - Brazil

WHERE THE MAIN BIOLOGICAL PRODUCTS ARE REGULATED?

## “PESTICIDES LAW”

### Chemical pesticides

Fungicides  
Herbicides  
Insecticides  
Miticides  
Nematicides

### Microrganisms

Biocontrol  
Biostimulants

### Biochemicals

PGR  
Natural substances

### Others

Semiochemicals  
Macrorganisms

#LAW n° 14785/2023

## “FERTILIZERS LAW”

### Fertilizers

Mineral  
Organic-mineral  
Organic  
Biofertilizers

### Inoculants

BNF  
(biological nitrogen fixation)  
Growth promoters

### Others

Limestones  
Soil conditioners

#LAW n° 6894/1980

# Requirements for registration

## BASIC INFORMATION

### “PESTICIDES LAW”

#### Microrganisms

*Biocontrol*

*Biostimulants*

#### Biochemicals

*PGR*

*Natural substances*

Lab Reports (phy-chem, tox, ecotox)

Product formula

Field efficacy

**Agriculture/Health/Environment  
(MAPA / ANVISA / IBAMA)**

Federal approval: 1 – 2 years

### “FERTILIZERS LAW”

#### Fertilizers

*Mineral*

*Organic-mineral*

*Organic*

*Biofertilizers*

#### Inoculants

BNF

Growth promoters

Product formula

Field efficacy (*overall, not required*)

**Agriculture (MAPA)**

Time final approval: automatically or 6-12 months

# Current scenarios and trends

WHAT WE HAVE BEEN DEALING WITH IN BRAZIL...

## “PESTICIDES LAW”

### Chemical pesticides

*Fungicides*  
*Herbicides*  
*Insecticides*  
*Miticides*  
*Nematicides*

## “BIOPRODUCTS LAW”

NEW!?

### Biochemicals

*PGR*  
*Natural substances*

### Inoculants

*BNF*  
*Growth promoters*

### Microrganisms

*Biocontrol*  
*Biostimulants*

#BILL n° 3668/2021

## “FERTILIZERS LAW”

### Fertilizers

*Mineral*  
*Organic-mineral*  
*Organic*

# FOR TODAY AND FOR TOMORROW

## KEY TAKEAWAYS

- Main drivers for product registration: security, performance and sustainability, supported by scientific data.
- The more plant needs are discovered by research the more potentially innovative products are developed and launched to market.
- Companies expect regulation to always be ready enough for enabling these innovative products.
- Therefore, Industry Associations around the world play an essential role in collaborating effectively in this process and build their future.

**THANK YOU**