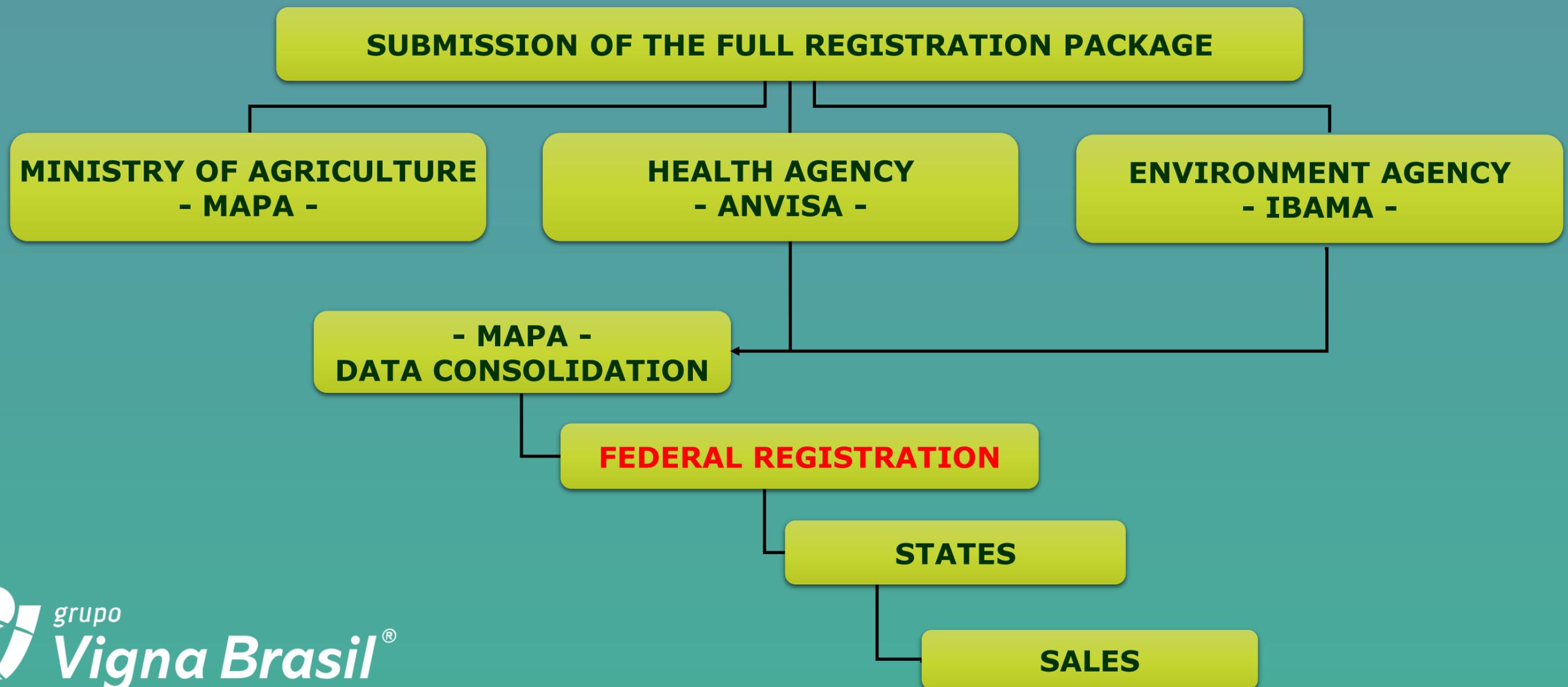




Reforms to the
Brazilian regulatory system,
the good and the areas



Brazilian Registration Process **Pesticides**



BIOPESTICIDES *Types of Products*

MICROBIOLOGICALS

Fungi, bacteria, virus (living organisms)

MACROBIOLOGICALS

Natural enemy, predator

BIOCHEMICALS

Products based on substances from “natural sources” with non-toxic mechanism of action against to the targets, unless plant extracts

PGR - Plant Growth Regulator (natural or synthetic)

Proteins, Aminoacids, Enzimes with claims as crop protection

SEMIOCHEMICALS

Pheromones, sexual attractives

PLANTS EXTRACTS

Until 2018, they were considered as Biochemicals. A new legislation is under discussion

Currently, it must be registered as conventional formulation.

Registration Procedures

Basic Steps

1. Registration of a Brazilian company
(federal and local Agencies)
2. Experimental Use Permit (EUP / RET)
 - “Active ingredient” already registered – only MAPA (approval in about 1 month)
 - “Active ingredient” not registered - all 3 Agencies (approval in about 3-4 months)
3. Samples importation or local production
4. Lab studies (GLP) and local field trials
 - Biologicals and Pheromones:
registration is per target (any crop)
 - Biochemical and Plant Extracts(?):
registration is per crop/target or claim



Registration Procedures

Basic Steps

5. Dossiers preparation

Official fees for BioPesticides

TECHNICAL PRODUCT (not usual - case by case): **± US\$ 5.100**

- R\$ 3.172,74 (ANVISA)
- R\$ 865,58 (checklist) + R\$ 17.336,05 (evaluation - IBAMA)

FORMULATION: **± US\$ 5.900**

- R\$ 3.172,74 (FP) + R\$ 3.172,74 (components – ANVISA)
- R\$ 865,58 (checklist) + R\$ 17.336,05 (evaluation – IBAMA)

CLONE (new brand): Same procedures/queue: **± US\$ 3.100**

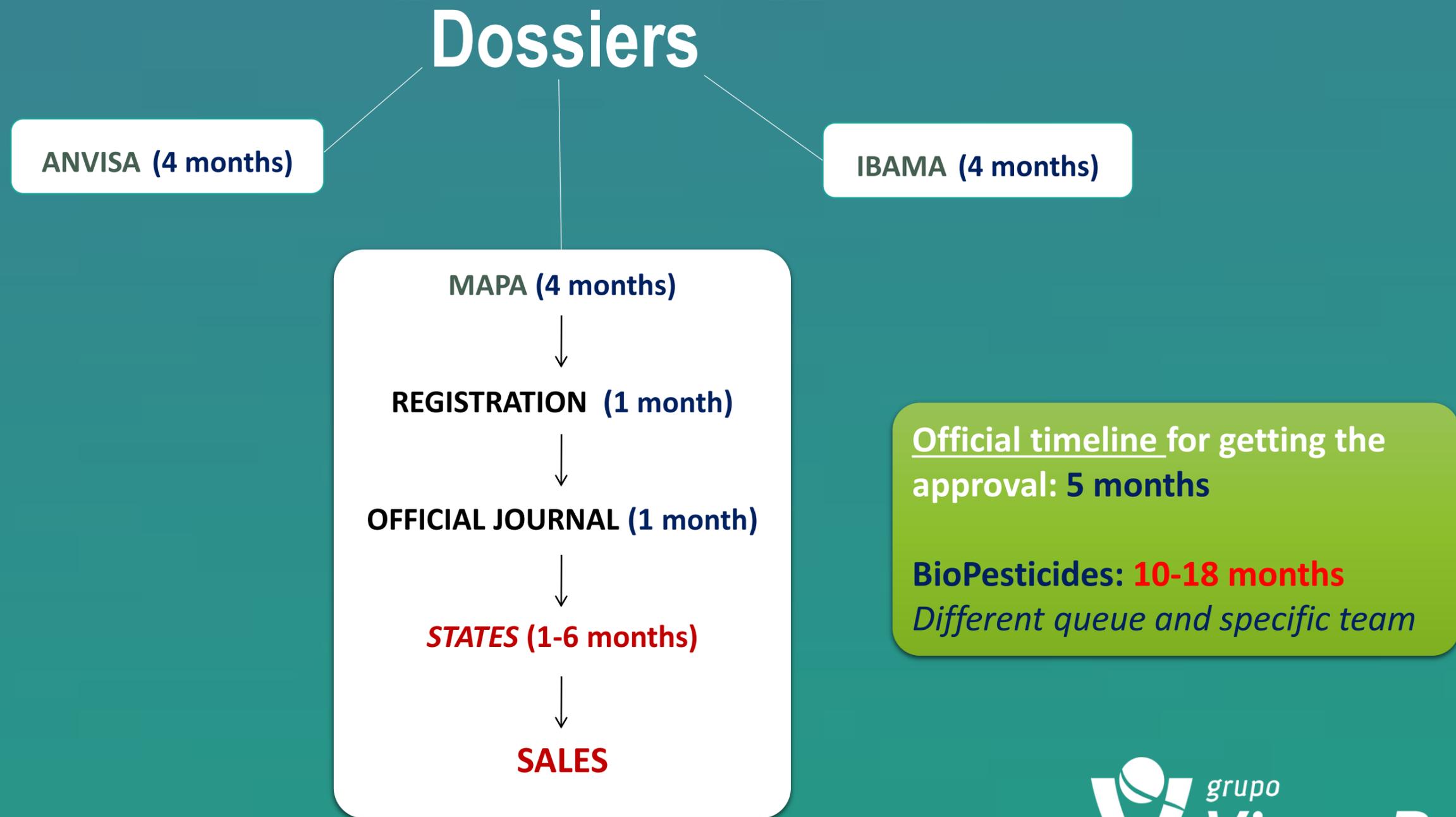
- R\$ 3.172,74 (FP) + R\$ 3.172,74 (components - ANVISA)
- R\$ 865,58 (checklist) + R\$ 5.779,59 (evaluation - IBAMA)

6. Submission to the Authorities **APPROVAL**

7. State Inscriptions (27)

8. Sales and post-registration procedures

REGISTRATION PROCESS *Timelines*



New Legislations

(Published on July 31, 2019) - ANVISA

RDC 294

Toxicological Evaluation and Classification

Based on **GHS** standard

Category 1	Category 2	Category 3	Category 4	Category 5	Product not Classified
Extremely Toxic Product	Highly Toxic Product	Moderately Toxic Product	Slight Toxic Product	Product Unlikely to cause Acute Damage	NO "skull and crossbones"

- Technical Products (TP): Category and belt color is not required.
- The tox classification for TP is based on each evaluated toxicological endpoints.
- No "new" product would be approved if the category is more TOX than a similar already registered (same a.i., concentration and formulation type).



New Legislations

ANVISA

RDC 296

Label and Leaflet Guidelines

Update according to GHS

Toxicological categories

Pictograms, warning and hazard recommendations

Registered Products: 1 year to update.

New Legislations

ANVISA

RDC 295 Dietary Risk Assessment

This is the first publication that establishes Dietary Risk Assessment Criteria (acute and chronic), resulting from the presence of pesticide residues, their metabolites and degradation products present in food.

No impact for BioPesticides: MRL is not established for most of products

New Legislations

ANVISA

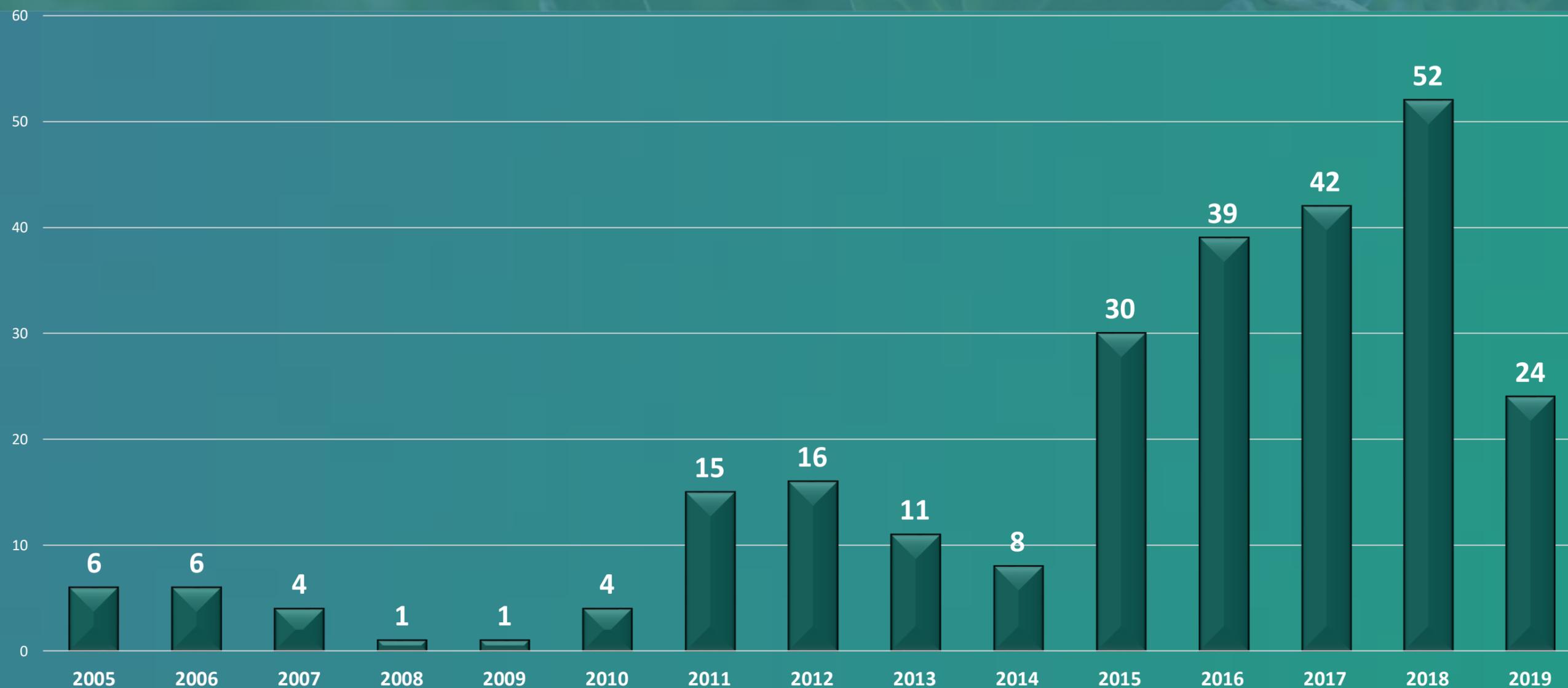
IN 34

**Negative list of ingredients used
in pesticide formulations**

Negative list of 9 substances not authorized.

**Registered products - review and change the
formulations: update until Jan/21 (if necessary).**

NUMBER OF BIOPESTICIDES APPROVED (PER YEAR)



Source: Ministério da Agricultura (MAPA), September 2019.



REGISTERED PESTICIDES IN BRAZIL

Number of registered products in Brazil	
BioPesticides	309
Formulations (conventional)	2.236
Technical Grade (new a.i.)	91*
Technical Product (generics)	1.216*
<i>*From 2005 to 2019</i> Total	3.852

BioPesticides	Number of Registered Products
Acaricide	13
MacroBiological	57
Insecticide	121
Bactericide	2
Pheromone	49
Nematicide	22
Fungicide	25
Biochemical	13
Plant Extract	7
Total	309

Number of Registered Products in 2019 (Sept)	
BioPesticides	24
Formulations	144
Technical Grade (new a.i.)	3
Technical Product (generics)	211
Total	382



THANK YOU!

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