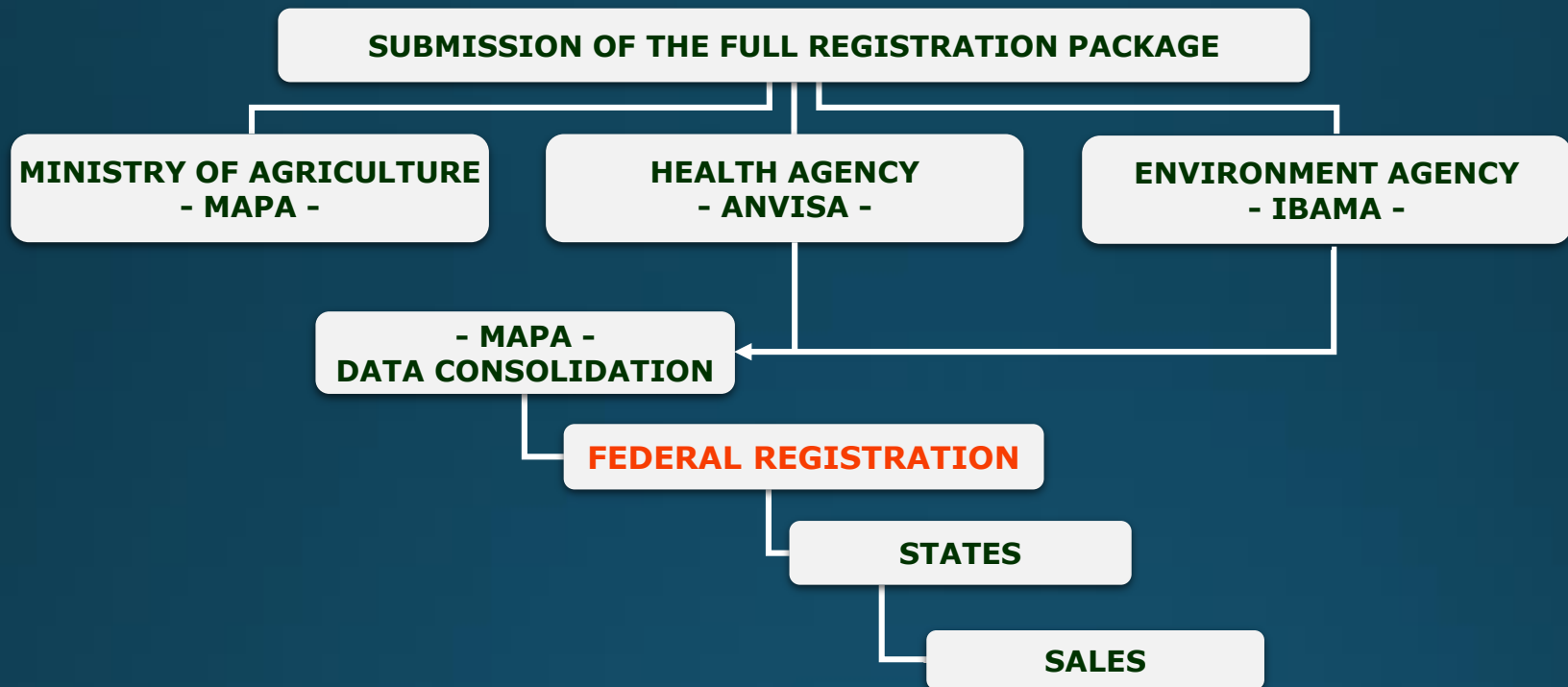




What's in force and what's to come for the biopesticides regulations in Brazil



Brazilian Registration Process Pesticides



BIOPESTICIDES - CATEGORIES

❖ MICROBIOLOGICALS

Fungi, bacteria, virus (living organisms)

❖ MACROBIOLOGICALS

Natural enemy, predator

❖ BIOCHEMICALS

Substances from “natural sources” **with a non-toxic mode of action to the targets**

Plant Growth Regulator (PGR) – natural or synthetic

Proteins, Aminoacids, Enzymes

❖ SEMIOCHEMICALS

Pheromones, sexual attractive

❖ PLANTS EXTRACTS

Specific legislation is under discussion

Currently, it must be registered as a conventional formulation.

❖ BIOSTIMULANTS

This terminology does not exist in Brazil

1° – Registration of a Brazilian company (Federal and local Agencies)

2° – Experimental Use Permit (EUP / *RET*)

- “Active ingredient” already registered – only MAPA (approval takes around a month)
- “Active ingredient” not registered - all the 3 Authorities (approval takes around 3-4 months)

3° – Samples importation

4° – Perform the lab studies and field trials

- LABORATORY (GLP)
- FIELD (must be performed in Brazil)
 - Biological and Pheromones: registration is per target (any crop)
 - Biochemical: registration is per crop/target or claim
 - Plant extracts: per crop/target
 - **New legislation:** per target

5° – Dossiers preparation

Official fees for Biopesticidas

TECHNICAL PRODUCT (not usual - case by case): ± **US\$ 4.200**

FORMULATION (+ components): ± **US\$ 4.900**

CLONE (same quali-quantitative composition):

Same procedures/queue: ± **US\$ 2.600**

Possibility to include different brand names in the same registration (**new**)

6° – Submission to the Authorities

**APPROVAL
TIMELINE FOR GETTING THE
APPROVAL: 8 - 10 MONTHS**

7° – State Inscriptions (27)

8° – Sales and post-registration procedures

- Text already approved by the technical area from the three authorities (now, bureaucrat procedures)
- Expectation to be published in the 1Q/2023

Main changes:

- Definition (inclusion):
 - Inactivated microorganism
 - GMO
 - Biostimulants (related to biotic factors)
- Clarity about no need of technical product registration and residues studies
- Possibility to waive tox/ecotox studies, through scientific publication
- Post-registration: evaluated only by MAPA (only specific processes, like composition change, will be still evaluated by the three authorities).
- Waiver of agronomic prescription

MICROORGANISMS ALREADY REGISTERED IN BRAZIL

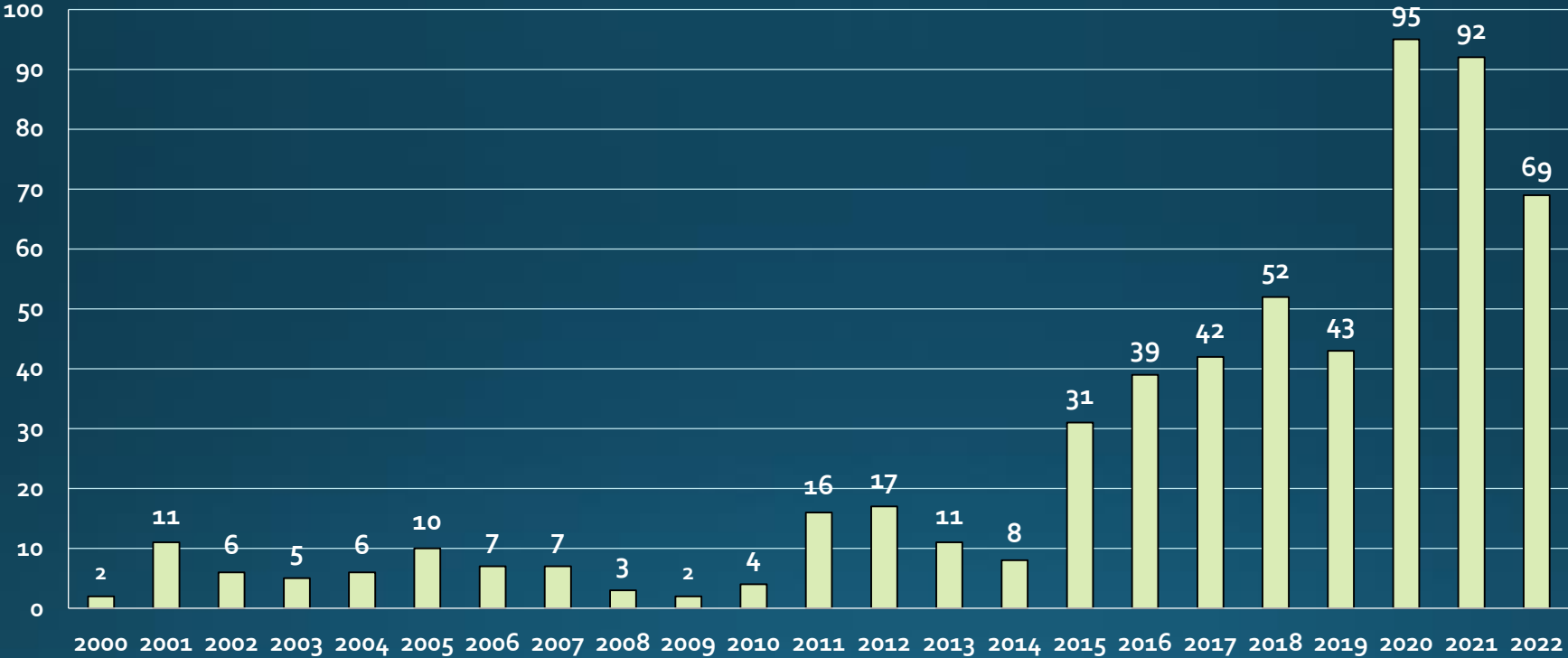
- A57 - *Aspergillus flavus*
- A61 - *Autographa californica multiple nucleopolyhedrovirus (AcMNPV)*
- B01 - *Bacillus thuringiensis*
- B30 - *Baculovirus anticarsia*
- B31 - *Bacillus sphaericus*
- B40 - *Beauveria bassiana*
- B43 - *Bacillus pumilus*
- B44 - *Bacillus subtilis*
- B45 - *Baculovirus condylorrhiza vestigialis*
- B47 - *Baculovirus helioverpa zea*
- B48 - *Baculovirus helioverpa armigera*
- B49 - *Bacillus amyloliquefaciens*
- B50 - *Bacillus methylotrophicus*
- B51 - *Baculovirus spodoptera frugiperda*
- B52 - *Bacillus firmus*
- B53 - *Bacillus licheniformis*
- B56 - *Bacillus velezensis*
- C76 - *Chrysodeixis includens nucleopolyhedrovirus*
- C77 - *Cordyceps fumosorosea*

MICROORGANISMS ALREADY REGISTERED IN BRAZIL

C80 - *Clonostachys rosea*
H18 - *Hirsutella thompsonii*
I28 - *Isaria fumosorosea*
I31 - *Isaria javanica*
M39 - *Metarhizium anisopliae*
M51 - *Metarhizium rileyi*
P56 - *Paecilomyces lilacinus*
P58 - *Pochonia chlamydosporia*
P59 - *Pasteuria nishizawae*
P64 - *Pseudomonas oryzihabitans*
P66 - *Pseudomonas chlororaphis*
P67 - *Pseudomonas fluorescens*
P68 - *Phthorimaea operculella granulovirus*
T60 - *Trichoderma harzianum*
T64 - *Trichoderma asperelum*
T65 - *Trichoderma stromaticum*
T67 - *Trichoderma koningiopsis*
T73 - *Trichoderma afroharzianum*
T76 - *Trichoderma atroviride*
T78 - *Trichoderma viride*

TOTAL: 39 different species (bacteria, fungi and virus)

NUMBER OF BIOPESTICIDES APPROVED PER YEAR



TOTAL OF 567 BIOPESTICIDES REGISTERED IN BRAZIL

Source: Ministério da Agricultura (MAPA), August 2022.

CONCLUSIONS

- Brazil has been developing at great strides the regulation of Biopesticides
- Reduction of timeline for registration approval (less than 1 year)
- The regulatory framework has been favorable for the development of an ecofriendly market
- The forecast represents that the market will continue to grow a lot in Brazil

THANK YOU!

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