



China International Agrochemical Conference Week 2024

# Brazil's New Pesticide Law

## Shanghai, March 13th, 2024

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# 赋能企业市场拓展



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**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.

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CAC

**Consulting in Agribusiness**

**Pesticide Registration**

**Technical & Commercial Partnership Development**

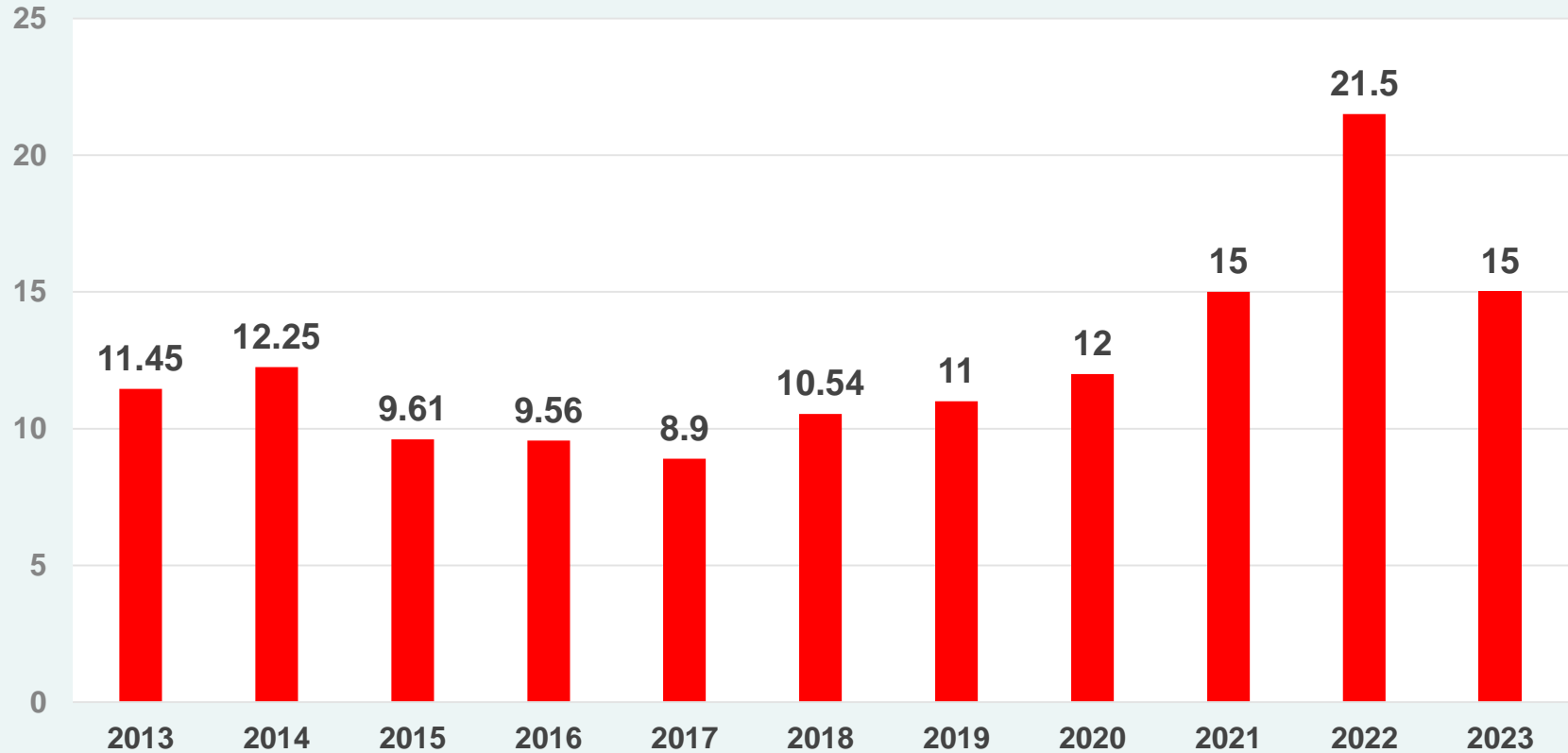
**We Promote Agro**

## Law No. 14785, December 27, 2023

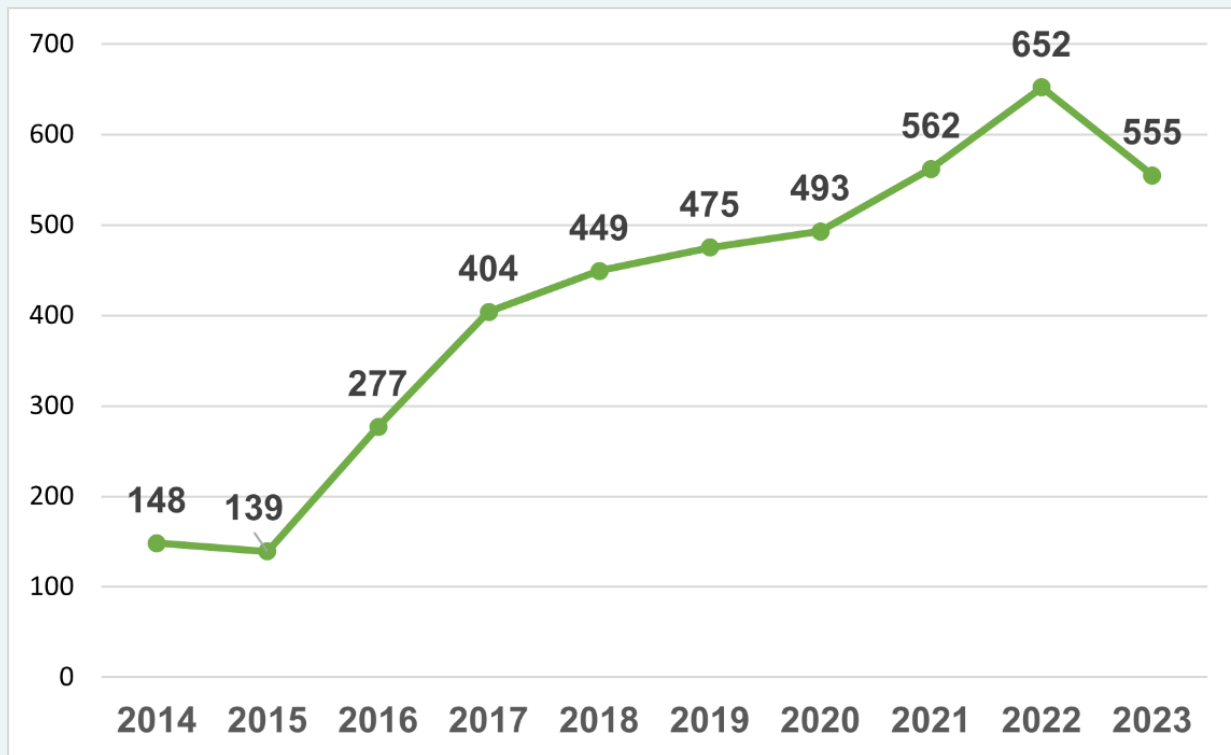
Provides for research, experimentation, production, packaging, labeling, transport, storage, marketing, use, import, export, final destination of waste and packaging, registration, classification, control, inspection and inspection of pesticides, environmental control products, their technical products 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



# PESTICIDE REGISTRATION APPROVALS



**Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil**

# Art. 3

## § Paragraph 1: Deadlines

Type of registration	Law 14785 Dec 27 <sup>th</sup> , 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
Notes:	METRARO (34122)	RAINBOW	Anvisa	S-metolachlor 960 g/L EC

**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 is 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: 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

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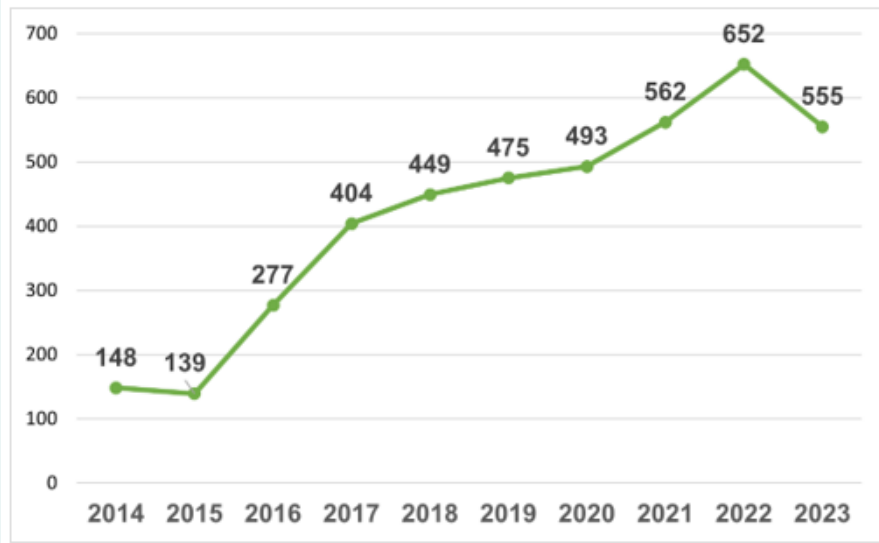
**AllierBrasil is a consulting firm dedicated to agribusiness, focusing on pesticide registration and on developing technical-commercial partnerships. For more than 25 years, AllierBrasil has promoted Brazilian agriculture and has enabled pesticide companies to enter the Brazilian market.**

*Creating the Future of Agribusiness*

# Pesticide Registration Approvals Decreased in 2023 in Brazil

In 2023, 555 pesticide registrations were approved, which was a 15% drop when compared to 2022, after seven continuous years of record-breaking approvals. Even so, the number of approvals was the 3<sup>rd</sup> highest ever recorded.

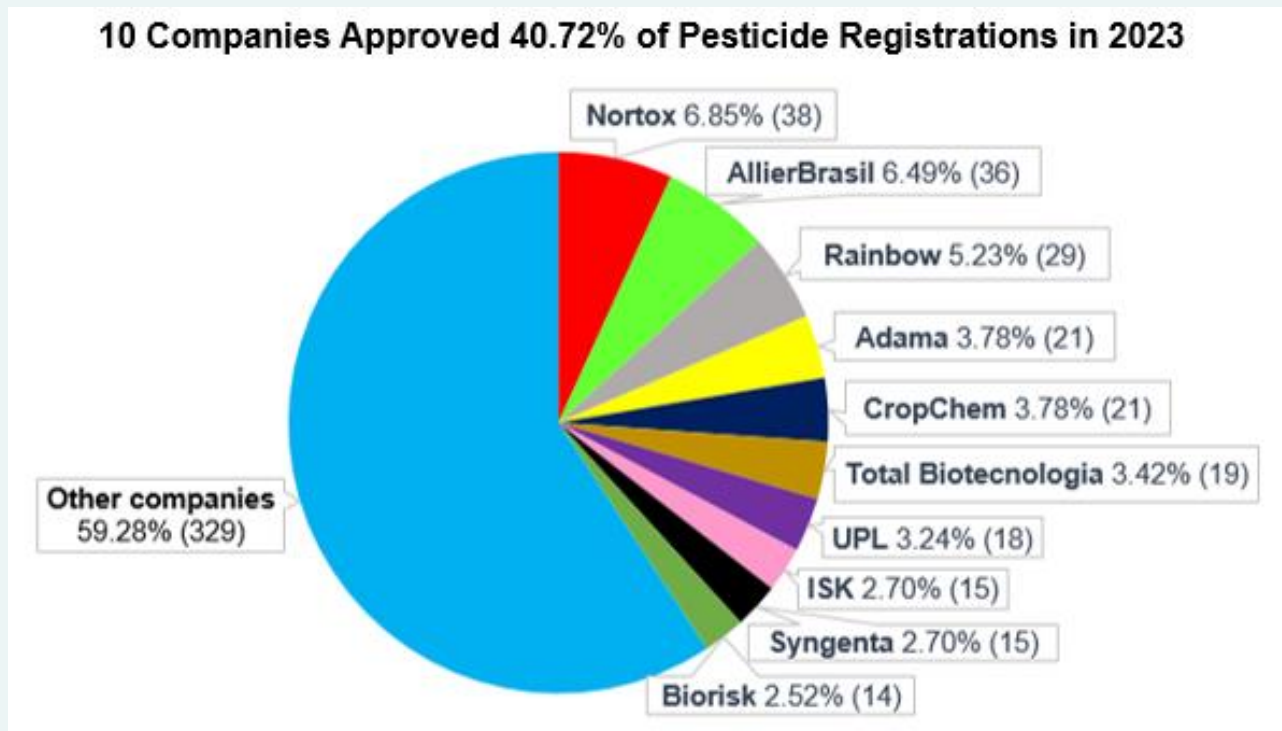
Pesticide Registrations Approved in the Last 10 Years (2014-2023)



Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil

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**A few companies concentrate a large share of pesticide registration approvals. In 2023, ten companies were responsible for approving 40.72% of the total. Highlight for Nortox (100% Brazilian); AllierBrasil (Brazilian consultancy company); and Rainbow (Chinese company), which together have 103 approvals (18.56%).**





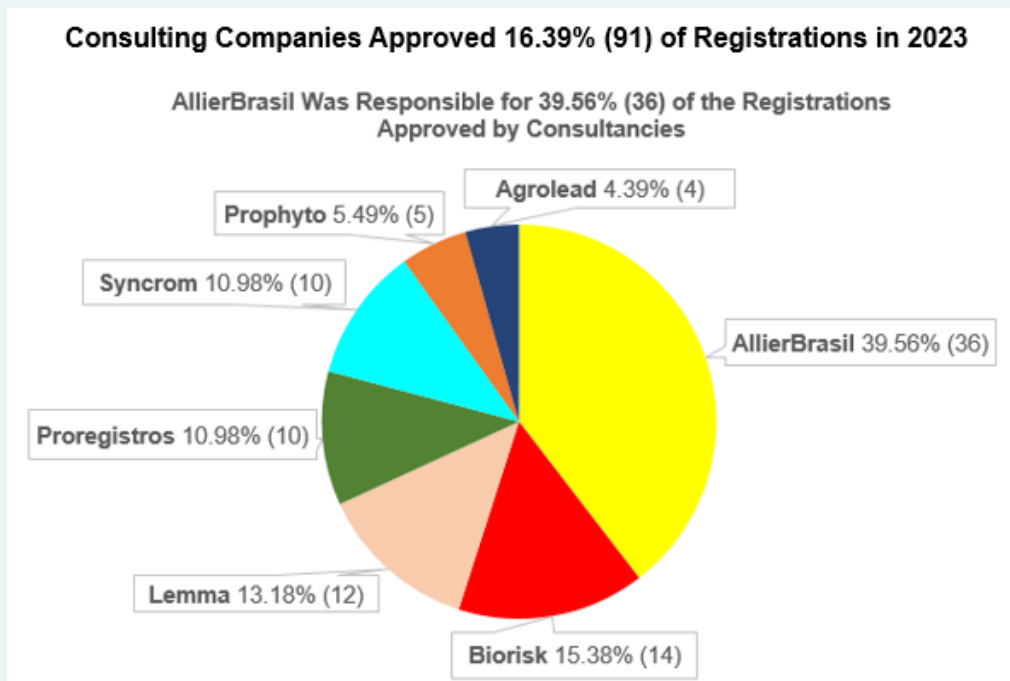
**Notes:**

**Registrations managed by consulting firms that are under the name of third parties were not included.**

**In the case of AllierBrasil, 41 registrations were approved, considering registrations held by third parties.**

**Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil**

Considering that pesticide registration is a very bureaucratic and long process, involving three ministries, registration consultancy firms play a very important role. These consultancies, which mostly represent foreign companies, were responsible for 16.39% of approvals. Highlight for AllierBrasil, which approved almost 40% of registrations held by consulting companies.



**Note:**

**Registrations managed by consulting firms that are under the name of third parties were not included.**

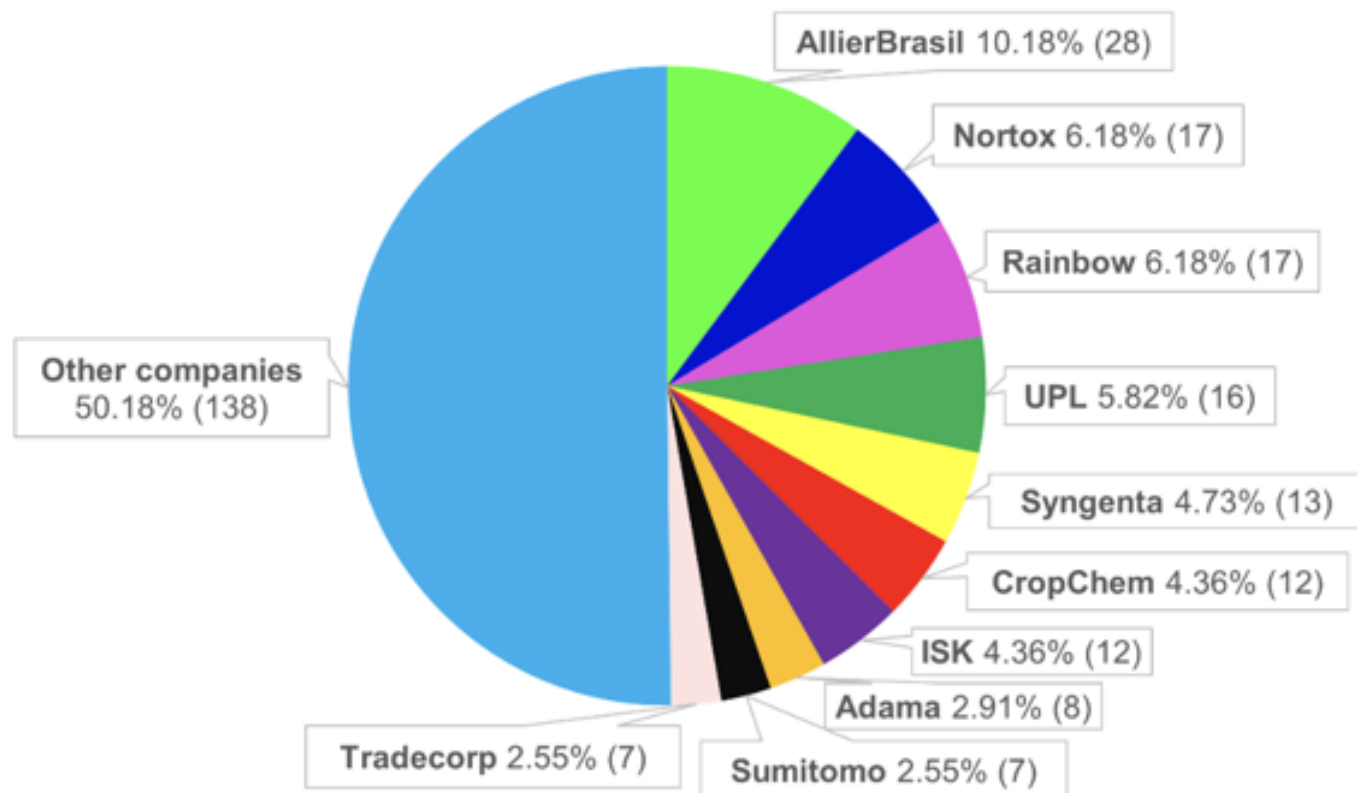
**Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil**

**Although the revenues of consultancy firms are considered modest, they are targets for acquisition by foreign consultancy firms. This created a new market, involving the opening up of companies with the intention of selling them, similar to what happens in the pesticide distributor and dealer market and in the biological products market. Furthermore, considering that the pesticide registration process requires experience and a lot of technical preparation, serious errors have been observed. This results in a much longer time for customs clearance, because inspections identify mistakes that come from the inadequate completion of product information/descriptions in the initial registration process, causing losses throughout the distribution chain.**

**Registration of formulated products is the main objective of distributors because it is the formulated product that goes to the final consumer, which is the farmer. In 2023, excluding biological and atypical products, 275 registrations of chemical formulated products were approved. Of the total, 137 were registered by 10 companies, which once again shows the concentration of approvals. Highlights include AllierBrasil, Nortox, Rainbow, and UPL, which together have 78 approvals, or 28.36% of the total.**

## Registration of Chemical Formulated Products

(Formulated Product, New Formulated Product, Formulated Product based on Equivalent Technical Product)

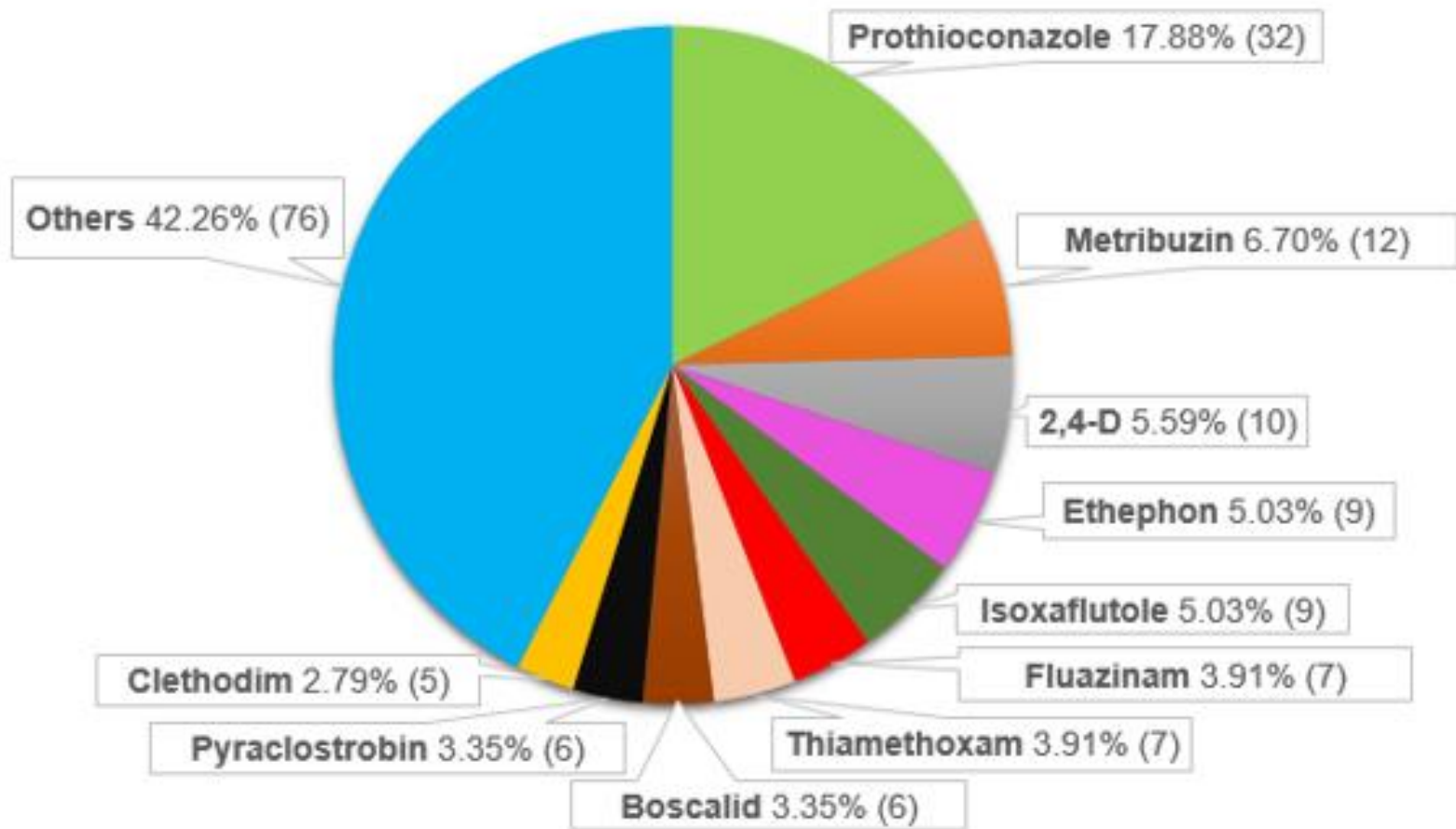


**Note:**  
**Registrations managed by consulting firms that are under the name of third parties were not included.**

**Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil**

**Concerning the registrations of Equivalent Technical Products, the 10 most approved active ingredients in 2023 reached 107 products out of a total of 179, and represented 59.77% of approvals. Prothioconazole (17.88%) and metribuzin (6.70%) were the most approved active ingredients. The number of prothioconazole registrations more than doubled when compared to 2022, going from 29 to 61, while metribuzin registrations went from 16 to 28. The biggest highlight, however, is ethephon, which increased from 2 registrations to 11.**

## Active Ingredients of Equivalent Technical Products Approved in 2023





Active ingredient	Number of registrations * approved in 2023	Total number of approved registrations
Prothioconazole	32	61
Metribuzin	12	28
2,4-D	10	70
Ethephon	9	11
Isoxaflutole	9	21
Fluazinam	7	24
Thiamethoxam	7	34
Boscalid	6	15
Pyraclostrobin	6	19
Clethodim	5	31
Others	76	2,117
<b>Total</b>	<b>179</b>	<b>2,431</b>

**Note: \* Equivalent Technical Product**

Source: Ministry of Agriculture and Livestock; adapted by AllierBrasil

**The approval of a pesticide registration is not just the result of submitting a request. There are several steps until approval. Briefly, the first is the definition of the product and manufacturer. Next, a laboratory is chosen - one of the most critical steps - to perform GLP studies, field efficacy and residue studies, depending on the type of registration; elaboration of the dossier; submission of the process itself; updating the dossier in accordance with the new regulations that come into force during the long waiting period for the evaluation; and continuous and detailed monitoring of the progress of the registration process. All of this is very expensive.**

**Considering the large number of foreign companies interested in registering products in Brazil, it is very important to show new players the rules and steps of the registration process, which differ greatly from country to country. Furthermore, what works abroad will not always work in Brazil. In this sense, AllierBrasil has been promoting seminars, lectures and training courses on pesticide registration for more than 20 years, for more than 8,500 in-person participants around the world.**

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# Thank you

