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CROP PROTECTION

Brazilian pesticide policy for crops with insufficient phytosanitary support

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ABSTRACT: Pesticides are products, such as insecticides and fungicides, applied by farmers to control pests, with the aim of guaranteeing food productivity and quality. The problem challenging Brazilian small and medium-scale farmers, who face limited availability, or even unavailability, of registered pesticides to produce minor crops, has been addressed by the publication of Normative Instruction No. 1/2014, where these crops are defined as Crops with Insufficient Phytosanitary Support (CIPS). This study investigated the profile of active ingredients approved for use on CIPS during the period from the publication of the Normative Instruction until December 2023 and discussed the results considering monitoring data on Brazilian pesticide residues. During this period, 5,185 label authorizations of 134 active ingredients of different chemical groups for use in 111 CIPS of human consumption were included on product labels, with the establishment of a Maximum Residue Limit by ANVISA. Fungicides and insecticides were the main pesticide agronomic classes, mainly authorized in peanuts, oats and sweet pepper, which, according to the Brazilian monitoring programs, are among the crops with the highest incidence of illegal pesticide use. These new authorizations considerably increased the pest management options for the minor crop farmers and should decrease the use of non-authorized pesticides in the future. However, it is important that the different Brazilian government bodies enforce the adoption of safe use and the compliance with Good Agricultural Practices of pesticides by the farmers.
Key words: pesticides, minor crops, crop grouping, maximum residue level.

Análise da aplicação da política brasileira de pesticidas para culturas com suporte fitossanitário insuficiente

RESUMO: Agrotóxicos são produtos aplicados no campo no controle de pragas, como inseticidas e fungicidas, para garantir produtividade e qualidade dos alimentos. O problema enfrentado pelos pequenos e médios agricultores brasileiros com disponibilidade limitada, ou mesmo indisponibilidade, de agrotóxicos registrados para a produção de alguns alimentos foi abordado pela publicação da Instrução Normativa nº 1/2014, em que são definidas como Culturas com Apoio Fitossanitário Insuficiente (CIPS). O objetivo deste estudo foi investigar o perfil dos princípios ativos aprovados para CIPS no período desde a publicação da Normativa até dezembro de 2023 e discutir os resultados em relação os dados de monitoramento de resíduos de pesticidas no Brasil. Nesse período, foram concedidas 5.185 autorizações no rótulo de produtos de 134 princípios ativos de diferentes grupos químicos para uso em 111 CIPS de consumo humano, com estabelecimento de Limite Máximo de Resíduos pela ANVISA. Os fungicidas e inseticidas foram as principais classes agronômicas de agrotóxicos, autorizados principalmente em amendoim, aveia e pimentão, que, segundo os programas de monitoramento brasileiros, estão entre as culturas com maior incidência de uso ilegal de agrotóxicos. Estas novas autorizações aumentaram consideravelmente as opções de gestão de pragas para os pequenos agricultores e deverão diminuir a utilização de agrotóxicos não autorizados para a cultura no futuro. Contudo, é importante que os diferentes órgãos governamentais brasileiros façam cumprir a adoção do uso seguro e o cumprimento das Boas Práticas Agrícolas de agrotóxicos pelos agricultores.
Palavras-chave: agrotóxicos, *minor crops*, agrupamento de culturas, limite máximo de resíduo.

INTRODUCTION

Pesticides are chemical compounds or biological products used in agriculture to control the organisms that can affect food production and quality. When not used appropriately, the levels of pesticide in food can pose a potential risk to human health. Pesticide registration in Brazil involves the Ministry of Agriculture and Livestock (MAPA), Ministry of Health, through the National Health Surveillance Agency (ANVISA), and Ministry of Environment, through the Brazilian Institute of Environment and Natural Resources (IBAMA) (BRASIL, 2023a). A sound registration process and pesticide use control are essential to provide safe and quality food for the domestic market and to increase the competitiveness

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of agricultural products on the international market (OECD, 2023).

As part of the registration process, pesticide companies are required to submit, among other things, supervised residue trial studies conducted according to Good Agricultural Practices (GAP; product label instructions) on the crop of interest, which are the basis for ANVISA to establish Maximum Residue Limit (MRL) (ANVISA, 2012). These studies are costly and time-consuming, which means that companies may not register the use of their product in crops with small acreage and consequently low use, as the financial resources invested may not be recovered within a short period (OECD, 2009). These crops that lack pesticide registration are known internationally as minor or specialty crops, and in Brazil they are legally defined as Crops with Insufficient Phytosanitary Support (CIPS; BRASIL, 2014). Pesticide registration for minor crops is also a demand in several countries, including the United States, Canada and Australia (OECD, 2023).

A lack of legally approved pesticides on the market for CIPS producers leads to the use of unauthorized pesticides on the crop (no MRL established) and illegal/noncompliant residues under current legislation. JARDIM & CALDAS (2024) evaluated the results of the official programs for monitoring pesticide residues in food of plant origin in the country - the Program for the Analysis of Pesticide Residues in Food (PARA), coordinated by ANVISA, and the National Program for the Control of Residues and Contaminants (PNCRC), coordinated by MAPA. From the 35,321 samples analyzed from 2010 to 2020, 18.9% were considered irregular, of which 86.7% were due to the presence of unauthorized pesticides for the crop; 26.3% were irregular due to residues above the established MRL. Similar results were found in the samples analyzed by the PARA in 2022 (ANVISA, 2023).

The results of the monitoring programs highlighted the need for a legal framework set by the government agencies responsible for pesticide registration that would provide a minimum grid of pesticide products that allow legal pesticide use for CIPS production. In Brazil, this was accomplished by Normative Instruction Nº. 1/2014 (MAPA, 2015), which is a framework to allow the use of existing supervised residue trial data for major crops that could be used to include CIPS on the product label, which would then have the same MRL established for the major crop. The main impact of this framework is to offer farmers a larger number of pesticide products to be legally applied on CIPS, complying with the phytosanitary demand, thus aiming to reduce the high levels of non-compliance pesticides in these crops in the country. This regulation adopted three actions to address the issue: (i) crop grouping; (ii) extrapolation of the group and subgroup representative crop MRLs to the CIPS; and (iii) inclusion of CIPS in the dietary risk assessment (BRASIL, 2014). In the dietary risk assessment for pesticides, the exposure (acute and/or chronic) is compared to the toxicological reference values, the Acute Reference Dose (ARfD) and the Acceptable Daily Intake (ADI), respectively. Food is considered safe when pesticide intake through food consumption does not exceed the toxicological reference (ANVISA, 2023).

This research investigated the profile of active ingredients authorized for use in CIPS during the period from the publication of the Normative Instruction (June 2014) to December 2023 and discussed the results in light of the Brazilian pesticide residue monitoring data.

MATERIALS AND METHODS

This study evaluated the authorizations for inclusion of CIPS on pesticide product labels following the publication of Joint Normative Instruction 01, in June 2014 (NI 1/2014). The data, covering the period from June 2014 up to December 2023, were primarily obtained from the Federal Official Gazette (DOU), which publishes the MAPA acts with the inclusion of CIPS on a pesticide product label. The information was confirmed in the MAPA Agrofit system, which contains all the registered pesticide products and the crops included on the labels, among other information (BRASIL, 2024). Additionally, in the pesticide active ingredient monographs published by ANVISA, the CIPS that had the MRL extrapolated from a major crop under the Normative are shown (ANVISA, 2025).

Table 1 shows an example of the crop grouping system issued by NI 1/2014, with the representative crops of the group and subgroup and all the CIPS included (MAPA, 2015). In general, crops are grouped based on botanical classification, morphology, growth practices, the portion of the commodity harvested and/or consumed and similar residue behavior (APVMA, 2023). Representative crops are the most economically important commodities in production and/or consumption; they contribute to a higher dietary intake and have residue characteristics similar to other members of the group or subgroup (REP12/PR-Appendix XI).

In this study, a new use authorization is defined as the first inclusion of a CIPS on a pesticide product label, and an ordinary use is

Table 1 - Example of crop grouping established in Brazil by NI 1/2014.

Crop Group	----Group Representative----	Subgroup Representative	----------CIPS----------
5 - Fruiting Vegetables	Tomato (*Solanum licopersicum*) Cucumber (*Cucumis sativus*)	5A Seweet pepper (*Capsicum annuum*)	Eggplants (*Solanum melongena*), Scarlet eggplant (*Solanum aethiopicum* L.), Pepper (*Capsicum* spp.), Okra (*Abelmoschus esculentus*)
		5B Cucumber (*Cucumis sativus*)	Pumpkin (*Cucurbita moschata*), summer squash (*Cucurbita pepo)*, chayote (*Sechium edule*), Gherkin (*Cucumis anguria*)
6 - Legumes and oilseeds	Bean (*Phaseulus vulgaris*) Soybean (*Glycine max*)	6A Bean (*Phaseulus vulgaris*) or Peanut (*Arachis hypogaea*)	Peanut (*Arachis hypogaea*), Pea (*Pisum sativum*), Cowpea (*Vigna unguiculata*), Chickpea (*Cicer arietinum* L.), Lentil (*Lens culinaris*)
		6B Sunflower (*Helianthus annuus*)	Canola (*Brassica napus*), Sesame (*Sesamum indicum* L.), Linseed (*Linum usitatissimum*)
7 - Cereals	Corn (*Zea mays*) Wheat (*Triticum aestivum*)	7A Corn (*Zea mays*)	Millet (*Panicum miliaceum*), Sorghum (*Sorghum bicolor* (L.) Moench)
		7B Wheat (*Triticum aestivum*)	Oat (*Avena* spp.), Rye (*Secale cereale*), Barley (*Hordeum* spp.), Triticale (*x Triticosecale Wittmack*)

the inclusion on labels of a pesticide previously authorized as new use.

In order for the pesticide company to apply for a new use authorization, the MRL of the representative crop of the group must be extrapolated to the respective CIPS (Table 1; BRASIL, 2014). This extrapolation is provisional and subject to the submission, within a two-year period, of supervised residue trial data for the representative will be evaluated to determine whether it supports the MRL previously established for the representative crop of the group. For example, tomatoes are representative of Group 5 (Fruiting vegetables) and sweet peppers are representative of subgroup 5A (Table 1). The MRL is provisionally extrapolated from tomatoes to sweet pepper and all the other CIPS of the subgroup (eggplant, scarlet eggplant and chili peppers; Table 1). If the residue levels provided for sweet pepper are lower than the tomato MRL, the provisional MRL is confirmed, but if the data show higher residues, a higher MRL is established for the sweet pepper subgroup. Further, all crops will be included in the pesticide exposure assessment. If residue studies are not submitted as agreed, all the CIPS of the subgroup will be excluded from the active ingredient monograph and the product label (BRASIL, 2014).

RESULTS AND DISCUSSION

A total of 5,185 CIPS were included on pesticide labels during the period of June 2014 to December 2023, of which 3,504 (68%) were new use authorization and 1,681 (32%) were ordinary use. Figure 1 shows the total number of CIPS inclusions on pesticide labels over the study period, including new use and ordinary use authorizations. Although, the authorizations for ordinary use are not a new tool for controlling pests and diseases for CIPSs, which was provided in the new use authorization, they are important for expanding the trade of generic products in the national territory, thus allowing greater competition in the market.

The year 2014 (from June), with 106 authorizations (Figure 1), can be considered a year of learning and incorporation of the NI 1/2014 guidelines by the pesticide industry and food producers. In 2015, there was a substantial increase in the number of authorizations (403, of which 380 were new uses). This is probably because the companies already had the supervised residue field trials for the representative crops of the groups, the data from which were used to extrapolate the MRL to the representative crops of the subgroups and their respective CIPS (see examples in Table 1). Between 2016 and 2019, there was a decrease in the number of authorizations granted, as new MRL extrapolations would require investments from the registering companies to carry out new residue trials. These new investments can be seen in action, as authorizations started to recover in 2020, reaching 1125 in 2023, 55% of which were new use authorizations. The gradual increase of ordinary use authorizations as a percentage of total authorizations, from 6% in 2014 to 45% in 2023, may be related to the end of the data protection period for residue studies submitted

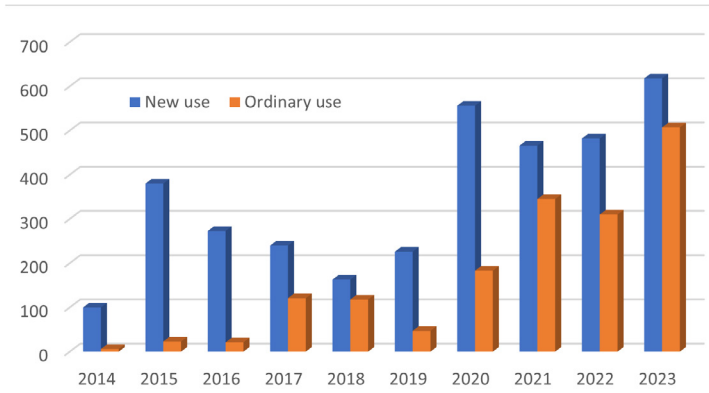

Figure 1 - Number of new and ordinary uses for Crops with Insufficient Phytosanitary Support (CIPS) included on pesticide product labels within the scope of NI 1/2014.

by the registering companies, which allowed other companies interested in the CIPS new-use authorizations to apply for ordinary authorization on their product labels (generic products).

The main agronomic classes and active ingredients of the pesticide products registered for CIPS are shown in figure 2A and figure 2B, respectively. The agronomic classes with the highest demand for new-use

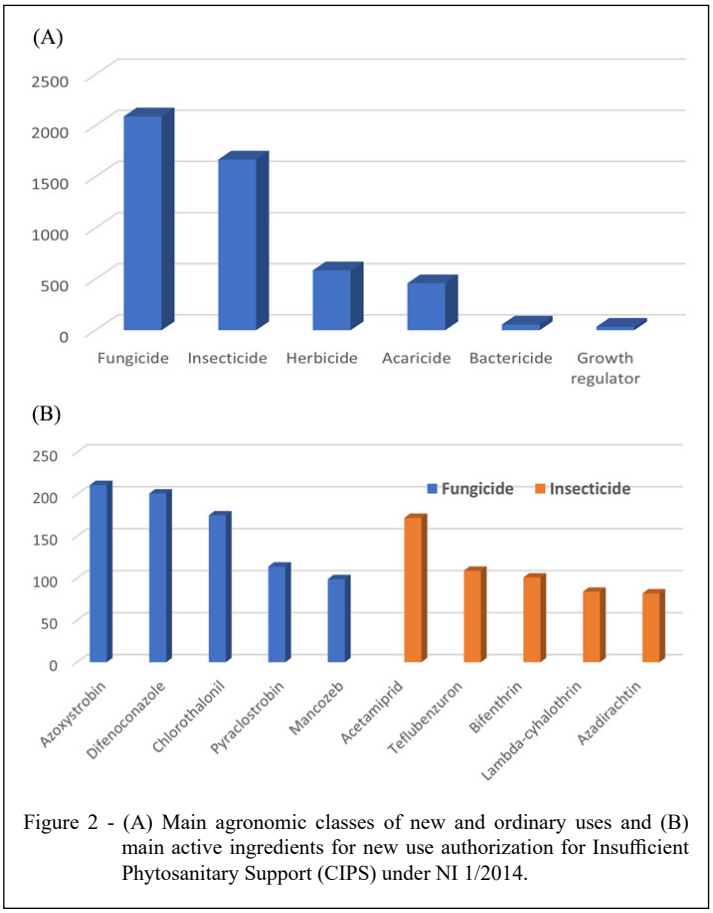

Figure 2 - (A) Main agronomic classes of new and ordinary uses and (B) main active ingredients for new use authorization for Insufficient Phytosanitary Support (CIPS) under NI 1/2014.

authorization were fungicides, mainly azoxystrobin, difenoconazole and chlorothalonil (Figure 2), followed by insecticides, mainly acetamiprid, teflubenzuron and bifenthrin. The active ingredients belong to different chemical groups and mechanisms of action, which is desirable in preventing the emergence of resistance in the target organism. Herbicides were the third most required authorization, followed by acaricide, bactericide and growth regulator (Figure 2A). The herbicide glyphosate, the pesticide most commercialized in Brazil (IBAMA, 2024), was authorized only for 47 CIPS, as it is mainly used in grains. Growth regulators, with only 34 authorizations, are specific products used to standardize the flowering or ripening period of some fruits and cereals. Further information on the chemical groups and active ingredients registered for CIPS can be found in Table S1 (Supplementary Material).

Most of the 111 different CIPS intended for food consumption that have been authorized for inclusion on pesticide labels are fruits, vegetables and legumes (Table S1). Horticulture is a major sector in Brazil, mainly involving small and medium-scale farmers, with a revenue of about R$ 20 billion in 2022 (WENDT, 2023), with an average of 2.4 jobs per hectare, or about 2.8 million direct jobs (PUIATTI, 2019).

The main eight CIPS included in the pesticide labels during the period of the study are shown in figure 3, with the highest number for peanut (137), oat (111) and sweet pepper (96). These crops belong to the legume vegetable, cereal grains and fruiting vegetable groups, respectively (Table 1). In fact, beans, wheat and tomatoes, which are the representative crops of these groups, are among the crops with the highest number of MRLs established in the country (156, 129 and 143 respectively), and the large residue database already available allowed the request for inclusion of the CIPS in the label, as discussed above. Soybean and cotton are the crops with the highest number of authorizations in Brazil, with 199 and 179, respectively (ANVISA, 2025).

Figure 4 shows the evolution of label authorization for the three main CIPS through the years. Peanut, which is a representative crop for subgroup 6A and also a CIPS of the same group (Table 1), attracted little interest from companies between 2014 and 2016. However, there was a gradual increase from 2017 onwards, with the highest number of new use authorizations in 2022 (19) and ordinary use authorizations in 2023 (17) (Figure 4). The majority of authorizations were for fungicidal and insecticidal products (28 each), followed by herbicides (9) and compounds with acaricidal action only or also insecticidal or fungicidal (10).

JARDIM & CALDAS (2024) reported that 9.5% of the 84 peanut samples analyzed by the PNCRC between 2010 and 2020 showed pesticide residues, of which 75% were considered irregular samples, all due to unauthorized residues for the crop. Conversely, none of the 101 peanut samples collected in 2022 and analyzed by PARA were considered unsatisfactory (ANVISA, 2023). This may be, at least in part, a reflection of the authorizations that took place for peanut under NI 1/2014.

Oat is not representative of any subgroup, but it is one of the CIPS of the cereal group, together with rye, barley and triticale (Table 1). A total of 111 inclusions of the oat crop on pesticide labels had

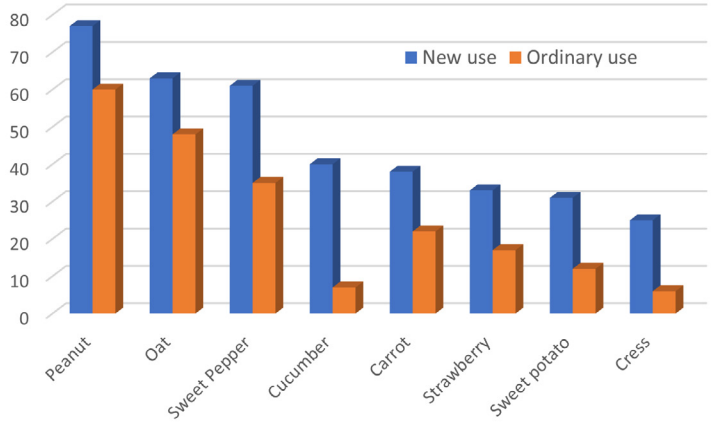

Figure 3 - Number of new and ordinary-use authorizations in pesticide labels for Insufficient Phytosanitary Support (CIPS) under NI 1/2014.

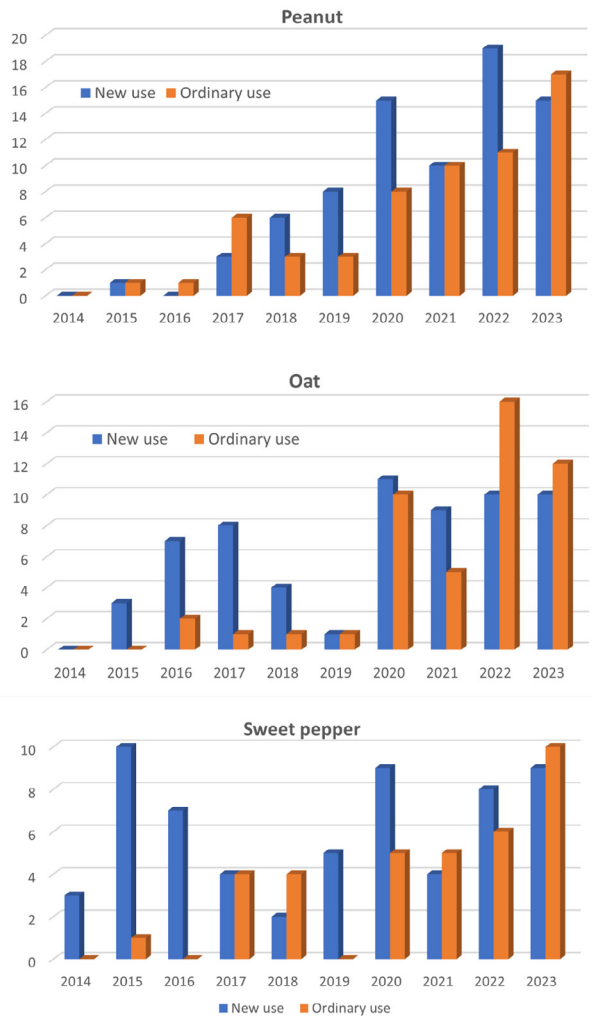

Figure 4 - Pesticide authorization for peanut, oat and sweet pepper over the years for Insufficient Phytosanitary Support (CIPS) under NI 1/2014.

been authorized until 2023, primarily from 2020 onwards, with 16 ordinary uses authorized in 2022, higher than new use authorizations (Figure 4). Of the total, 44 (39.6%) were for fungicide and insecticide compounds, while 9 were for herbicides. Furthermore, seven additional agronomic classes were authorized (including herbicides, acaricides alone or with other classes), demonstrating the extensive range of products available for the control of pests and diseases affecting the oat crop. Almost 78.6% of the 277 oat samples analyzed by PARA in 2018/2019 contained pesticide residues, of which 97.6% were irregular, all due to the presence of compounds not authorized for the crop (JARDIM & CALDAS, 2024). The organophosphorus insecticide pirimiphos-methyl, not authorized for oat during the PARA sampling period, was detected in 95% of the positive samples (ANVISA, 2023). The use of this insecticide was authorized on oat in August 2022, under the auspices of a Normative Instruction (BRASIL, 2022), and new samples containing pirimiphos-methyl residues would only be considered illegal if the levels were higher than the MRL.

The first three authorizations for sweet pepper, a representative crop of subgroup 5A (Fruiting vegetables, Table 1), were granted in 2014, reaching ten new use authorizations in 2015 (Figure 4). A decline in authorizations was observed between 2016 and 2019, followed by an increase from 2020 onwards. In 2023, there were 19 authorizations, nine new uses and ten of ordinary uses. About 46% (28) of the 61 pesticides

with new use authorizations for sweet peppers were fungicides, while 29.5% (18) were insecticides. Monitoring data from the PARA and PNCRC between 2010 and 2020 showed that 95% of the 1,209 sweet pepper samples analyzed contained pesticide residues, of which 84.8% were irregular, mostly (98.0%) for containing pesticides not authorized for sweet pepper (JARDIM & CALDAS, 2024). Data from the 2022 PARA showed that about 70% of the 142 sweet pepper samples analyzed were unsatisfactory, of which 74% contained pesticides not authorized for the crop, mainly the insecticides acephate (24% of cases) and profenofos (12.8%) and the fungicide procymidone (12.7%) (ANVISA, 2023). Profenofos was later approved for new use on sweet pepper under NI 1/2014 (BRASIL, 2023). Acephate is only authorized in Brazil for tractor application with the intention of reducing worker exposure, a method of application not commonly employed in sweet pepper cultivation, so it is unlikely that a registration of acephate for this crop will be granted under the Normative.

Guidelines for countries to implement strategies to respond to the demands related to the registration of pesticides for CIPS have been outlined by the Organization for Economic Co-operation and Development (OECD) to be applied by the countries. The guidelines include the establishment of specific programs that work directly with minor crop producers to identify needs and priority solutions; generate residue data; and implement the pesticide registration for crop protection (OECD, 2023). The competent Brazilian bodies have followed the guidelines when a legal framework (NI 1/2014) was published with all the necessary information to allow the pesticide companies to apply for label authorization, and have worked in collaboration with food producers, research institutions, and registering companies to identify priority needs and solutions.

Similar to Brazil, other countries also apply a crop grouping system to extend the label authorization to minor crops (OECD, 2023; IR-4, 2024; PMC, 2024; APVMA, 2023). The Codex Alimentarius developed a large crop grouping system aiming at covering minor crops grown worldwide, and it is used as the basis for the MRL recommendation by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) that are later adopted as Codex MRL and used to facilitate international trade (FAO, CAC, 2023).

In the United States, the IR-4 Project, established in 1963 by the United States Department of Agriculture, has been the primary resource for facilitating the registration of conventional chemical pesticides and biopesticides on minor food crops, as well as non-edible ornamental crops. In its 60th year of operation, the IR-4 has approved more than 75,000 chemical and biopesticide use registrations on USA labels (IR-4, 2024). These figures are expressive, and reflect the maturity and consolidation of the program over the years. In Brazil, biopesticides are registered based on the biological target and therefore do not require the inclusion of CIPS on the pesticide label (MAPA, 2014), and MRL for non-edible ornamental plants are not necessary (BRASIL, 2019).

In Canada, the activities related to minor crops started in June 2002 as a joint initiative between the Pest Management Center (PMC) of Agriculture and Agri-Food Canada and Health Canada's Pest Management Regulatory Agency. Since 2003, the PMC has granted more than 2,300 new use registrations for conventional chemicals and an additional 850 uses for biopesticides (PMC, 2024). These numbers for uses of new chemicals are much lower than in Brazil (3,504) for a shorter period (2014-2023).

Both the IR-4 and the PMC programs have direct government funding to obtain the necessary supervised residue data to support the registration of pesticides for minor crops (OECD, 2023). Currently, the Brazilian government does not financially support the CIPS program, a responsibility that lies entirely with the pesticide companies. This policy can be changed in the future if resources are available.

The main challenge encountered in implementing the Normative was to foster awareness among companies about the need to invest in the regularization of the situation of CIPS. Undoubtedly, the outcomes of the program for the analysis of pesticide residues in food (PARA), in conjunction with the growing public concern for improved food quality, have contributed to this.

The impact of the Normative on the percentage of unauthorized pesticide use in Brazil is not clear from the monitoring residue data. In 2014, about 30% of positive food samples were irregular, a level that dropped to 20 and 15% in the next two years, increased to about 30% in 2017 and 2018 and dropped to 14% in 2020 (JARDIM & CALDAS, 2024). A follow-up of the present study in the next years, along with monitoring data investigation, are necessary to confirm the expected positive impact of the legislation on decreasing the irregular use of pesticides on CIPS.

CONCLUSION

In conclusion, the application of the NI 1/2014 framework provided a larger number of phytosanitary options for CIPS farmers that could

increase the yield and quality of the food offered to the internal and international market. With the consequent MRL setting for these crops, the number of irregular residues is expected to decrease more significantly over the years. Furthermore, these crops are also included in the dietary exposure assessment that occurs during the registration process for additional uses of the pesticide.

Finally, it is important to enforce the application of good agricultural practices among farmers and raise awareness among professionals who are legally qualified to issue agronomic prescriptions, with the aim of ensuring that they only prescribe pesticides that are duly authorized for CIPS.

DECLARATION OF CONFLICT OF INTEREST

The authors declare no conflict of interest in this research.

AUTHORS' CONTRIBUTIONS

CAO Gomes: conceptualization, data analysis and writing of the original manuscript. ED Caldas: supervision, data curation, review and editing

DATA AVAILABILITY STATEMENT

<https://docs.google.com/file/d/1jeRA01yjVUBGwLcAXLtgOVQzyhaaGofB/edit?filetype=msword&pli=1>.

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