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International regulatory situation of pesticides authorized for use in Brazil: potential for damage to health and environmental impacts

Situação regulatória internacional de agrotóxicos com uso autorizado no Brasil: potencial de danos sobre a saúde e impactos ambientais

Situación regulatoria internacional de pesticidas con uso autorizado en Brasil: potencial de daños sobre la salud e impactos ambientales

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Abstract

The Brazilian legislation does not provide for a periodic review of the registration of pesticides and, even nowadays, products banned in other countries are still used. Based on the pesticide active substances registered in the country, the present study investigated the international regulatory situation in the following member countries: Organization for Economic Co-operation and Development (OECD), European Community, and the BRICS (Brazil, Russia, India, China, and South Africa). Moreover, we sought to relate the main chronic effects to human health and the environment of the most commercialized pesticide active substances in Brazil in lists of classification of carcinogenic potential (US Environmental Protection Agency – USEPA and International Agency for Research on Cancer – IARC), endocrine disruption, and candidates for substitution, both from the European Community. A total of 399 pesticide active substances registered in Brazil for agricultural use were identified, excluding microbiological and biological control agents. Of these, the percentage of unauthorized pesticide active substances according to countries is as follows: 85.7% in Iceland; 84.7% in Norway; 54.5% in Switzerland; 52.6% in India; 45.6% in Turkey; 44.4% in Israel; 43.4% in New Zealand; 42.4% in Japan; 41.5% in the European Community; 39.6% in Canada; 38.6% in China; 35.8% in Chile; 31.6% in Mexico; 28.6% in Australia; and 25.6% in the United States. 120 pesticide active substances were related to damage to health and the environment. Considering the pesticide active substances for which commercialization data are available in the country, 67.2% of this volume is associated with at least one serious chronic damage assessed in this study. The results of the present study indicate the need for promoting transparency of international databases, regarding the motivations of the respective regulatory decisions and the Brazilian regulatory bodies to reevaluate the registration of obsolete products and to strengthen public policies related to the reduction of the use of pesticides.

Agrochemicals; Neoplasms; Risk Assessment

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Introduction

The registration of pesticides that allows their use and consumption, commercialization, and production, import and export in Brazil is granted by the Ministry of the Environment and the Ministry of Agriculture, Livestock and Supply of Brazil after the authorization of three regulatory bodies: the Brazilian Health Regulatory Agency (Anvisa), of the Brazilian Ministry of Health; the Brazilian Institute of Environment and Renewable Natural Resources (Ibama); and Ministry of Agriculture, Livestock and Supply, which are the bodies that assess the potential impacts on health, the environment and agronomic efficiency, respectively [1,2].

In this context, some effects on human health, such as genetic mutation, effects on the reproductive system, teratogenicity, hormonal disorders, and cancer, are considered prohibitive for the purposes of registration, as provided for in the letters "c" and "d", §6, Art. 3, of *Law n. 7,082/1989* [1]. The observation of these effects leads to the ban of such pesticides in the process of registration review and the dismissal of new active substances.

Nevertheless, there is no legal provision in Brazil for a minimum periodicity for the reevaluation of registration. According to *Decree n. 4,074/2002,* theoretically, this review could occur at any time, guided by international warnings, new scientific studies or complaints made by reference institutions, under the terms of item VI, art. 2. Within the scope of Anvisa, the toxicological reassessment is carried out according to criteria established in the *Resolution of the Collegiate Board – RDC n. 221 of March 28, 2018* [3]; however, the norm does not provide for minimum periodicity or the deadline for its conclusion as well.

Nevertheless, it is clear that, even in cases of international warnings, the limitation of resources available in the agencies or the legal actions carried out by corporations linked to agribusiness often hinder and delay such reviews, aggravating the situation of population's exposure to these dangerous products [4].

In addition to the fragility of the current Brazilian regulatory context, recent proposals to change the legislation [5] point to flexibility, a fact that has been worrying research institutions, legal entities, democratic interests, and social organizations, especially with the national expansion of commercialization products that are not used in other countries [6]. Within this context, Brazil may consolidate itself as a large market for obsolete products, which can cause damage to the exposed population and biodiversity [7].

Taking this into consideration, the objective of this study was to identify and analyze the profile of the active substances of pesticides registered in Brazil and their international regulatory status in member countries of the Organisation for Economic Co-operation and Development (OECD), the European Community, India, and China, identifying the associated potential damages to health and the environment.

Methodology

This study is a documentary research. The pesticide active substances authorized in Brazil were identified based on the consultation of the list of authorized monographs, available on the Anvisa website. Of these, microbiological products and biological control agents were excluded from the study.

Based on the Anvisa monographs, pesticide active substances were identified in terms of the following aspects: chemical group, acute toxicity classification, indication of use, and approval status for other uses (nonagricultural, over-the-counter or specialized sale of household cleaning products; use in public health campaigns, use in amateur gardening, and application as a wood preservative). Those exclusively intended for nonagricultural uses were excluded from the study.

To identify the carcinogenicity of pesticide active substances authorized in Brazil, the classification lists of the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) [8] and of the US Environmental Protection Agency (USEPA) [9] were consulted. Lists of the European Community were also searched for pesticide candidates for substitution [10] and those potentially endocrine disruptors [11].

For the research, pesticides with the highest volume of commercialization in Brazil in 2017 were highlighted, based on the commercialization report available on the IBAMA website (https://www.ibama.gov.br/index.php).

Registration information was collected for 35 of the 36 OECD member countries (Australia, Canada, Chile, United States, Iceland, Israel, Japan, Mexico, New Zealand, Norway, Switzerland, Turkey, United Kingdom, and the European Community bloc, which includes 22 OECD member countries), and two countries of the BRICS bloc, India and China, whose databases were available in English. The United Kingdom ceased to be part of the European Community during the course of this study, but health and safety information remains unchanged until December 31, 2020. Although South Korea is an OECD member country, its data were not included due to the difficulty in accessing the active substances of authorized pesticides on the country's official website.

Information regarding the registration situation in Brazil and in other countries was collected on the websites of the respective official bodies, from May 15, 2017 to August 31, 2019: Australian Pesticides and Veterinary Medicines Authority (https://portal.apvma.gov.au/pubcris;jsessionid=3WzzhEaPP5w4Pd19oL+xuTkv); Anvisa (http://portal.anvisa.gov.br/registros-e-autorizacoes/agrotoxicos/produtos/monografia-de-agrotoxicos/autorizadas); Health Canada (http://pr-rp.hc-sc.gc.ca/pi-ip/index-eng.php); Agricultural and Livestock Service, Chile (Servicio Agrícola y Ganadero – http://www.sag.cl/ambitos-de-accion/evaluacion-y-autorizacion-de-plaguicidas/1367/registros); Food Safety-Plants-Pesticides-Pesticides Database, European Community (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN); The Environmental Agency of Iceland (https://www.ust.is/english/chemicals/biocides/active-substances/); Ministry of Agriculture & Farmers Welfare, India (http://ppqs.gov.in/sites/default/files/registeried_formulation_29.02.2020.pdf); Ministry of Agriculture and Rural Development, Israel (http://www.hadbara.moag.gov.il/hadbara/english/search/NoKotelForm.asp); Food and Agricultural Materials Inspection Center, Japan (http://www.acis.famic.go.jp/eng/ailist/index.htm); Federal Commission for the Protection against Sanitary Risks, Mexico (Comisión Federal para la Protección contra Riesgos Sanitarios – http://siipris03.cofepris.gob.mx/Resoluciones/Consultas/ConWebRegPlaguicida.asp); Norwegian Food Safety Authority (https://www.mattilsynet.no/plantevernmidler/godk.asp?sortering=virkestoff&preparat=Alle&sprak=In%20English); Ministry for Primary Industries - *Manatu Ahu Matua* – New Zealand government (https://eatsafe.nzfsa.govt.nz/web/public/acvm-register); Federal Office for Agriculture, Switzerland (Bundesamt fur Landwirtschaft – Pflanzenschutzmittelverzeichnis, https://www.psm.admin.ch/de/wirkstoffe); Ministry of Food, Agriculture and Livestock, Turkey (https://bku.tarim.gov.tr/BKURuhsat/Index).

Information on the registration situation in the United States was obtained from the Pesticide Database available from the Pesticide Action Network (PAN) (http://www.pesticideinfo.org/Search_Chemicals.jsp#ChemSearch); as for China, information was obtained from a document published by the Food and Agriculture Organization (FAO) [12].

In all databases, the registration status of each pesticide active substances authorized in Brazil was researched. Those that were unauthorized in the European Community and/or in at least 3 OECD member countries were highlighted. This prominence is based on one of the proposed amendments to *Law n. 7,802/1989*, which authorizes the granting of temporary pesticides active substances registration in Brazil approved in at least three OECD member countries, in case the regulatory bodies do not evaluate registration dossiers in 24 months [5].

The survey also sought to identify the technical reasons for ban in Europe for pesticide active substances whose commercialization data for the year 2017 were made available and published through reports on the Ibama website, deepening the qualitative aspect of the study.

Results

General profile of pesticides active substances authorized in Brazil

On the Anvisa website, we found 450 authorized monographs of chemical, biochemical, semi-chemical, microbiological pesticide active substances and biological control agents authorized in Brazil.

For this study, we only considered pesticide active substances classified as chemical and semi-chemical, totaling 401 pesticide active substances, including paraquat in this list, which was banned in Brazil on September 22, 2020.

We identified metabolites in some monographs, which are recognized as active ingredients in products commercialized in Brazil or in other countries and, therefore, were individually treated, totaling 458 pesticide active substances. Of these, we observed that 318 are exclusively used for agricultural purposes; 59, for nonagricultural purposes; 78, for both agricultural and nonagricultural purposes; and three (3) are exclusively authorized for export (the herbicides aclonifen, bromoxynil, and diflufenicam). Considering that the surveyed international databases refer to products authorized for agriculture use, those for exclusive nonagricultural use were excluded, totaling 399 pesticide active substances surveyed.

Among the 78 pesticide active substances that are permitted for agricultural and nonagricultural use, 54 are permitted for household use, 24 of which are authorized for over-the-counter sale and 13 for specialized restricted sale. Use in public health campaigns is permitted for 27 pesticide active substances. A total of 25 pesticide active substances are authorized for amateur gardening, and eight (8), for use as wood preservatives in addition to the permission for agricultural use.

Chronic health effects and environmental impacts

Of the total 399 active substances considered in this study, 116 were directly related to chronic effects on human health or the environment. According to the list of carcinogenic potential assessment of USEPA [7], 52 pesticide active substances were classified as "probable" or "possible" carcinogens for humans, of which four (4) had reservations about the level of exposure or the type of effect. A total of 16 pesticide active substances had evidence suggestive of the carcinogenic potential for humans, whereas another 8 had evidence suggestive of carcinogenicity, but without enough information to assess the carcinogenic potential for humans (Box 1). The nomenclature of the different classes of carcinogenic potential of USEPA has been updated, in such a way there are pesticides with similar potentials to cause cancer, but allocated in different classes.

The IARC analyzed 36 pesticide active substances and, of this total, 15 pesticide active substances are authorized for use in Brazil, with diazinon, glyphosate, and malathion being classified as probable carcinogens (group 2A), and chlorotanolil and 2,4-D as possible carcinogens (group 2B) (Box 1).

Among the pesticide active substances classified according to endocrine disruption, 17 were classified as potential for humans or wildlife, namely: category 1 – evidence of endocrine disruption in in vivo studies; category 2 – evidence of endocrine disruption in in vitro studies; category 3 – without evidence of endocrine disruption or without available data (Box 1). It is noteworthy that some pesticide active substances were simultaneously classified in more than one category (alachlor, atrazine, 2,4-D, and malathion), in such a way that 5 were classified in category 1 (4 for humans and 1 for wildlife) and 15, in category 2 (9 for humans and 6 for wildlife) (Box 1). In the list of 77 pesticide candidates for substitution of the European Community, 68% are authorized in Brazil.

Pesticide active substances authorized in Brazil and unauthorized in other countries

Of the total active substances studied and authorized in Brazil, 3.5% (n = 14) (abamectin, clethodim, dicamba, dimethomorph, glyphosate, imidacloprid, lambda-cyhalothrin, MCPA, metribuzin, metalaxyl-M, propamocarb, tebuconazole, thiaclopride, and thiophanate-methyl) are approved in all OECD member countries. When including the studied BRICS countries, this number decreases to 12, as we observed that clethodim and dicamba are unauthorized for use in India.

Box 1

Pesticides authorized in Brazil and included in lists related to impacts on human health and the environment.

CLASSIFICATION	COMPOUND
United States Environmental Protection Agency (USEPA) – carcinogenic potential	
Group B – probable carcinogen for humans	Daminozide (1991), diuron (2004), etridiazole, (terrazole) (1999), fentin hydroxide (1990), mancozeb (1999), metiram (1999), procymidone (1991), propargite (1992), thiodicarb (1996)
Probably carcinogenic to humans	Benthiavalicarb isopropyl (2005), carbaryl (2002), chlorothalonil (1997), kresoxim-methyl (1999), diclofop-methyl (2000), epoxiconazole (2001), spirodiclofen (2004), hexythiazox (2009), imazalil (1999), iprodione (1998), iprovalicarb (2002), isoxaflutole (1997), metam-sodium (2009), oxadiazon (2001), oxyfluorfen (2010), pymetrozine (1999), pyraflufen-ethyl (2002), pirimicarb (2005), propineb (2013), thiaclopride (2012), thiophanate-methyl (1999)
Probably carcinogenic to humans: with exposure to high and prolonged doses; Probably not carcinogenic to humans at doses that do not cause cytotoxicity and regenerative cell hyperplasia	Captana (2004)
Probably carcinogenic to humans: at high doses; Probably not carcinogenic to humans at low doses	Alachlor (1997), lactofen (2006), thiabendazole (2002)
Grupo C – possível cancerígeno para seres humanos	Acefato (1985), alfa-cipermetrina (2012), asulam (2001), bifentrina (2003), bromacila (1993), carbendazim (1989), cipermetrina (1988), dimetenamida (1995), dimetoato (2002), fipronil (1995), linurom (2001), metidationa (1988), pendimetalina (1992), propiconazol (1992), tebuconazol (1993), triadimefom (1996), triadimenol (1988), trifluralina (1986), zeta-cipermetrina (1988)
Group C – possible carcinogen for humans	Acephate (1985), alpha-cypermethrin (2012), asulam (2001), bifenthrin (2003), bromacil (1993), carbendazim (1989), cypermethrin (1988), dimetenamide (1995), dimethoate (2002), fipronil (1995), linuron (2001), methidathione (1988), pendimethalin (1992), propiconazole (1992), tebuconazole (1993), triadimefon (1996), triadimenol (1988), trifluralin (1986), zeta-cypermethrin (1988)
Evidence suggestive of carcinogenicity, but not enough to assess the potential for carcinogenicity in humans	Bioallethrin (2003), boscalid (2002), buprofezin (2000), clorfenapir (2003), fluazinam (2001), phosmet (1999), malathion (2000), penoxsulam (2011)
International Agency for Research on Cancer (IARC) – carcinogenic potential	
Group 2A – probable carcinogen	Diazinon (2017), glyphosate (2017), malathion (2017)
Group 2B – possible carcinogen	2,4-D (2018), chlorothalonil (1999)
European Community – potential endocrine disruption	
Category 1 – evidence of disruption in at least one species using intact animals	Humans: acetochlor, alachlor, atrazine, thiram; wild life: fentin acetate
Category 2 – *in vitro* evidence of biological activity related to endocrine disruption	Humans: 2,4-D, methyl bromide, dimethoate, diuron, iprodione, malathion, propanil, simazine, triadimefon; wild life: 2,4-D, alachlor, atrazine, carbendazim, diazinon, and malathion
European Community – pesticide active substances candidates for substitution	
Bifenthrin, bromuconazole, carbendazim, cyproconazole, cyprodinil, diclofop, diphenoconazole, diflufenican, dimethoate, dimoxistrobin, diquat, epoxiconazole, esfenvalerate, etofenprox, ethoprophos, etoxazole, famoxadone, fenamiphos, fipronil, fludioxonil, flumioxazin, fluopicolide, fluquinconazole, glufosinate, haloxyfop-P, imazamoxi, lambda-cyhalothrin, linuron, lufenuron, metam, metconazole, methylcyclopropene, methomyl, metribuzin, metsulfuron-methyl, myclobutanil, nicosulfuron, oxadiargyl, oxadiazon, copper oxychloride, fenbutatin oxide, oxyfluorfen, paclobutrazol, pendimethalin, pirimicarb, profoxydim, propiconazole, quizalofop-P, copper sulfate, tebuconazole, tepraloxidim, thiaclopride	

A total of 17 pesticide active substances are unauthorized in all OECD member countries, and 16 pesticide active substances are unauthorized in China and India as well. We observed that 81% of pesticides authorized in Brazil have no use permit in at least three OECD countries, and 31% are not approved in China and India.

The percentage of unauthorized pesticide active substances or those that were not found in the countries' databases for product authorization was: 85.7% in Iceland; 84.7% in Norway; 54.5% in Switzerland; 52.6% in India; 45.6% in Turkey; 44.4% in Israel; 43.4% in New Zealand; 42.4% in Japan; 41.5% in the European Community; 39.6% in Canada; 38.6% in China; 35.8% in Chile; 31.6% in Mexico; 28.6% in Australia; and 25.6% in the United States (Figure 1). Among the pesticides with commercialization data available in Brazil, the percentage of non-authorizations was: 77% in Norway; 75% in Iceland; 44% in Switzerland; 38% in Turkey; and 35% in the European Community.

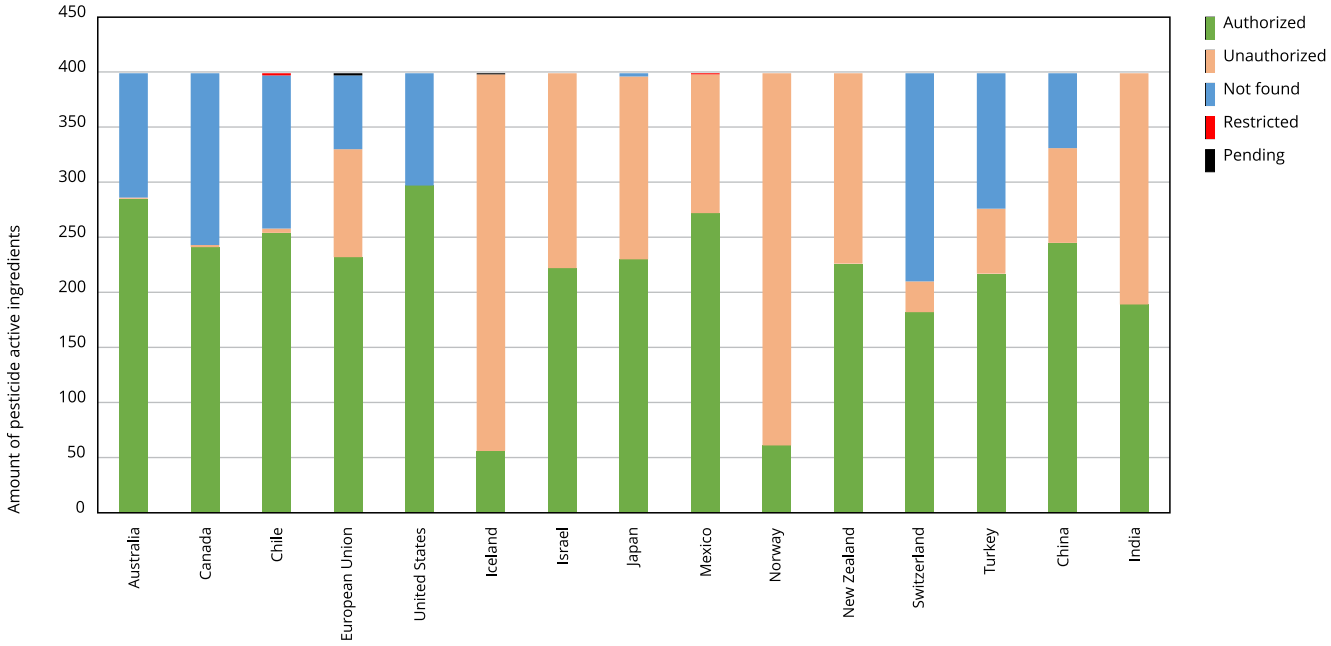
International authorization of the most commercialized pesticide active substances in Brazil and association with chronic health and environmental effects

In terms of total commercialization volumes of pesticide active substances in Brazil, 539,944.95 tons were sold in 2017. Of these, 9.7% were not specified for substances that do not have at least three companies with the registration to preserve commercial confidentiality.

Among the 79 pesticide active substances mentioned in the 2017 commercialization report, 14 had a decrease in sales in the aforementioned period. Considering the 20 pesticide active substances with the highest volume of commercialization, 18 accounted for an increase in the period, especially tetraconazole, which increased more than 22 times (Table 1).

Figure 1

Authorization of the pesticide active substances permitted in Brazil in member countries of the Organization for Economic Co-operation and Development (OECD), China and India.



Considering all pesticide active substances with commercialization data released by Ibama, about 67.2% of the volume traded in 2017 presents at least one criterion related to damage to human health and the environment, which is included in lists that identify effects on human health or wildlife, i.e., a list of potential carcinogens according to IARC (possible or probable carcinogen) or USEPA (recognized, possible and probable carcinogen), endocrine disruptors, and candidates for substitution in Europe (Box 1). In Table 1 we present data for the 20 pesticide active substances with the highest volume of commercialization, excluding mineral and vegetable oils, representing 75% of the total volume sold in 2017, in which 11% of them meet at least one criterion that shows potential chronic damage according to the consulted lists.

Still in relation to pesticide active substances with commercialization data, 54% are unauthorized in at least three OECD countries, and 34% are unauthorized in the European Community. As for the BRICS countries surveyed in this study, 15 pesticide active substances are unauthorized for use in India (clethodim, fluazinam, flumetralin, imazalil, imazaquin, lactofen, mesotrione, MSMA, nicosulfuron, picloram, procymidone, simazine, sulfluramid, tebuthiuron, and triclopyr-butotyl) and 5 pesticide active substances cannot be used in China (cyproconazole, flumetralin, MSMA, sulfentrazone, and tebuthiuron). Among the 20 most traded pesticide active substances, 11 (55%) are unauthorized in at least three OECD countries and 5 (25%), in the European Community (Table 2).

Among pesticides active substances without authorization in at least three OECD countries and/or in the European Community, the total traded volume was 129,727.67 tons, corresponding to 24% of the total pesticide active substances sold in 2017. In Brazil, 16.4% of the total sales volume correspond to products unauthorized in the European Community (Tables 1 and 2).

Criteria for non-authorization of pesticide active substances in the European Community

In Box 2 we present data concerning effects on health and the environment for 19 out of 27 pesticide active substances with commercialization data in Brazil and unauthorized in the European Community. We did not include in the Box 2: 4 pesticide active substances without information (chlorimuron-ethyl, sulfentrazone, sulfluramid, and triclopyr-butotyl); 2 pesticide active substances (diafenthiuron and MSMA) were banned according to *Regulation n. 2,076/2002* of the European Community for not complying with the current regulations (*Directive n. 91/414*), including the need for proving the absence of less harmful alternatives or the need for further studies; and for 2 pesticide active substances (imazetapir and novaluron), other regulations on the approval of specific pesticide active substances were mentioned. It is worth mentioning sulfluramid, whose degradation products are perfluorooctane sulfonate (PFOS), included in Annex B (restriction) of the Stockholm Convention [13].

The completion reports of the European Community registration assessment processes of 11 active substances mentioned harmful effects on humans and the environment. 15 active substances were associated with critical toxic effects, according to *European Directive n. 1,272/2008*, which implemented the Globally Harmonized System (GHS) criteria. We also observed that 12 pesticide active substances had indications of damage to human health or the environment in the consulted lists of chronic effects (USEPA, IARC, candidate for substitution Europe, and potentially endocrine disruptors).

Discussion

The present study shows, in an unprecedented way, that approximately 80% of pesticides authorized for use in Brazil have no use permit in at least three OECD countries, including those that have an important economic activity in agriculture. In Australia, which has 40% of its territory under similar agricultural conditions, 114 pesticide active substances permitted in the Brazilian territory were not found in the records of this country. Although Brazil and India have relatively similar edaphoclimatic conditions, more than 50% of pesticides registered in Brazil do not have use permit in India. We also verified that the list of pesticide active substances authorized in Brazil includes examples with recognized toxicity on human health and the environment.

Table 1

Indications for agricultural and non-agricultural use of the 20 pesticide active substances authorized in Brazil with the highest volume of commercialization in 2017 and their aspects related to human health.

Active substances	Sales 2017 (%)	Sales variation 2009-2017 (%)	Agricultural use	Other non-agricultural uses *	HU	OS	SS	PHC	AG	WP	Lists of health effects				
											USEPA	IARC	CfS	Disrup. H	Disrup. WL
Glyphosate	173,150.75	47.13	H	Y	Y	N	N	N	Y	N	Not likely	2A	NI	NI	NI
2,4-D	57,389.35	381.20	H	Y	N	N	N	N	N	N	Group D: not classificable	2B	NI	2	2
Mancozeb	30,815.09	804.82	A, FG	N	N	N	N	N	N	N	Group B: probable carcinogen	NI	NI	NI	NI
Acephate	27,057.66	421.16	A, I	N	N	N	N	N	N	N	Group C: possible carcinogen	NI	NI	NI	NI
Atrazine	24,730.90	191.76	H	Y	N	N	N	N	N	N	Not likely	3	NI	1	2
Paraquat **	11,756.39	581.33	H	N	N	N	N	N	N	N	Group E: non-carcinogenic	NI	NI	NI	NI
Imidacloprid	9,364.57	646.57	I	N	Y	Y	Y	Y	Y	N	Group E – non-carcinogenic	NI	NI	NI	NI
Copper oxychloride	7,443.62	136.17	FG; B	N	N	N	N	N	N	N	Group D – not classifiable	NI	Y	3	3
Sulfur	7,392.44	-35.75	A, FG	N	N	N	N	N	N	N	NI	NI	NI	NI	NI
Diuron	6,999.47	237.25	H	Y	N	N	N	N	N	N	Probable carcinogen	NI	NI	2	3
Chlorpyrifos	6,471.19	120.88	A, GP, I	N	Y	Y	N	N	N	Y	Group E: non-carcinogenic	NI	NI	NI	NI
Malathion	6,094.65	476.24	A, I	N	Y	Y	Y	Y	Y	N	Suggestive but not enough	2A	NI	2	2
Chlorothalonil	5,771.99	193.78	FG	N	N	N	N	N	N	N	Probable carcinogen	2B	NI	NI	NI
Clomazone	4,559.90	71.47	H	N	N	N	N	N	N	N	Not likely	NI	NI	NI	NI
Tetraconazole	4,477.19	2237.39	FG	N	N	N	N	N	N	N	Not likely	NI	NI	NI	NI
Tebuthiuron	4,092.41	344.21	H	Y	N	N	N	N	N	N	Group D: not classifiable	NI	NI	NI	NI
Methomyl	3,766.44	895.83	A, I	N	Y	Y	Y	Y	N	N	Group E: non-carcinogenic	NI	Y	NI	NI
Carbendazim	3,748.26	-42.78	FG	N	N	N	N	N	N	Y	Group C: Possible carcinogen	NI	Y	2	3
Cypermethrin	3,570.28	14.49	GP, I	N	Y	Y	Y	Y	N	Y	Group C: possible carcinogen	NI	NI	NI	NI
Picloram	3,127.41	368.84	H	Y	N	N	N	N	N	N	Group E: non-carcinogenic	3	NI	NI	NI

AG: amateur gardening; CfS: candidates for substitution Europe; Disrup. H: endocrine disruption for humans; Disrup. WL: endocrine disruption for wildlife; IARC: International Agency for Research on Cancer; HU: household use; N: no; NI: not informed; OS: over-the-counter sale; PHC: public Health Campaigns; SS: specialized sale; Usage classes – H: herbicide; I: insecticide; F: fungicide; A: acaricide; GP: granular pesticide; B: bactericide; FG: fungicide; USEPA: US Environmental Protection Agency; WP: wood preservative; Y: Yes.

* use on road margins of highways, railways, and in electricity networks and hydropower plants;

** Banned in September 2020.

Table 2

International authorization of the 20 pesticide active substances with the highest volume of commercialization in 2017 in Brazil.

Active ingredients	Australia	Canada	Chile	China	India	Israel	Japan	Mexico	New Zealand	USA	European Community	Iceland	Norway	Turkey	Switzerland
Glyphosate	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	P	Y	Y	Y
2,4-D	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Mancozeb	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	Y	Y	Y
Atrazine	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	UN	UN	UN
Acephate	Y	Y	Y	Y	Y	UN	Y	Y	Y	Y	UN	UN	UN	UN	UN
Paraquat *	Y	UN	R	Y	Y	Y	Y	Y	Y	Y	UN	UN	UN	UN	UN
Imidacloprid	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Copper oxychloride	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Sulfur	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Diuron	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Chlorpyrifos	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Malathion *	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	UN
Chlorothalonil	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Clomazone	Y	Y	Y	Y	Y	Y	UN	Y	Y	Y	Y	Y	Y	Y	Y
Tetraconazole *	Y	Y	Y	Y	Y	Y	Y	Y	UN	Y	Y	UN	UN	Y	UN
Tebuthiuron *	Y	Y	Y	UN	UN	UN	Y	Y	UN	Y	UN	UN	UN	UN	UN
Methomyl	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	UN	Y	Y
Carbendazim *	Y	Y	Y	Y	Y	Y	UN	Y	Y	Y	UN	UN	UN	UN	UN
Cypermethrin	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	UN	Y	Y
Picloram *	Y	Y	Y	Y	UN	Y	UN	Y	Y	Y	Y	UN	UN	Y	Y

* Y: yes (Authorized); UN: unauthorized; P: pending but with temporary use authorization; R: restricted use.

* Pesticide active substances banned in at least 3 Organisation for Economic Co-operation and Development countries.

It is worth emphasizing that even for products authorized in Brazil and other countries, the conditions of use and preventive measures can be more rigid in these places, reducing the damage caused [14,15]. Among them, we can mention the permitted use for few cultures and the restriction of use to trained workers such as the case of glyphosate in Europe [16]. In addition, measures that condition the safety of pesticide use in Brazil have not been effective for several reasons such as distances between properties and places of sale or disposal of packaging and access to information on use and potential damage [17].

Brazilian agriculture, in addition to the use of large volumes of pesticides, extensively cultivates transgenic crops resistant to herbicides, such as glyphosate, 2,4-D, and dicamba, resulting in greater demand for the application of these substances and, consequently, in greater damage to ecosystems [18].

Considering pesticide active substances with commercialization data in Brazil, for 41 of them, including the pesticides glyphosate, 2,4-D, acephate, and atrazine, there were already records of authorization for use in the country in 1985, through *Ordinance n. 10* of the National Health Surveillance System, from the Brazilian Ministry of Health [19]. Other 34 pesticide active substances, among the 79 listed in the 2017 commercialization report, were included in *Resolution n. 165* of August 29, 2003 of Anvisa [20].

Still on the difference between Brazil and other analyzed countries and economic blocks, in the European Community, malathion had its use restricted to closed environments due to the serious

Box 2

Pesticide active substances with commercialization data in Brazil and unauthorized in Europe and damage to the environment and human health associated with pesticide active substances at the databases of Europe, US Environmental Protection Agency (USEPA) and International Agency for Research on Cancer (IARC).

Active susbtances	Final report on banning registration of Europe	Main damages according to classification criteria – *Directive 1,272/2008*	Effects on health and the environment reported in databases
Acephate	Acute toxicity to consumers Damage to non-target organisms: arthropods, birds, mammals, and aquatic animals	Toxic effects if swallowed	Possible carcinogen for humans
Ametryn	Not informed	Toxic to aquatic life (acute and chronic)	Possible carcinogen for humans
Atrazine	Insufficient monitoring and recovery studies on contaminated groundwater	Dermal sensitization, allergy, toxic with repeated exposure, toxic to aquatic life (acute and chronic)	Endocrine disruption for humans and wildlife
Methyl bromide	Insufficient studies regarding impacts on human and environmental health and risk to workers.	Not informed	Endocrine disruption for humans
Carbendazim	Not informed	Toxic to aquatic life (acute and chronic) Mutagen category 1B	Endocrine disruption for wildlife, carcinogenic potential for humans
Paraquat dichloride	Not informed	Fatal if inhaled, eye and skin irritation, toxic to aquatic life (acute and chronic)	Not informed
Phenoxaprope-P-ethyl	Not informed	Not informed	Possible carcinogen for humans
Fipronil	Insufficient studies on environmental impacts (pollinators). Damage to bee colonies	Toxic to aquatic life (acute and chronic)	Possible carcinogen for humans, candidates for substitution EuropeNot informed
Glufosinate – Ammonium Salt	Not informed	Reproductive toxicity potential for humans	Not informed
Hexazinone	Not informed	Immediate and delayed effects on aquatic life, toxic if swallowed, eye irritation	Not informed
Lactofen	Not informed	Not information	Probable carcinogen for humans
Permethrin	Ecotoxicity to aquatic ecosystems	Immediate and delayed effects on aquatic life	Not informed
Procymidone	Insufficient studies on endocrine disruption	Human carcinogenic potential	Not informed
Propanil	Insufficient studies on impurities, environmental impacts, and effects on consumers. Transport in long distances by air; high risk for birds, mammals, aquatic organisms, non-target arthropods	Endocrine disruption for humans, evidence of carcinogenicity for humans	Not informed

(continues)

Box 2 (continued)

Active susbtances	Final report on banning registration of Europe	Main damages according to classification criteria – *Directive 1,272/2008*	Effects on health and the environment reported in databases
Propargite	Risk to consumers, operators, workers, and bystanders. Chronic risk to mammals and aquatic life	Skin irritation, eye damage. Suspected carcinogen. Toxic to aquatic life (acute and chronic)	Probable carcinogen for humans
Simazine	Insufficient environmental impact studies	Suspected carcinogenic. Toxic to aquatic life (acute and chronic)	Endocrine disruption for humans
Tebuthiuron	Not informed	Toxic to aquatic life (acute and chronic)	Not informed
Thiodicarb	Insufficient studies on risk to consumers. Serious dietary risk to babies (grapes) and adults (wines); Risk for applicator. Groundwater contamination (use as molluscicide)	Not informed	Probable carcinogen for humans
Trifluralin	Insufficient studies on environmental impacts. Toxic to sediments; aquatic organisms, bioaccumulation and persistence in soil; transport in long distances by air	Skin sensitization. Toxic to aquatic life (acute and chronic)	Possible carcinogen for humans

Note: the following pesticide active substances were not included in the Box, although they are banned in the European Community: chlorimuron-ethyl, sulfentrazone, sulfluramid, and triclopyr-butotyl (as they had no information); diafenthiuron and MSMA (ban under *Regulation 2.076*/2002 EC); imazethapyr and novaluron (not approved according to 2001/861/EC) 2004/129/EC and 2012/187/EU, 2009/579/EC).

acute and chronic effects on birds [21], but it is widely used in Brazil for ultra-low volume dispersion (popularly known as fumigation) for vector control in public health initiatives. Aggravating this scenario, the application of pesticides, such as malathion, in densely populated areas by agricultural aircraft was authorized in Brazil according to *Federal Law n. 13,301*, of 2016 [22], even with experts' warning about the inefficiency and insecurity of this method [23].

The findings of the present study reiterate the losses resulting from increased contamination, evidenced in national surveys [6], including the presence of pesticides in food. Data from the Pesticide Residue Analysis in Food (PARA), of Anvisa, show that, among the 20 pesticide active substances most found in the surveyed foods, 7 (representing 40% of the total findings) are banned in at least three OECD countries. Mixtures of pesticides are also frequent, as 35% of the surveyed food samples contained from 2 to 21 residues [24].

Recent studies show the contamination of rivers, soil, flora, and fauna with products extremely harmful to life and not permitted in other countries, such as endosulfan (banned in Brazil in 2013), cypermethrin, and ametryn [25,26], the latter with potential toxicity to aquatic life (Box 2).

The existence of damage to the environment and evidence indicating serious and potentially irreversible effects on humans, such as endocrine disruption and carcinogenicity, should be sufficient for the adoption of precautionary measures, provided for in the Brazilian legislation. The importance of this study is reinforced by the recent approval of *RDC n. 294* of July 29, 2019, which provides for the criteria for toxicological assessment and classification without indicating the mandatory toxicological studies for registration and reevaluation procedures [27].

In Brazil, pressure from economic sectors on legislators seeks to make *Law n. 7,802/1989* more flexible, which regulates the registration, evaluation, and use of pesticides in the country. Among the

proposed changes is the removal of the registration prohibition criteria for potentially carcinogenic agents, toxic to the reproductive system, endocrine disruptors, and teratogens, which are currently similar to the criteria adopted in Europe. With the changes, the use of substances associated with these effects may be permitted through risk assessment. In Europe there is also pressure on this prospect, but studies have shown that the supposed economic losses would not be higher than health costs, loss of individual quality of life, deaths, reduced productivity due to absenteeism, among others [28].

In addition to other effects, endocrine disruption has a ban indication in the European Community [29]. However, the implementation of this measure encounters resistance to be fully effective, due to controversies and doubts raised by economic sectors to define the necessary criteria for this classification, common strategies regarding the regulation, and use of toxic substances [30].

The European legislation also provides for the definition of pesticide candidates for substitution, which may have their use authorization canceled [10]. For inclusion in the list, the pesticide active substances must meet at least one of the following criteria: (a) values of acceptable daily intake (ADI), acute reference dose (ARfD), or Acceptable Operator Exposure Level (AOEL) lower than most substances approved in the same category; (b) to meet two criteria, including persistence, bioaccumulation, or toxicity; (c) association with effects considered critical (for example, neurotoxicity or immunotoxicity) in contexts where exposure control measures are not effective, such as the potential for groundwater contamination, the use of personal protective equipment (PPE), or long distances from application; (d) a significant proportion of non-active isomers; (e) classification as a carcinogen, toxic to the reproductive system or endocrine disruptor, but which has not been banned for reasons established in regulations. This list, composed of 77 pesticide active substances, contains 52 pesticides authorized in Brazil, including carbendazim, epoxiconazole, chlorpyrifos, and linuron which, together with thiophanate methyl, procymidone and chlorothalonil, are scheduled be reassessed by Anvisa based on *RDC n. 221/2018* [31].

In 2002, in Brazil, the registration review for 18 pesticide active substances started due to effects on human health. The following pesticide active substances monocrotophos, pentachlorophenol, and lindane were banned in 2006; cyhexatin, in 2009; endosulfan and trichlorfon, in 2010; methamidophos, in 2011; methyl parathion and phorate, in 2015; prochloraz, in 2016; and carbofuran, in 2017. Prochloraz is authorized in 77% of the studied countries; phorate, in 31%; carbofuran, endosulfan and pentachlorophenol, in 23%; monocrotophos and cyhexatin, in 15%; metamidophos and methyl parathion, in 8%; and lindane, in none of them. This finding demonstrates that these bans imposed by Brazil are in line with other countries.

Paraquat, in 2017, was indicated for ban, but it had use permit in the country until September 22, 2020. The records of acephate, phosmet, lactofen, and 2,4-D were kept, and until May 2020 the processes of toxicological reevaluation of glyphosate and abamectin were inconclusive. For comparison purposes, China banned 50 pesticides in 2014 alone, started the banning process of another 30 pesticides, and announced the ban of another 12 pesticide active substances in 2022 [12].

For reevaluations that had not been concluded six years after they started, a deadline for finalization was judicially determined by a Public Civil Suit of the Federal Attorney General's Office (*ACP n. 21371-49.2014.4.01.3400* – 7th Federal Court-District Federal, Brazil), considering the possibility of effects on exposed populations. In the case of thiram and lactofen, whose reevaluations started in 2008, the technical opinion of Anvisa indicated the maintenance of the record, even without the assessment of important aspects of its toxicity: "*due to the short time granted by the courts, it was not possible to analyze all available studies*" [32] (p. 29). In both thiram and lactofen reevaluation opinions, studies on toxicokinetics (metabolism) and acute, subchronic, and chronic toxicity have not been presented, although they are crucial for the assessment of danger, risk, and the calculation of safety limits such as ARfD and ADI [33]. In this study, we observed that thiram is listed as unauthorized in Japan, Norway, and Iceland, whereas lactofen is unauthorized in almost all surveyed countries, except the United States and China.

Acephate and 2,4-D, which underwent toxicological reevaluation in Brazil, but had their records maintained, are unauthorized in several countries, as shown in Table 2. The remaining reevaluated products maintained or with a still unfinished process have no use permit in the following countries: (i) phosmet – India, Japan, New Zealand, Switzerland, Norway, and Iceland; (ii) lactofen – Australia, Canada, Chile, India, Israel, Japan, Mexico, New Zealand, Switzerland, Turkey, European Com-

munity, Norway, and Iceland; (iii) 2,4-D – Norway and Iceland; and (iv) thiram – Japan, Norway and Iceland. During the course of this study, thiram was indicated for ban by the European Community due to acute effects on workers and consumers, damage to birds and mammals, incomplete information for one of the metabolites, and formation of N,N-dimethylnitrous amide (NDMA) in drinking water [34].

In 2012, Ibama indicated the suspension of dispersion by aircraft of four insecticides due to damage to bees: imidacloprid, thiamethoxam, clothianidin, and fipronil. This decision was immediately suspended due to economic reasons [35]. The European regulatory body banned fipronil in 2010, adopted severe restrictions in 2013 for imidacloprid, thiamethoxam, and clothianidin [36] and, in May 2018, announced a ban on the use of these three active substances in open areas due to damage to bees [37].

The reduction of impacts of pesticides on human health and the environment is indicated in Europe through measures, such as those of *Directive n. 128/2009* [38], aimed at promoting integrated pest management and the adoption of methods without using chemical substances, in addition to other sustainable approaches. Guidelines from organizations, such as FAO, Pan American Health Organization (PAHO), and WHO, also provide guidance on the importance in promoting other models of agriculture, whether by reducing the use of pesticides or even transitioning to organic and agroecological production modes [39]. In Brazil, governmental initiatives, such as the National Policy on Agroecology and Organic Production, instituted by *Decree n. 7,794* of August 2012, encouraged the elaboration of a National Program for the Reduction of Pesticides, which was never implemented [40], but goes through legislative proceedings in the National Congress, via *Bill n. 6,670/2016* that intends to institute it as a public policy.

One of the study limitations was the difficulty in comparing the volumes of pesticide active substances commercialized in Brazil and in Europe, considering that in the researched databased data are presented by groups, according to indication of use and chemical group [41]. Another noteworthy issue was the difficulty in accessing information related to the authorization of pesticides on the official databases of the United States and China. Therefore, information about registration in the United States should be considered with reservations. Information on registration in China was obtained from a FAO document published in 2015 and may have been updated in that period. Moreover, we could not identify the reasons for the non-authorization of pesticide active substances, which overall are not presented in a clear and systematic way by the regulatory agencies.

Hence, the classifications of these pesticides for serious chronic effects have also been researched on official databases. The list of authorized monographs of Anvisa included pesticide active substances for agricultural use with the potential for serious damage, included in the list of candidates for substitution, endocrine disruptors, and probable or possible carcinogens, effects which are indicative of ban under the current legislation. It should be noted, however, that the ban of a pesticide active substances in Brazil can also occur due to other effects that were not investigated in this study (such as teratogenesis and reproductive toxicity), but also others that are equally serious (neurotoxicity, immunotoxicity, etc.) depending on the dose-effect relationship applied to the intended use. Deepening the investigation, including other toxic effects, may increase the number of authorized pesticides in Brazil with the potential for serious damage to health.

Three central issues stand out from this study. First, Brazil, a large global consumer market for pesticides, uses products that are not permitted in other countries, almost all of which have been available in the national market for more than four decades, which may not attract the attention of industries that may choose to launch more modern products in locations that review environmental, health, and agronomic issues more frequently.

Second, the need for adopting more protective criteria with regard to the registration of pesticides in the country. In this sense, the study is relevant in highlighting the importance of reviewing the registration of unauthorized products in at least three OECD member countries or in the European Community. In cases where the non-authorization of use has occurred due to damage to the environment or human health, the registration should be immediately canceled in Brazil.

Finally, the study points to the need for greater transparency by international regulatory agencies regarding the reasons for authorizing or not the pesticide active substances, in order to subsidize protection actions and encourage the global market to develop less harmful and more sustainable

technologies. Greater transparency is essential to support actions to protect biodiversity and human populations, especially the most vulnerable ones such as traditional communities and peoples in periphery countries. In addition, it would also promote the development of less harmful technologies and sustainable agricultural production methods, such as Agroecology, considered by FAO [39] as a way to achieve the *Sustainable Development Goals* of the 2030 Agenda.

Contributors

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Resumo

A legislação brasileira não prevê revisão periódica do registro dos agrotóxicos e, ainda hoje, são utilizados produtos proibidos em outros países. Partindo dos ingredientes ativos de agrotóxicos registrados no país, o presente estudo investigou a situação regulatória internacional nos países-membros da Organização para a Cooperação e Desenvolvimento Econômico (OCDE), da Comunidade Europeia e BRICS. Também se buscou relacionar os principais efeitos crônicos à saúde humana e ao meio ambiente dos ingredientes ativos de agrotóxicos mais comercializados no Brasil, em listas de classificação de potencial cancerígeno (Agência de Proteção Ambiental dos Estados Unidos – USEPA e Agência Internacional de Pesquisa em Câncer – IARC), desregulação endócrina e candidatos para substituição (estes dois últimos da Comunidade Europeia). Foram identificados 399 ingredientes ativos de agrotóxicos registrados no Brasil para uso agrícola, excluindo-se os microbiológicos e agentes biológicos de controle. Destes, não têm autorização 85,7% na Islândia, 84,7% na Noruega, 54,5% na Suíça, 52,6% na Índia, 45,6% na Turquia, 44,4% em Israel, 43,4% na Nova Zelândia, 42,4% no Japão, 41,5% na Comunidade Europeia, 39,6% no Canadá, 38,6% na China, 35,8% no Chile, 31,6% no México, 28,6% na Austrália e 25,6% nos Estados Unidos. Foram relacionados a danos à saúde e ao ambiente 120 ingredientes ativos de agrotóxicos. Considerando os ingredientes ativos de agrotóxicos para os quais estão disponíveis dados de comercialização no país, 67,2% deste volume está associado a pelo menos um dano crônico grave avaliado neste estudo. Os resultados do presente estudo indicam a necessidade de promover a transparência das bases de dados internacionais, no que tange às motivações para as respectivas decisões regulatórias e os órgãos reguladores brasileiros reavaliarem o registro de produtos obsoletos, fortalecendo políticas públicas relacionadas à redução do uso de agrotóxicos.

Agroquímicos; Neoplasias; Medição de Risco

Resumen

La legislación brasileña no prevé una revisión periódica del registro de los pesticidas e incluso hoy se utilizan productos prohibidos en otros países. Partiendo de los ingredientes activos de pesticidas registrados en el país, el presente estudio investigó la situación regulatoria internacional en los siguientes países-miembros: Organización para la Cooperación y Desarrollo Económico (OCDE), Comunidad Europea, y BRICS. También se buscó relacionar los principales efectos crónicos para la salud humana y en el medio ambiente de los ingredientes activos de pesticidas más comercializados en Brasil en listas de clasificación con potencial cancerígeno (Agencia de Protección Ambiental de Estados Unidos – USEPA e Agencia Internacional de Investigación sobre el Cáncer – IARC), desregulación endocrina y candidatos para sustitución, ambos de la Comunidad Europea. Se identificaron 399 ingredientes activos de pesticidas registrados en Brasil para uso agrícola, excluyéndose los microbiológicos y agentes biológicos de control. De estos, no tienen autorización en Islandia 85,7%, Noruega 84,7%, Suiza 54,5%, India 52,6%, Turquía 45,6%, Israel 44,4%, Nueva Zelanda 43,4%, Japón 42,4%, Comunidad Europea 41,5%, Canadá 39,6%, China 38,6%, Chile 35,8%, México 31,6%, Australia 28,6% y Estados Unidos 25,6%. 120 ingredientes activos de pesticidas estuvieron relacionados con daños en la salud y medioambiente. Considerando los ingredientes activos de pesticidas para los cuales están disponibles datos de comercialización en el país, un 67,2% de este volumen está asociado a por lo menos una enfermedad crónica grave evaluada en ese estudio. Los resultados del presente estudio indican la necesidad de promover la transparencia de las bases de datos internacionales, en lo que respecta a las motivaciones de las respectivas decisiones regulatorias, con el fin de que los órganos reguladores brasileños reevalúen el registro de productos obsoletos, así como para fortalecer políticas públicas relacionadas con la reducción del uso de pesticidas.

Agroquímicos; Neoplasias; Medición de Riesgo

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