# Impact of legislation on registration of acutely toxic pesticides in Brazil

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## **Keywords**

Pesticides, classification. Pesticides, toxicology. Agrochemicals, classification. Agrochemicals, toxicology. Legislation. Safety management. Hazard classification.

### Abstract

### Objective

To evaluate the impact of the application of the "Pesticides Law" (Law no. 7,802/89) on the toxicological classification profile of registered pesticides in Brazil, from 1990 to 2000.

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### Methods

Data on registered commercial products in the years 1990 and 2000 were analyzed according to toxicological class, date of registration of the active ingredient (before or after the Law) and usage class (insecticides, fungicides, herbicides and others). Relative Identified Distribution Analysis was utilized for verifying statistical differences between distributions according to toxicological classes.

### Results

Among the 863 registered commercial products in 2000, 46.6% were already registered before the Pesticide Law. Among the 461 commercial products registered after the Law, 59.2% were derivatives of active ingredients registered before the Law, and 41.4% were classified as highly hazardous (classes I and II of the Brazilian toxicological classification). No significant differences in toxicological classification profile were identified between the group of pesticides derived from active ingredients registered before the Law and the group derived from active ingredients registered after the Law (p<0.0859).

# Conclusions

Ten years after the Pesticide Law came into effect, no significant improvement had been observed in the toxicological classification profile of registered pesticides. This was due especially to the continuing presence of products registered before the Law and the registration of new commercial products derived from "old" active ingredients. There was still a high proportion of registrations in the most hazardous classes. It is recommended that compulsory periodic reevaluation of all registered pesticides should be reestablished.

# INTRODUCTION

It is common to allege that the problems caused by pesticides result from using these products inadequately, since the rigor of the legislation and registration system and their progress have ensured that the products made available to users would be safe if well utilized. The inconsistency of the arguments that

hold only the method of utilization and the users of pesticides responsible for the problems was discussed in detail by Garcia<sup>8</sup> (2001).

The importance of legal instruments for controlling hazardous substances is indisputable. In the case of chemical substances utilized for controlling pests and diseases in agriculture, the so-called "Pesticides Law", which came into effect in 1989 (Law no. 7,802/89),<sup>6</sup> has special importance. Prior to this, the legislation that regulated the sector had been based on a decree that came into effect 55 years earlier: Decree no. 24,114,<sup>2</sup> of April 14, 1934, a time when the synthetic organic products that are widely utilized today were not even utilized as pesticides.

Among the various matters that the Law regulated, the registration of pesticides has great importance. During the registration process, the results from prior studies required for this purpose are evaluated with regard to the agronomical efficiency of the pesticide and its potential impact on public health and the environment. Registration defines whether a given substance or commercial product can be utilized, and under what conditions, and it is from this that practically all other aspects of the control and use of pesticides are defined.

The practice of registering pesticides already existed previously,<sup>2</sup> but the Pesticides Law was considered to be an advance from the point of view of preserving public health and the environment. One of the important points of the Law is that it only permits the registration of new pesticide products if it can be proven that they have the same or lower toxicity than those already registered for the same purpose.

But some aspects of the regulations accompanying the Law brought in concerns. The initial regulations, which were based on Decree no. 98,816,<sup>3</sup> of January 11, 1990, were altered by Decree no. 991/93,<sup>4</sup> of November 24, 1993, which eliminated the five-year validity for pesticide registrations and therefore the need for periodic reevaluations for renewal of the registration. Decree no. 4,074/02,<sup>5</sup> which is currently in force, revoked Decree nos. 98,816/90 and 991/93 and incorporated the modification established by this latter.

The five-year validity had been in operation since 1934,² but Decree no. 991/93 modified all the articles that dealt with this matter. It eliminated the need for renovation, while maintaining the possibility of reevaluating the registration at any time, if the pesticides presented reduction in their agronomical efficiency or risks to health or the environment. In practice, this has very important implications from the point of view of controlling pesticides: it does not give the possibility that products already registered necessarily come to be periodically reevaluated in the light of new knowledge and tests that are more modern and more precise. Consequently, consider-

ing that when there is renewal of the registration, the article in the Law that only permits the registration of products of the same or lower toxicity than those already registered for the same purpose should be applied, the opportunity for applying this provision for eliminating old products of greater toxicity is lost.

The regulations also leave something to be desired with regard to the role of toxicological (hazard) classification. The specific regulations for the Pesticides Law were made by the Brazilian Ministry of Health by means of SNVS Ordinance no. 3/92,11 thereby defining classification parameters that are similar to those recommended by the World Health Organization (WHO).7,17 Pesticides are classified into four toxicological classes, which are defined principally by the DL<sub>50</sub>\* of the products formulated, although other indicators related to damage to the cornea, lesions in the skin and the CL<sub>50</sub> \*\* may also determine the classification of the product.11 It is not necessary for all the toxicological data to be in the same class. The classification is defined by the worst data, i.e. the data that, because of their values, determine that the pesticide is put into the class with greater toxicity.<sup>11</sup>

The basic purpose of classifying pesticides is to distinguish between those presenting greater and lesser hazards. 17 In Brazil, however, the toxicological classification has basically served only for defining the communication of risks on the labeling. Bearing in mind that pesticides should only be utilized under very controlled conditions, which is especially the case for the most hazardous pesticides, due value needs to be given to the principal purpose of the toxicological classification. This means enabling legal definition of the implications of a technical, administrative and economic nature corresponding to each toxicological classification. The classification could, for example, have an influence on the distribution of pesticides, thereby causing there to be greater restrictions on the use of the most hazardous products, as recommended by WHO,7,16 the Food and Agriculture Organization (FAO)12 and the United States Environmental Protection Agency (EPA).8,15 A recommendation along these lines, including restrictions on the availability and prohibition of the most hazardous products was also expressed by the Intergovernmental Forum on Chemical Safety (IFCS), at its fourth meeting, held in Bangkok, Thailand, in November 2003.<sup>10</sup>

In view of this, one question was posed as the guideline for the present study: "Is the new legislation in

<sup>\*</sup>DL<sub>50</sub> (50% Lethal Dose) is a statistical estimate of the quantity of a toxin required to kill 50% of a large population of animals utilized in toxicological tests. In the case of pesticides, the parameters generally adopted are the oral DL<sub>50</sub> and dermal DL<sub>50</sub> for rats, expressed in milligrams per kilogram of body weight. 11.17

\*\*Cl<sub>50</sub> (50% Inhalatory Lethal Concentration) is determined similarly to how Dl<sub>50</sub> is determined, but from a statistical estimate of the concentration of the toxin in the ambient

<sup>\*\*</sup>CL<sub>50</sub> (50% Inhalatory Lethal Concentration) is determined similarly to how DL<sub>50</sub> is determined, but from a statistical estimate of the concentration of the toxin in the ambient medium that is capable of producing the death of 50% of the population exposed. In the case of pesticides, it is generally expressed in mg/l of air for one hour of exposure. 11

Table 1 - Distribution of registered pesticides in 1990, "new" products that were registered after the Pesticides Law and registered pesticides in 2000, according to usage class.

Usage class**	1990		"New" products		2000*	
	N	%	N	%	N	%
Insecticides	237	40.6	194	42.1	350	40.6
Fungicides	132	22.6	90	19.5	186	21.6
Herbicides	179	30.7	149	32.3	278	32.2
Others	36	6.2	28	6.1	49	5.7
Total	584	100.0	461	100.0	863	100.0

\*Includes the products of 1990 that remained registered and the "new" products

pheromones, growth regulators, agricultural surfactants Sources: a) Andrei¹ (1990); b) Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasília (DF): 1998; c) Agrotis. Agronomical pharmacopoeia system [computer program]. Version 4.0. Curitiba: February 2000

fact favoring the registration of commercial products (formulations) with lower acute toxicity?"

From this perspective, the present study had the objective of evaluating the consequences of the application of the Pesticides Law and its respective regulations in the toxicological classification profile of the pesticides registered in Brazil.

# **METHODS**

The distribution of commercial products registered within the scope of the Pesticides Law was analyzed in terms of when the active ingredient was registered and according to the usage class (insecticides, fungicides, herbicides and "others"). The distribution of the products in the toxicological classes was analyzed with the aim of verifying whether there were any differences between products originating from "old" active ingredients registered before the Law and those derived from "new" active ingredients registered after the Law. The study was based on secondary data relating to registered pesticides in Brazil in the years 1990 and 2000.1,\*,\*\*\*\*

Two interrelated databanks were set up, utilizing the Epi Info software (version 6.04b). The structuring and inputs for the databanks were done by just one person, to avoid duplication of the interpretations. Data entry checking mechanisms available in the software were utilized to control for possible typing errors.

The first databank, relating to the active ingredients, was formed from 367 records that each contained the technical or common name of the active ingredient, the usage class registered and confirmation that it was registered in 1990 and 2000.

The second databank, relating to the commercial (formulated) products, was formed from 1,045 records that each contained, for registered products in 1990 and for registered products in 2000, the commercial trademark, the registered usage class, confirmation of registration in 1990 and 2000 and the toxicological class.

The identification of the commercial products registered within the scope of the Pesticides Law (Lei no. 7,802/89)6 and the analysis of the distribution of these new registrations, in terms of when the active ingredient was registered and according to the usage class (insecticides, fungicides, herbicides and others) and the toxicological classification was done.

The commercial products registered within the scope of the Pesticide Law were considered to be those that appeared in the AGROFIT phytosanitary pesticides system of the Ministry of Agriculture (1998), supplemented with information from the AGROTIS agronomical pharmacopoeia system (February 2002) and which did not appear in the Compendium of Agricultural Pesticides<sup>1</sup> (1990).

The data on commercial product registrations made under the Pesticides Law were studied by considering three groups: those derived from active ingredients already registered in 1990; those derived from active ingredients registered after 1990, and the total of the data on these new commercial products.

To verify statistical differences between the distributions in accordance with the toxicological classes of the products registered, Relative Identified Distribution Analysis was utilized.14 The SAS software (version 8) was utilized, and the significance level was set at  $p \le 0.05$ .

<sup>\*\*</sup>Insecticides: insecticides, acaricides, formicides, fumigants, molluscicides, nematicides; Fungicides: fungicides, antibiotics, bactericides; Herbicides: herbicides, desiccating agents; Others: adjuvants, anti-budding agents, adhesive spreads, stimulants,

<sup>\*</sup>Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasília (DF): Coordination Office for Pesticide Supervision: 1998.

<sup>\*\*</sup>Agrotis. Agronomical pharmacopoela system [computer program]. Version 4.0. Curitiba: Agrotis; February 2000.

\*\*\*Ministry of Health. National Agency for Sanitary Surveillance (Anvisa). Monographs on pesticide products [online monographs]. Brasília (DF): Anvisa; 2000. Available at URL: http://www.anvisa.gov.br/ legis/resol/05\_99rdc.htm [July 10, 2000]

Table 2 - Distribution of pesticides registered within the scope of the Pesticides Law, from 1990 to 2000, according to usage class and time when their active ingredients were registered.

Usage class***	"Old" activ	Derivation of a e ingredients*	ctive ingredients "New" active	nts active ingredients**		Total	
	N	%	N	%	N	%	
Insecticides	111	57.2	83	42.8	194	100.0	
Fungicides	51	56.7	39	43.3	90	100.0	
Herbicides	98	65.8	51	34.2	149	100.0	
Others	13	46.4	15	53.6	28	100.0	
Total	273	59.2	188	40.8	461	100.0	

<sup>\*&</sup>quot;Old" active ingredients: registered before the Law

\*\*"New" active ingredients: registered after the Law

\*\*\*New" active ingredients: registered after the Law

\*\*\*See note regarding usage class in Table 1

Sources: a) Andrei¹ (1990); b) Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasilia (DF): 1998; c) Agrotis. Agronomical pharmacopoeia system [computer program]. Version 4.0. Curitiba: February 2000

### **RESULTS**

The data in Table 1 indicate that, of the 584 registered commercial (formulated) products in 1990, 182 registrations were no longer identified in 2000. Therefore, of the 863 registered products in 2000, 402 (46.6%) were already registered before the Pesticides Law.

According to Table 2, of the 461 commercial products registered after the Pesticides Law, 59.2% were derived from "old" active ingredients, i.e. ingredients that were already registered before the Law. In decreasing order, these were: herbicides (65.8%); insecticides (57.2%); fungicides (56.7%); and others (46.4%).

Table 3 considers only the commercial products registered after the Law and shows that 41.4% of them are in the toxicological classes I and II, i.e. the most hazardous categories. In the usage class of insecticides, this proportion reaches 49.5%.

It can be seen in Table 4 that the products derived from "new" active ingredients, registered after the Pesticides Law, present a smaller proportion of registrations in the most hazardous classes than do the products derived from "old" active ingredients, registered before the Law. However, the Relative Identified Distribution Analysis,14 did not reveal any statistically significant difference between the distributions according to toxicological classes of the products derived from the "old" and "new" active ingredients (Z=-1.7174 and p<0.0859).

It can be seen from the Figure that, in the usage class of insecticides, the products derived from "new" active ingredients (36.2%) proportionally have much fewer registrations in the toxicological classes I and II than do those derived from the "old" ones (59.4%). The same occurs in the class of "others", in which the proportion of products derived from "new" active ingredients (26.7%) that are in toxicological classes I and II is half the proportion of those derived from "old" ones (53.9%). Among the herbicides, there is practically no difference between the "new" (39.2%) and "old" ones (39.8%). On the other hand, among the fungicides, there is a greater proportion of registrations of products in toxicological classes I and II (the most hazardous classes) among those derived from "new" active ingredients (38.5%), and this is almost twice the proportion of fungicides derived from "old" active ingredients (19.6%).

# DISCUSSION

The development of this study suffered from limitations caused by the lack of official sources with complete information that was up-to-date and available,

Table 3 - Distribution of pesticides registered within the scope of the Pesticides Law, from 1990 to 2000, according to usage class and toxicological class.

Usage class*	Toxicological class**									
						III		IV	To	otal
	N	%	N	%	N	%	N	%	N	%
Insecticides	49	25.3	47	24.2	41	21.1	57	29.4	194	100.0
Fungicides	11	12.2	14	15.6	33	36.7	32	35.6	90	100.0
Herbicides	20	13.4	39	22.6	57	38.3	33	22.1	149	100.0
Others	4	14.3	7	25.0	5	17.9	12	42.9	28	100.0
Total	84	18.2	107	23.2	136	29.5	134	29.1	461	100.0

<sup>\*</sup>See note regarding usage class in Table 1.

\*\*Toxicological class: I - Extremely toxic; II - Highly toxic; III - Moderately toxic; IV - Slightly toxic

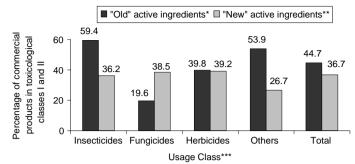
Sources: a) Andrei¹ (1990); b) Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasilia (DF): 1998; c) Agrotis. Agronomical pharmacopoeia system [computer program]. Version 4.0. Curitiba: February 2000

relating to the products registered before and after the Pesticides Law. This had the implication of making it necessary to resort to a diversity of sources. Shortages of data, out-ofdate data, dispersion of data and discrepancies in the data were found in relation to the registered products, even among the bodies responsible for the sector. Limited transparency with regard to the information from the registration procedures themselves was also observed. Until recently, approvals of registrations were not even published (the need to publish is now made explicit in Decree no. 4,074/02<sup>5</sup>). All this not only makes it difficult to do research but also limits the actions of the specific bodies responsible for registration and control. Moreover, it limits action by society in general, with regard to knowing about and monitoring everything that has already been, is or may come to be registered and utilized as a pesticide in the country.

There is a diversity of issues relating to the control of pesticides, and these involve political, social, economic and technical questions. Legislation is just one of the essential factors for controlling these substances, and it generally reflects the evolution of these questions within society. In this respect, the Pesticides Law is in a constant process of implementation and has been going through modifications and supplementation, with the issuing of new ordinances and regulatory decrees.

Among other matters regulated, the legislation has established mechanisms that should favor the registration of products with lower impact on health and the environment. However, the data analyzed indicate that, 10 years after the Pesticides Law came into effect, no significant advances had been achieved with regard to the indicators for health hazards (toxicological classification) relating to the registered pesticides.

The data in Tables 1 and 2 reveal that, over this



- \*"Old" active ingredients: registered before the Law
- \*\*"New" active ingredients: registered after the Law
- \*\*\*Insecticides: insecticides, acaricides, formicides, fumigants, molluscicides, nematicides; Fungicides: fungicides, antibiotics, bactericides; Herbicides: herbicides; desiccating agents; Others: adjuvants, anti-budding agents, adhesive spreads, stimulants, pheromones, growth regulators, agricultural surfactants Sources: a) Andrei¹ (1990); b) Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasília (DF): 1998; c) Agrotis. Agronomical pharmacopoeia system [computer program]. Version 4.0. Curitiba: February 2000

Figure - Proportions of pesticides registered within the scope of the Pesticides Law, from 1990 to 2000, in toxicological classes I and II, according to usage class and time when the active ingredient was registered.

period, despite the new instruments that the Law offered, the commercial (formulated) pesticides derived from "new" active ingredients, i.e. substances registered under the new Law, were still in the minority.

The continuing presence of products that were already registered before the Law could perhaps, in itself, be considered sufficient to explain the high proportion of products classified in toxicological classes I and II, i.e. the most hazardous classes. However, Table 3 shows that, even after the Law, there was still a large proportion of registrations in the most hazardous classes, I and II. The case of insecticides can be highlighted, which is still the usage class that offers the greatest potential for acute harm to health. From what can be observed in the Figure, this seems particularly to be the result of registrations of insecticides derived from "old" active ingredients that were already registered before the Pesticides Law. For herbicides too, as seen in the Figure, there was not much progress during the period studied, with regard to the matter of acute toxicity.

On the other hand, with fungicides, which in a gen-

Table 4 - Distribution of pesticides registered within the scope of the Pesticides Law, from 1990 to 2000, according to toxicological class and time when their active ingredients were registered.

	Derivation of active ingredients					
Toxicological class	"Old" activ	e ingredients*	"New" actri	"New" actrive ingredients*		
	N	%	N	%		
I - Extremely toxic	53	19.4	31	16.5		
II - Highly toxic	69	25.3	38	20.2		
III - Moderately toxic	79	28.9	57	30.3		
II - Highly toxic III - Moderately toxic IV - Slightly toxic	72	26.4	62	33.0		
Total	273	100.0	188	100.0		

<sup>\*</sup>See note on registration in Table 2

Sources: a) Andrei¹ (1990); b) Ministry of Agriculture and Supply. Agrofit 98. Information on phytosanitary products registered with the Ministry of Agriculture [computer program]. Brasilia (DF): 1998; c) Agrotis. Agronomical pharmacopoeia system [computer program]. Version 4.0. Curitiba: February 2000

eral manner have always given rise to concern more because of their potential effects of chronic toxicity than because of acute damage to health, the inverse of what was expected occurred: the new fungicides derived from the "new" active ingredients presented greater potential for acute harm to health than did those derived from the "old" ones.

These high proportions of pesticides still registered in the more hazardous classes gain greater importance with the analysis of the data in Table 4. If the proportions identified in the different toxicological classes were compared separately, class by class, between the products derived from the "old" active ingredients and those derived from the "new" ones, this could perhaps suggest a possible tendency towards improvement. However, in comparing "new" and "old" in relation to the distribution of the set of products according to different toxicological classes, the statistical analysis indicated that these modifications in the proportions were still insufficient to define a set of "new" products with a different toxicity profile, in this case better than the profile for the "old" ones.

The prevalence of "old" products registered before the Law, and of products registered after the Law derived from "old" active ingredients, may in large part result from the issuing of Decree no. 991/93,4 which revoked the need for periodic renovation of the registration. The results indicate that, in practice, the absence of periodic reevaluation in the light of new knowledge and tests that are more modern and more precise makes it possible for products to remain registered when, perhaps because of their more hazardous toxicological characteristics, they could already have been eliminated.

It is recommended that compulsory periodic reevaluation of registered substances and products should be reestablished. There should also be better regulation in order to prohibit the registration of more hazardous products for the same purpose.

Another matter brought up by the results is that it is probably easier and consequently faster to register products derived from substances that are already registered, even if these substances have greater toxicity than other new ones that have not yet been registered. WHO has pointed out that, in developed countries, few new compounds come onto the market each year, because of the high cost of developing these substances in such a way as to satisfy the rigid requirements regarding toxicological and environmental effects.<sup>16</sup>

It therefore becomes necessary to discuss adminis-

trative mechanisms that would speed up the registration of new substances that have lower impact, to the detriment of the "old" ones. In the United States, the Environmental Protection Agency (EPA), which is responsible for registering pesticides, works with the benefit-risk concept, i.e. it seeks to assess the risks to health and the environment from exposure to the product against the benefits from its use for society and the economy.<sup>15</sup> According to Osteen<sup>13</sup> (1993), the idea that the risks from using some pesticides could outstrip their benefits changed the regulatory policy. The role of pesticides in agricultural production is recognized, but the need for protection against the risks is emphasized: the focus is on withdrawing the "unsafe" pesticides from the market and speeding up the entry of others that are safer.

In Brazil, Decree no. 4,074/02,<sup>5</sup> which is currently in force, provides for the possibility of prioritizing the registration processes for products of low toxicity and hazard. It is hoped that regulating and implementing it will promote its effective application and that it may serve to stimulate research into new substances and products with lower impact on health and the environment.

Reflection is also due at this point: after all, what purpose does it serve to toxicologically classify pesticides if this does not imply any type of control? What difference does it make for a product to be in class I or class IV if it can be recommended, commercialized and utilized in the same way and by any user? It is not taken into consideration that the more hazardous products require more knowledge and technical capacity for their utilization, as well as a better technological structure. Classification of a pesticide according to its hazards enables adequate labeling, with the information needed for alerting users to the risks in utilizing it and the means for controlling them. But it should also serve as a parameter for defining measures for risk control and management.

Possible measures include restriction on commercialization and controlled use of the most hazardous pesticides, only under certain conditions and under the responsibility of trained professionals, and also the definition of economic factors (taxation and price controls). These actions should inhibit the consumption of the most hazardous pesticides, as discussed by Garcia<sup>8</sup> (2001) and recommended by the international agencies that deal with this question (International Labor Organization, WHO and FAO)<sup>7,8,12,16</sup> and by the Intergovernmental Forum on Chemical Safety (IFCS).<sup>10</sup> However, alternatives of this nature, based on the toxicological (hazard) classification, have not been adopted.

Legislation and acutely toxic pesticides

These measures could be discussed and defined at federal, state and municipal levels, since the Pesticides Law defines jurisdiction at different levels. Among these, the federal government has the power to legislate with regard to classification and toxicological and technological control; the states, to legislate with regard to utilization, consumption and trade; and the municipalities, to enact supplementary legislation regarding utilization. There is certainly much to be done in order to reach the speed, transparency and efficacy required by society today. There is a need to give the registration and control bodies the greater capacity and better instruments that are required for this.

Despite the difficulties observed, analyses of a general nature on the registered pesticides, like what has been carried out in the present study, are necessary and should be done frequently by research entities and by the control bodies themselves. Such practices would make it possible to face up to the economic pressure to give flexibility to the requirements, by offering backing for improvements to the legislation and for the development of a registration and control policy for these substances that would aim to meet society's yearning for greater control over the agents and conditions that degrade health and the environment, in the search for better quality of life.

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