



CACW²⁰²⁴ China International Agrochemical Conference Week 2024

New Brazilian Pesticide Law

Shanghai, March 13th, 2024

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赋能企业市场拓展

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Flávio Hirata, 农学家（巴西圣保罗大学路易斯·德·奎罗斯学院），农药注册专家和**AllierBrasil**（巴西农药登记咨询公司）的合作伙伴。

AllierBrasil是一家致力于农商业的咨询公司，专注于农药注册和发展技术商业合作。25年来，AllierBrasil一直在推广巴西农业，并帮助农药公司能够进入市场

Flávio Hirata, agronomist (ESALQ-USP), expert in pesticide registration and partner at **AllierBrasil**.

AllierBrasil is a consulting firm, focused on pesticide registration and on developing technical-commercial partnerships. For more than 25 years, **AllierBrasil** has promoted Brazilian agriculture and has enabled pesticide companies to enter the Brazilian market.



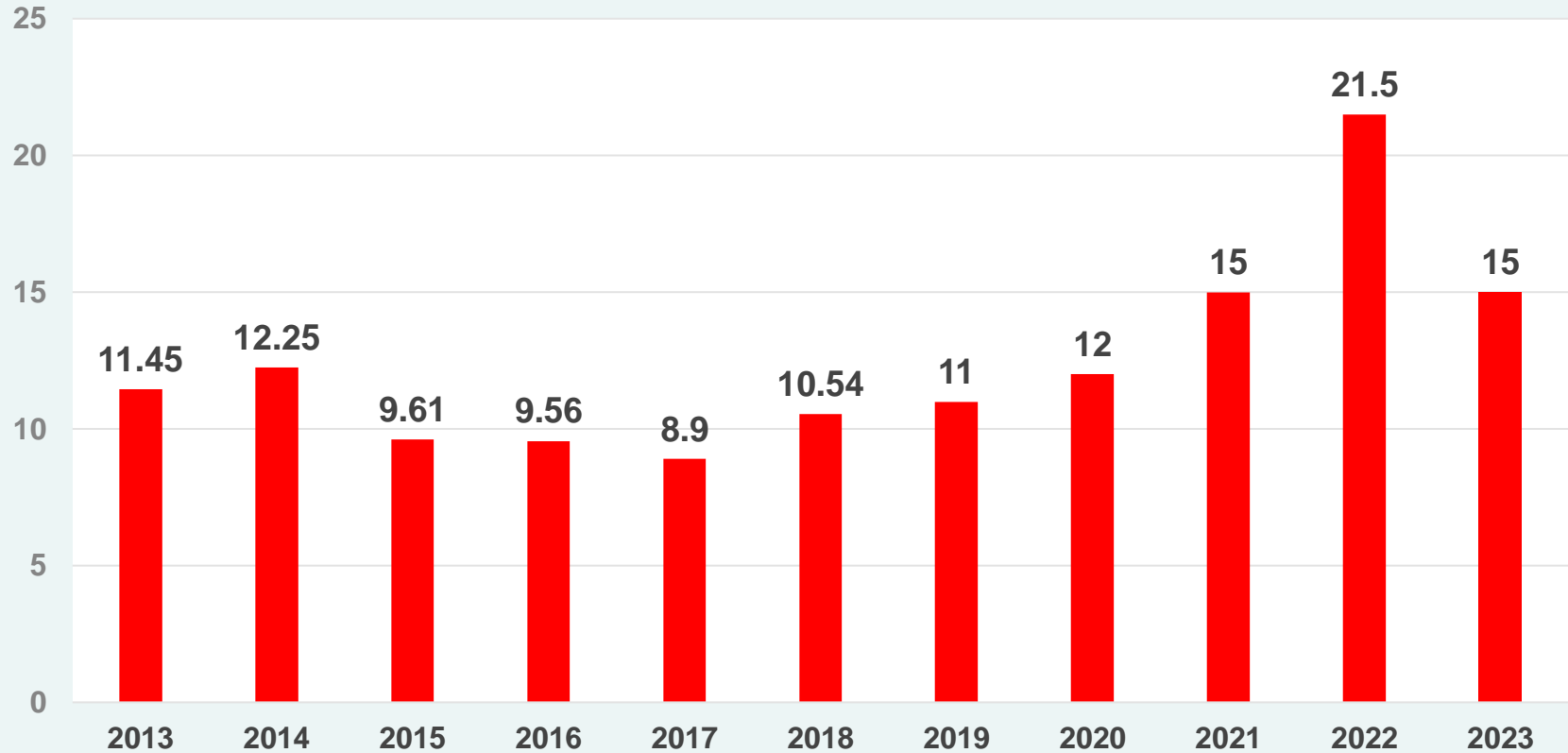
Consulting in Agribusiness
Pesticide Registration
Technical & Commercial Partnership Development
We Promote Agro

Law No. 14785, December 27, 2023

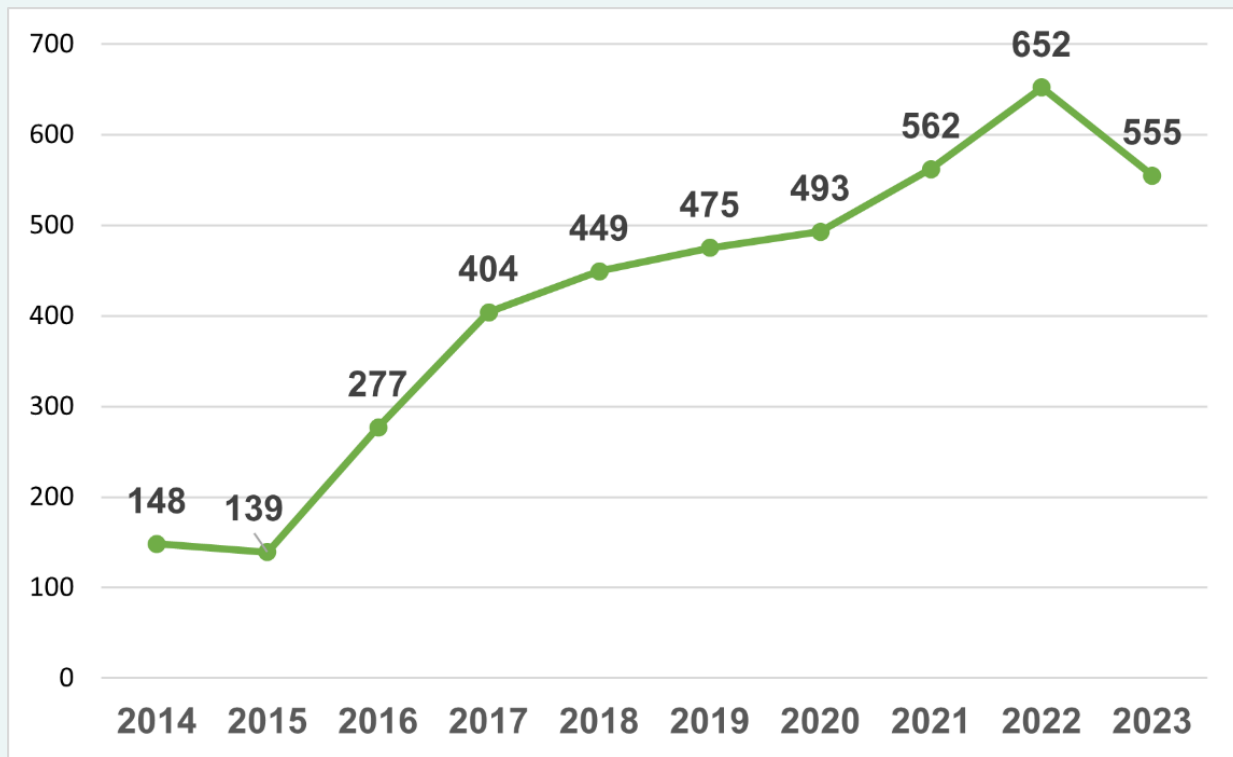
Provides for research, experimentation, production, packaging, labeling, transport, storage, marketing, use, import, export, final destination of waste and packaging, registration, classification, control, inspection and inspection of pesticides, environmental control products, their technical products and the like; **revokes Laws 7802** (July 11, 1989) and **9974** (June 6, 2000), and parts of the annexes from Laws **6938** (August 31, 1981) and **9782** (January 26, 1999)

PESTICIDES

US\$ Bi



过去10年（2014-2023）批准的农药注册 PESTICIDE REGISTRATION APPROVALS



Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil

来源：农业和畜牧业部；由AllierBrasil改编

Art. 3

§ Paragraph 1: Deadlines

| Type of registration | Law 14785 Dec 27 th , 2024 | Decree 10833 Oct 7,2021 |
|------------------------------|--|----------------------------|
| | Months | |
| new formulated product | 24 | 12* |
| new technical product | | 36 |
| formulated product | 12 | 24 |
| generic formulated product | | 24* |
| equivalent technical product | | 24 |
| atypical | | |
| organic farming | | |
| biological | | |
| pre-mixture | | |
| identical formulated product | 2 | |
| EUP/RET | 1 | |

Lawsuits in 2022

| Type | Brand Name (registration No.) | Registrant | Agency | Product |
|--------|--|------------|---------------|--|
| FP | DORAI MAX (322) | IHARABRAS | Ibama | Amicarbazone 50 + diquat dibromide 373.5 g/L SC |
| FP | XEQUE MATE HT (422) | IHARABRAS | Anvisa | Glyphosate - potassium salt 720 g/L SL |
| FP/ETP | ARQUERO (722) | ADAMA | Anvisa | Acetamiprid 375 + bifenthrin 165 g/L SC |
| FP/ETP | ADVER 240 SC (1522) | TECNOMYL | Anvisa | Chlorfenapyr 240 g/L SC |
| FP/ETP | CROPPER (1622) | ADAMA | Anvisa, Ibama | Prothioconazole 31.5 + fluxapyroxad 22.5 + mancozeb 440 g/L OD |
| FP | BURNER (2522) | IHARABRAS | Anvisa, Ibama | Diquat dibromide 373.5 + flumioxazin 25 g/L SC |
| FP/ETP | FORASTEIRO (4422) | ADAMA | Anvisa, Ibama | 2,4-D 322 + fluroxypyr-meptyl 92.2 + picloram 64 g/L EC |
| FP/ETP | UPL 1014 FP (4822) | UPL | Anvisa | Acephate 850 + bifenthrin 30 g/kg WG |
| FP/ETP | WINOUT XTRA (5922) | RAINBOW | Anvisa, Ibama | Fluazinam 800 g/kg WG |
| FP/ETP | AMICARBAZONE NORTOX (6222) | NORTOX | Anvisa | Amicarbazone 700 g/kg WG |
| FP/ETP | GARROTEBR (6322) | OURO FINO | Anvisa, Ibama | Fluroxypyr-meptyl 115.3 + picloram 143.4 g/L ME |
| FP/ETP | COFENRIN (6922) | RAINBOW | Anvisa | Bifenthrin 400 g/L EC |
| FP/ETP | WIKING 600 WG (7122) | CROPCHER | Anvisa | Metsulfuron-methyl 600 g/kg WG |
| FP/ETP | VIGORBR (7422) | OURO FINO | Ibama | Imidacloprid 600 g/L FS |
| FP/ETP | ARBUST (8822) | OURO FINO | Anvisa, Ibama | Triclopyr-butotyl 667 g/L EC |
| FP/ETP | JUMBO BR (8622) | ADAMA | Anvisa, Ibama | Sulfentrazone 360 + tebuthiuron 450 g/kg WG |
| FP/ETP | CHLOROTHALONIL C 720 SC PERTERRA (9622) | PERTERRA | Anvisa, Ibama | Chlorothalonil 720 g/L SC |
| FP/ETP | SONDA HT (10122) | IHARABRAS | Anvisa, Ibama | Terbuthylazine 500 g/L SC |
| FP | TARGA MAX HT (10222) | IHARABRAS | Anvisa, Ibama | Quizalofop-P-ethyl 100 g/L EC |
| FP/ETP | BORDALO PRO (10722) | TRADECORP | Anvisa, Ibama | Lufenurom 50 + profenofos 500 g/L EC |

| | | | | |
|--------|-------------------------------------|-----------|---------------|--|
| FP/ETP | KANPAI (11722) | IHARABRAS | Anvisa, Ibama | Acetamiprid 200 + lambda-cyhalothrin 250 g/L OD |
| FP/ETP | TRICLOPIR 667 EC PERTERRA (11922) | PERTERRA | Anvisa, Ibama | Triclopyr-butotyl 667 g/L EC |
| FP/ETP | SUNGAIN XTRA (12222) | RAINBOW | Anvisa, Ibama | Flumioxazin 800 g/kg WG |
| FP/ETP | CROPPER BR (12722) | ADAMA | Anvisa, Ibama | Prothioconazole 31.5 + fluxapyroxad 22.5 + mancozeb 440 g/L OD |
| FP | SHODAN (12822) | IHARABRAS | Ibama | Flumioxazin 60 + sulfentrazone 450 g/L |
| FP/ETP | OSBAR DUO (13222) | CROPCHAM | Anvisa, Ibama | Flumioxazin 100 + imazethapyr 212 g/L SC |
| FP/ETP | LONGAR 480 EC (13322) | SUMITOMO | Anvisa | Triclopyr-butotyl 667.32 g/L EC |
| FP/ETP | ACARIGEN (13622) | TECNOMYL | Anvisa | Abamectin 18 g/L EC |
| FP/ETP | EDDUS EC (14022) | SYNGENTA | Anvisa | S-metolachlor 517.83 + fomesafen 119.54 g/L EC |
| FP | PRIMACY (16022) | IHARABRAS | Anvisa, Ibama | Amicarbazone 250 + sulfentrazone 250 g/L SC |
| FP/ETP | THUMB-TACK NORTOX (16322) | NORTOX | Anvisa | Acetamiprid 100 + bifenthrin 67 g/L SL |
| FP/ETP | RICEPAL (16422) | RAINBOW | Ibama | Propanil 800 g/kg WG |
| FP/ETP | GEMPOX (18022) | SYNCROM | Anvisa, Ibama | Glufosinate-ammonium 850 g/kg SG |
| FP/ETP | TRICLOMAX (18122) | RAINBOW | Anvisa | Triclopyr-butotyl 667 g/L EC |
| FP/ETP | LANFOR PRO (19022) | ALBAUGH | Anvisa, Ibama | Azoxystrobin 400 + cyproconazole 160 g/L SC |
| FP/ETP | BRAULTA 720 SC (19122) | CAC | Anvisa, Ibama | Chlorothalonil 720 g/L SC |
| FP/ETP | CLETHODIM R 240 EC PERTERRA (20922) | PERTERRA | Ibama | Clethodim 240 g/L EC |
| FP/ETP | TANREK 500 SC (21322) | AVGUST | Ibama | Imidacloprid 500 g/L SC |
| FP/ETP | EQUINOX (21722) | ROTAM | Anvisa | S-metolachlor 480 + sulfentrazone 128 g/L EC |
| FP/ETP | AUG 134 (22422) | AVGUST | Ibama | Imidacloprid 500 g/L SC |
| FP/ETP | SENSUS (22622) | OURO FINO | Anvisa, Ibama | Clomazone 250 + sulfentrazone 100 g/L OD |
| FP/ETP | CROPCARE SC (22922) | CROPCHAM | Anvisa, Ibama | Azoxystrobin 125 + tebuconazole 240 g/L SC |
| FP/ETP | POTENZA SINON PLUS 36 EC (23222) | SINON | Anvisa | Abamectin 36 g/L EC |
| FP/ETP | FLUAZINAM 800 WG PERTERRA (23422) | PERTERRA | Ibama | Fluazinam 800 g/kg WG |
| FP/ETP | VALLEX (23522) | TECNOMYL | Anvisa, Ibama | Pyriproxyfen 100 g/L EC |

| | | | | |
|--------|---|--------------|---------------|---|
| FP/ETP | TRIPLEC (23722) | TECNOMYL | Anvisa, Ibama | Trinexapac-ethyl 250 g/L EC |
| FP/ETP | VERACE (24322) | ALTA | Anvisa, Ibama | Flumioxazin 500 g/L SC |
| FP/ETP | DOMADO 200 SL (24422) | SYNCROM | Anvisa, Ibama | Glufosinate-ammonium 200 g/L SL |
| FP/ETP | AGROSBAN (24522) | SYNCROM | Anvisa, Ibama | Chlorpyrifos 480 g/L EC |
| FP/ETP | CROPSHIELD (24822) | SYNCROM | Anvisa, Ibama | Chlorothalonil 825 g/kg WG |
| FP/ETP | GHALOR (25922) | ALBAUGH | Anvisa, Ibama | 2,4-D diethanolamine salt 442.8 + 2,4-D-dimethylamine 361.2 g/L SL |
| FP/ETP | DIQUATE NORTOX (26122) | NORTOX | Anvisa | Diquat dibromide 373.5 g/L SL |
| FP/ETP | DIQUAT VANON 200 SL (26222) | SYNCROM | Anvisa | Diquat dibromide 374 g/L SL |
| FP/ETP | LANDRIN (27622) | LANDRIN | Anvisa, Ibama | Fipronil 0.02 + indoxacarb 0.24 g/kg RB |
| FP/ETP | GLUFOSINATO 200 SL PERTERRA (28722) | PERTERRA | Anvisa, Ibama | Glufosinate-ammonium 200 g/L SL |
| FP/ETP | GRASIDIM FULL (23922) | RAINBOW | Anvisa, Ibama | Clethodim 360 g/L EC |
| NFP | STRIKE (29522) | IHARABRAS | Ibama | Metamifop 300 g/L EC |
| FP/ETP | AZOXYSTROBIN+CYPROCONAZOLE+OXIC LORETO DE COBRE SC ALBAUGH 01 (29722) | ALBAUGH | Anvisa, Ibama | Azoxystrobin 110 + cyproconazole 80 + copper oxychloride 436.8 g/L SC |
| FP/ETP | BOKSIA 300 WG (30422) | CROPChem | Anvisa, Ibama | Indoxacarb 300 g/kg WG |
| FP/ETP | PROTERRA 200 SL (31122) | ALLIERBRASIL | Anvisa, Ibama | Glufosinate-ammonium 200 g/L SL |
| FP/ETP | GLINT FULL (31222) | RAINBOW | Anvisa, Ibama | Haloxifop-P-methyl 540 g/L EC |
| FP/ETP | ALON (31422) | GLOBACHEM | Anvisa, Ibama | Bifenthrin 120 + lufenuron 140 g/L SC |
| FP/ETP | METOMY (31522) | RAINBOW | Anvisa, Ibama | Methomyl 900 g/kg SP |
| FP/ETP | HDB 276 (32122) | HELM | Anvisa, Ibama | Chlorothalonil 750 + tebuconazole 60 g/L SC |
| FP/ETP | MEDEIRO WG (32822) | TRADECORP | Anvisa | Fosetyl 800 g/kg WG |
| FP/ETP | TRACKING 720 WG (33522) | ALLIERBRASIL | Ibama | Glyphosate 792.5 g/kg WG |
| FP/ETP | METRARO (34122) | RAINBOW | Anvisa | S-metolachlor 960 g/L EC |

Notes:

FP: Chemical Formulated Product

NFP: New Chemical Formulated Product

FP/ETP: Chemical Formulated Product based on Equivalent Technical Product

Sources: Anvisa, Ibama, MAPA, Mazza & Manente de Almeida Advogados (mazza@mzma.com.br); adapted by AllierBrasil

§ Paragraph 2 - **EUP/RET for new products** intended for research and experimentation.

It been required at customs to any product to import

§ Paragraph 9 - When **international organizations** (health, food or environment) of which Brazil is a member or with which it is a signatory to agreements and conventions **warn of risks or advise against the use of pesticides**, ..., the competent authority should take steps to **evaluate the risks**, taking into account economic and phytosanitary aspects and the possibility of using substitute products.

§ Paragraph 10 - A **risk assessment shall be carried out** for the granting of registrations for **new products**, as well as for changes in use which involve **increase in dose, inclusion of crop, application equipment** ...

§ Paragraph 11 - Efficacy studies ... shall not be required for products which, when compared to formulated products already registered, have the following cumulative characteristics:

- I - same type of formulation**
- II - same recommendations** (crops and dose) and uses already registered

§ Paragraph 13 - **Residue studies:**

I - same type of formulation

II - same crop and use

III – same or lower amount of AI

IV - same or greater PHI

§ Paragraph 14 - For the comparison referred to in §13, formulated products that have already been registered should have:

II - residue studies

§ 15 – **To perform residue trials**, formulation type EC, WP, WG, SC and SL will be considered similar

§ Paragraph 17 - In regulating this Law, the public authorities shall seek to simplify and reduce bureaucracy in procedures and to reduce costs and required time to conclude the analyses of registration processes

Art. 9

It is the responsibility of the **States ... to legislate on a supplementary basis on the use, production, consumption, trade and storage of pesticides ...**, as well as to supervise the use, consumption, trade, storage and interstate transportation

Sole paragraph. ... **municipalities are responsible for legislating on the use and storage of pesticides ...**

Art. 11

The states shall use the data in the federal agencies' register to carry out their control and inspection activities.

Sole paragraph. The publication of pesticide registration on the website of the registering federal agency authorizes sales and use in the states

Sao Paulo State: revoked product state registration

Art. 12

Art. 12: The registrant should submit an application for registration of technical products, formulated products, pre-mixtures ... to the federal registering body, in accordance with the data, studies, reports, opinions and information required under the guidelines and requirements of this Law, using a computerized system.

§ Paragraph 2 - The registrant should submit the risk analysis together with the application for registration or post-registration changes of products with new AIs in Brazil and others that change the level of exposure, such as dose increases, crop inclusion and changes in the application equipment

Art. 14. The raw materials specified in the synthesis process of the registered technical product and the equivalent registered technical product, as well as other ingredients and additives used in the manufacture of generic and formulated products ..., shall be considered authorized.

Sole paragraph. The federal agency shall publish and keep updated the list of raw materials, other ingredients and authorized additives.

Art. 17

Art. 17: Pesticides, ... , exclusively for export shall not be required to be registered, which shall be replaced by a production notice for export

§ Paragraph 1 - The exporter should notify the registration agency the product and amount to be exported and destination

Art. 18

Art. 18 - A state of **phytosanitary emergency due to an epidemiological situation that indicates an imminent risk of introducing an exotic disease or quarantine pest not present in the country, or a risk of an outbreak or epidemic of an already existing disease or pest, in which case the Government is **authorized to consent to the import and grant temporary emergency permission** for the production, distribution, sales and use of pesticides**

Art. 29 - Revaluation: should be carried out and concluded within a period of up to 1 year, extendable by 6 months upon technical justification, without prejudice to the analysis of applications and registration changes in progress, as well as the maintenance of the commercialization, production, import

§ Paragraph 1 - The Government should develop a phytosanitary plan to replace the product, with the objective to control biological targets that may be left without alternatives for integrated pest management.

Art. 32

Art. 32: No different treatment will be given to registration applications or registration change requests and already registered products in regards to sales, produce, import, export and use

Imidacloprid

Already approved registrations: keep foliar application

New registrations: forbidden foliar application

Art. 35

Art. 35 - Registration holder has up to 2 years to produce and market the product, under penalty of registration cancellation.

§ Paragraph 1 - Once registration is approved, the registration holder should inform the Government about the start of production and marketing.

**Imported formulated product
Technical product
?**

Art. 37

Art. 37: ... every company that manufactures, formulates or imports pesticides, ..., should have a quality control unit, which may be in its own laboratory or outsourced

Art. 63

Regulation

Art. 63: Agencies carrying out activities regulated by this Law **should comply with its provisions within 360 days of the publication of this Law.**

PESTICIDE REGISTRATION

Discourages investment, inhibits competition

Increases costs, unpredictable

**A fourth institution becomes part of the registration process,
the Federal Court**

It is a tool for market access

Registration does not guarantee success

However those who have it, have more changes to succeed

It is a very valuable asset

AllierBrasil (2023)

Approved registrations

Registros aprovados

Total: 41

AllierBrasil (as registration holder): 36

Registration under clients' name: 5

AllierBrasil (registrante): 36

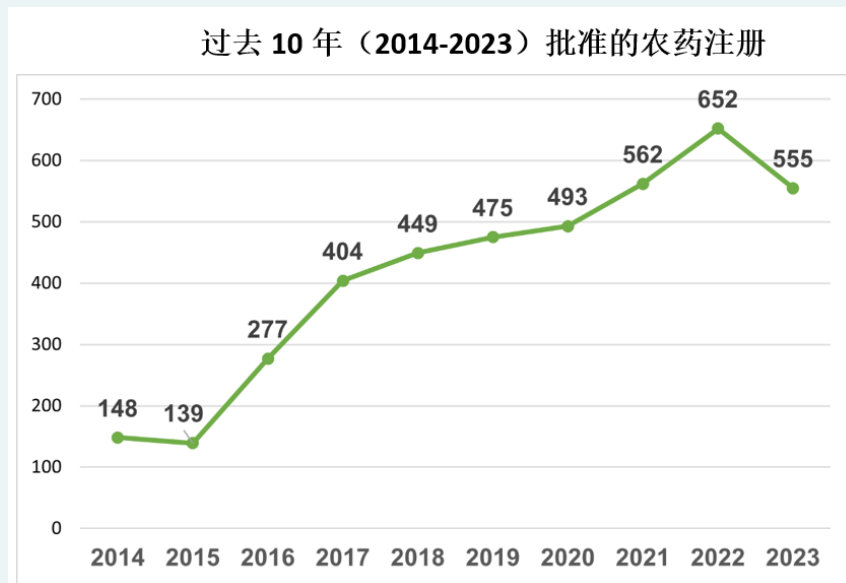
Registro sob titularidade de clientes: 5

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2023年巴西农业部审批了555项农药注册

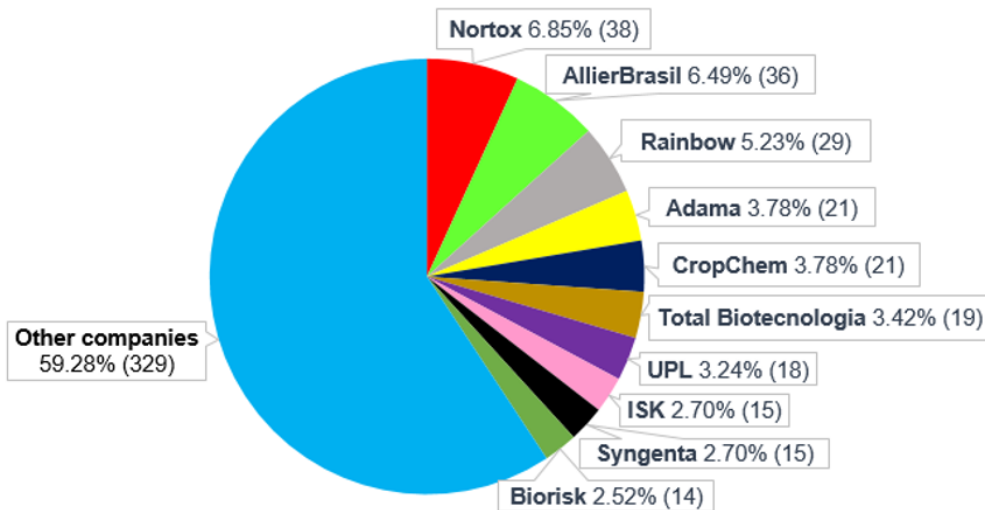
在连续七年破纪录的批准之后，**2023** 年农业部批准了 **555** 项农药注册，与 **2022** 年相比下降了 **15%**。即便如此，批准数量还是有史以来第三高的。



来源：农业和畜牧业部；由**AllierBrasil**改编

很大一部分审批集中在少数几家公司。其中十家公司就负责了**40.72%** 注册的批准。亮眼的是**Nortox**、**AllierBrasil**和**Rainbow**三家公司总计获得了**103**项批准（占**18.56%**）。

2023 年，10 家公司负责了 40.72%的农药注册



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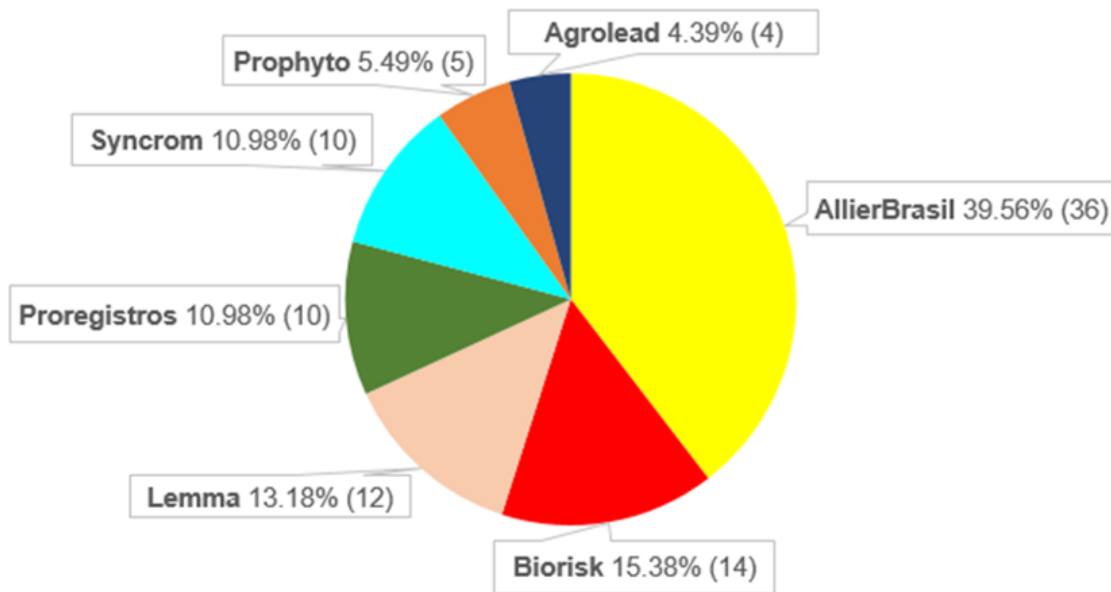
由第三方名义的咨询公司管理的注册不包括在内。

就**AllierBrasil**而言，考虑到第三方持有的注册，共有**41**个注册获得批准。

来源：农业和畜牧业部；由**AllierBrasil**改编

考虑到注册是一个非常官僚和漫长的过程，涉及三个部委，因此注册咨询公司发挥着重要作用。这些公司大多代表境外公司，获得了**16.39%**的批准。亮眼的是**AllierBrasil**，该公司批准了咨询公司持有的近**40%**的注册。

2023 年 咨询公司批准了 16.39% (91) 的注册



注：

由第三方名义的咨询公司管理的注册不包括在内。

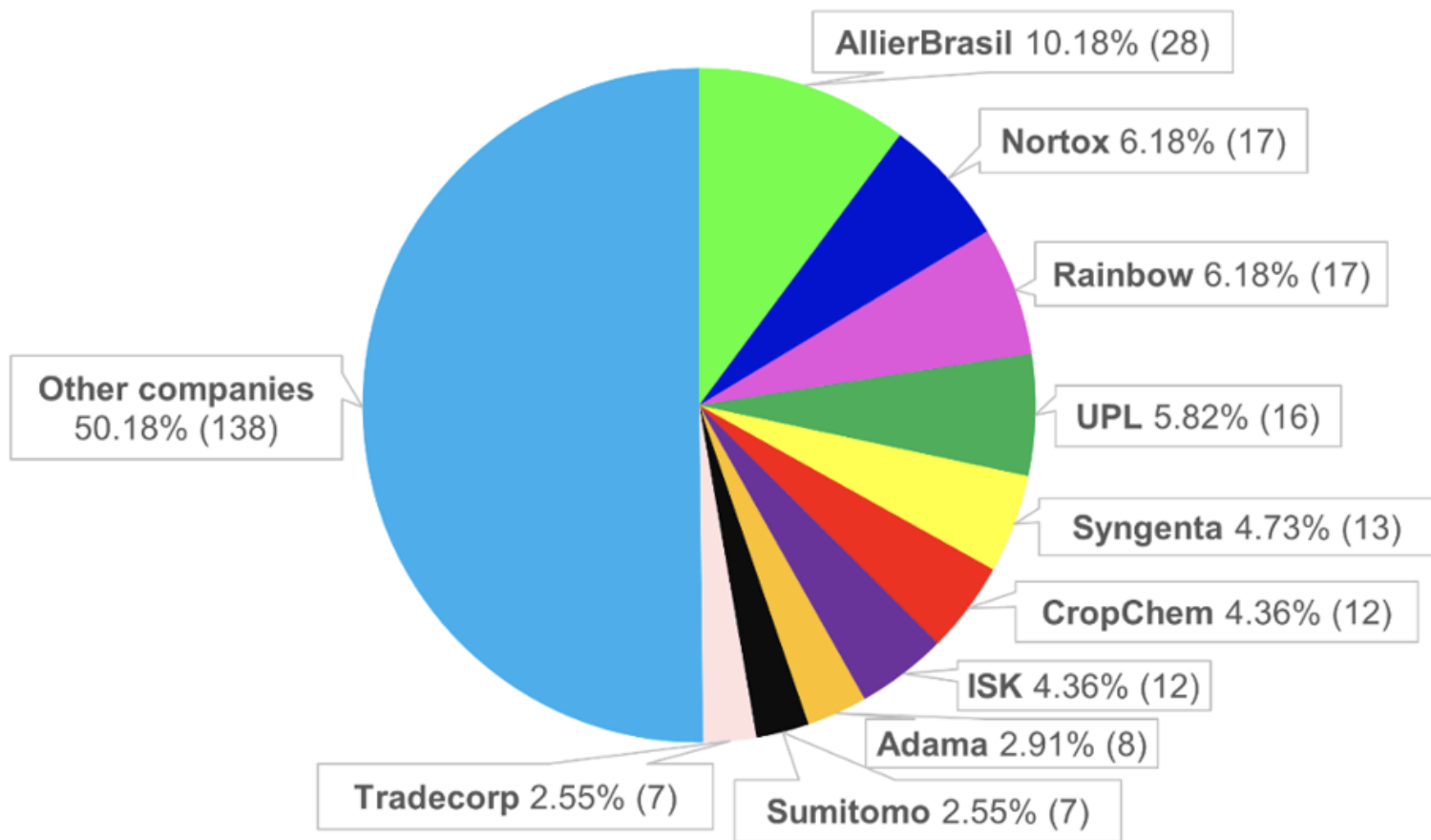
来源：农业和畜牧业部；由AllierBrasil改编

虽然咨询公司的收入被认为不高，但它们是外国咨询公司收购的目标。这创造了一个新的市场，涉及开设公司以销售这些公司，类似于农药分销和生物产品市场的情况。考虑到农药注册过程需要经验和大量的技术准备，严重的错误已经被注意到了。这导致清关时间更长，因为检查发现了因初始注册过程中没有充分完成档案阐述而造成的可悲错误，导致整个分销链的损失。

配方产品的注册是分销商的主要目标，因为配方产品流向最终消费者---农民。**2023**年，除生物和非典型产品外，批准了**275**个化学配方产品的注册。其中，**137**个由**10**家公司注册。亮点包括**AllierBrasil**、**Nortox**、**Rainbow**和**UPL**四家公司，它们总共获得了**78**项批准，占**28.36%**。

化学配方产品的注册

(配方产品, 新配方产品, 基于等效技术产品的配方产品)



注：

由第三方名义的咨询公司管理的注册不包括在内。

来源：农业和畜牧业部；由AllierBrasil改编

考虑到大量外国公司都在关注在巴西市场的产品注册，因此重要的是需要向新近参与者展示注册过程的规则和步骤，这些规则和步骤因国家而有很大不同。此外，在国外有效的东西并不总是在巴西有效。从这个意义上说，20 多年来，AllierBrasil 一直在为全球 8,500 多名参与者现场推广有关农药注册的研讨会、讲座和培训课程。

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Thank you

