Revista Bioética
Print version ISSN 1983-8042 | On-line version ISSN 1983-8034

Rev. Bioét. vol.34 Brasília 2026

# Ethical implications and civil liability of regulatory authorities in the authorization of carcinogenic pesticides

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## Abstract

While the European Union prohibits pesticides with proven carcinogenic potential, in Brazil such substances are approved by regulatory agencies. This study questions the ethical implications and civil liability of regulatory authorities that, despite available evidence, authorize the commercialization of pesticides proven to cause cancer. The ethical stance and vices of regulatory agencies and their agents, by benefiting a rural elite, place society as a whole at risk, especially farmers who directly handle these pesticides and constitute the most vulnerable group, contrary to the principles of the *Universal Declaration on Bioethics and Human Rights*, given the violation of personal integrity, the breach of social and health responsibility, and negligence. In addition to transgressing ethical values, regulatory authorities, as state agents, by approving the registration of known carcinogenic pesticides, may incur civil liability for negligence and omission as provided by law.

**Keywords:** Bioethics. Social vulnerability. Agrochemicals. Neoplasms. Social responsibility.

## Resumo

**Implicações éticas e responsabilidade civil de autoridades regulatórias na autorização de agrotóxicos cancerígenos**

Enquanto a União Europeia proíbe agrotóxicos carcinogênicos comprovados, no Brasil eles são aprovados pelas agências regulatórias. Questiona-se as implicações éticas e a responsabilidade civil das autoridades regulatórias, que, a despeito das informações disponíveis, aprovam para comercialização agrotóxicos comprovadamente causadores de câncer. A postura ética e os vícios das agências regulatórias e de seus agentes, ao beneficiarem uma elite ruralista, colocam em risco toda a sociedade, principalmente os agricultores que manipulam diretamente esses agrotóxicos, sendo a parcela mais vulnerável, em contrariedade aos princípios da *Declaração Universal sobre Bioética e Direitos Humanos*, dadas a violação da integridade pessoal, a ruptura com a responsabilidade social e de saúde e a negligência. Além de transgredir valores éticos, as autoridades regulatórias, como agentes de Estado, ao aprovarem o registro de agrotóxicos reconhecidamente carcinogênicos, estariam cometendo infração de responsabilidade civil por negligência e omissão prevista em lei.

**Palavras-chave:** Bioética. Vulnerabilidade social. Agroquímicos. Neoplasias. Responsabilidade social.

## Resumen

**Implicaciones éticas y responsabilidad civil de las autoridades regulatorias en la autorización de pesticidas cancerígenos**

Mientras que la Unión Europea prohíbe pesticidas con comprobado potencial carcinogénico, en Brasil estos son aprobados por las agencias regulatorias. Se cuestionan las implicaciones éticas y la responsabilidad civil de las autoridades regulatorias que, a pesar de la información disponible, autorizan la comercialización de pesticidas comprobadamente causantes de cáncer. La postura ética y los vicios de las agencias regulatorias y de sus agentes, al beneficiar a una élite ruralista, ponen en riesgo a toda la sociedad, especialmente a los agricultores que manipulan directamente estos pesticidas y constituyen el grupo más vulnerable, en contradicción con los principios de la *Declaración Universal sobre Bioética y Derechos Humanos*, debido a la violación de la integridad personal, la ruptura con la responsabilidad social y sanitaria y la negligencia. Además de transgredir valores éticos, las autoridades regulatorias, como agentes del Estado, al aprobar el registro de pesticidas reconocidamente carcinogénicos, podrían estar incurriendo en responsabilidad civil por negligencia y omisión previstas por la ley.

**Palabras clave:** Bioética. Vulnerabilidad social. Agroquímicos. Neoplasias. Responsabilidad social.

The authors declare no conflict of interest.

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Civil liability means that individuals may not commit acts that violate rights or cause harm to others, thereby infringing applicable law. The Brazilian Civil Code [1], in Article 186, establishes that anyone who, through omission or voluntary action, negligence, or recklessness, violates a right or causes harm to another, is required to compensate for the harm. Anyone who performs an activity or makes a decision that results in damages to third parties arising from such conduct is held civilly liable.

The association between pesticide exposure and cancer incidence is already well established, with substantial data from epidemiological studies on farmers who handle these substances. The types of cancer most commonly reported among farmers include lung, pancreatic, kidney, breast, prostate, and stomach cancers, as well as leukemia and non-Hodgkin lymphoma [2,3]. Moreover, there is an extensive body of literature showing the carcinogenicity of pesticides in toxicological bioassays with laboratory animals.

According to Ribeiro and Rocha [4], the massive use of pesticides with the expansion of agribusiness in Brazil imposes a heavy burden on society, as it causes illness in the population and overloads the public health system, in addition to causing contamination in the water we drink, the air we breathe, and the food we consume. The entire Brazilian society bears the costs generated by agribusiness rural elites, in what is known as a negative externality. However, the economic gains remain exclusively with the agribusiness producers.

Article 37, paragraph 6, of the Federal Constitution of 1988 [5] provides for the liability of public legal entities for damages their agents cause to third parties. This raises an ethical question concerning the harm to public health caused by the commercial approval, by State regulatory agencies, of pesticides with scientific evidence of causing cancer.

This research aims to discuss ethical issues in pesticide registration processes in Brazil from a novel perspective. It raises ethical questions about the fact that many pesticides, banned in other countries because of their carcinogenic risks, are authorized for registration in Brazil by regulatory agencies. It also shows the contradiction between carcinogenesis studies produced by private laboratories, that is, laboratories contracted for this purpose, and studies conducted by independent institutions/researchers, and, consequently, raises questions about the ethics of chemical companies registering pesticides in Brazil.

## Method

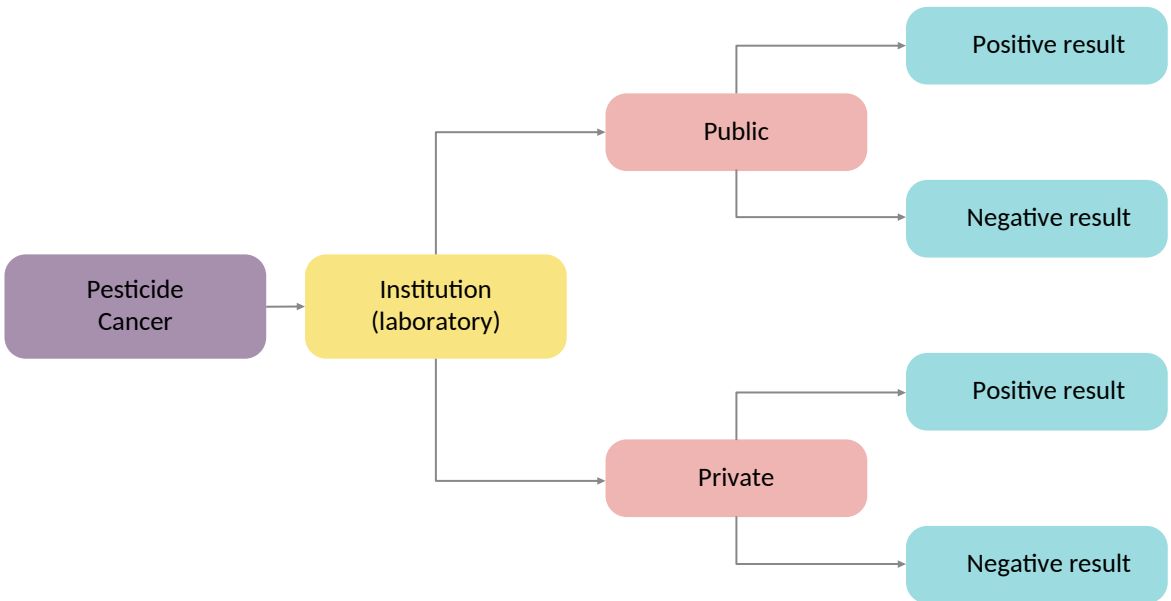
Searches were conducted in different scientific journal databases—such as the journal portal of the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (Capes), ScienceDirect, Scopus, and Medline—for scientific articles related to the scope of the research, that is, articles presenting findings on exposure to pesticides associated with cancer development. For this purpose, the following keywords were used: "pesticide and cancer," "fungicide and cancer," "insecticide and cancer," "herbicide and cancer." A total of 198 scientific articles containing the indicated keyword pairs and published between 1990 and 2020 were identified and included in the analysis of the association between pesticides and cancer. Duplicate articles, inconclusive articles, and articles that cited the keywords but were not within the research scope were excluded.

In addition to the bibliographic research, searches were carried out in the archives of the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), based on the Access to Information Law [6], to access toxicological studies that chemical companies submit to regulatory agencies on the carcinogenicity of pesticides for registration purposes. An analysis was made of 247 formulations of the best-selling pesticides in Brazil based on the results of carcinogenesis bioassays, all performed in private laboratories, that is, contracted studies.

Using these two databases—the 198 articles obtained from the scientific literature and the 247 carcinogenesis bioassays from the IBAMA archives—an analysis was conducted contrasting the results. The 198 articles found were analyzed, and their results were noted: positive or negative for cancer. The 247 bioassays from the IBAMA archives were analyzed, and their results were noted: positive or negative for cancer.

The aim was to compare the positive cancer findings produced by public institutions or independent researchers with those produced by private laboratories, contracted by the chemical industry, for registration purposes, as schematized in Figure 1.

**Figure 1.** Methodological process of bibliographic searches for positive and negative results for cancer generated by public and private laboratories




## Results

In the international scientific literature, of the 198 articles found, 153 (77.2%) were positive and 45 (22.3%) were negative for cancer. When analyzing the origin of the studies, that is, whether from private or public institutions (laboratories), the results are even more striking. Public institutions, in articles that declared no conflict of interest, reported 84% positive results and 16% negative results for cancer. In contrast, private institutions reported 21% positive results and 79% negative results for cancer, in studies identified as contracted. Private institutions included private universities, research institutes providing services for product regulation, and corporate research laboratories of chemical companies. These data are thoroughly detailed in Rocha and Grisolia [7].

In the IBAMA archives, all carcinogenesis studies submitted by chemical companies to State bodies for pesticide registration purposes were generated by private laboratories contracted by the companies requesting registration, or by these companies' own laboratories. The results indicate that, according to the pesticide chemical industry, none of the 247 pesticides cause any type of cancer, that is, they are 100% negative [7].

## Discussion

The discussion of the ethical implications of the pesticide registration process in Brazil and its repercussions draws on the discourse of intervention bioethics, which aims to examine this global problem from the local perspective of the Brazilian reality, raising new ways of thinking about emerging problems within the context of Latin American environmental complexity. Given the abusive use of pesticides, as well as the supremacy of agribusiness in the harsh Brazilian socioeconomic reality, the approval of pesticide registrations with carcinogenic risk reflects a coercive system.

The *Universal Declaration on Bioethics and Human Rights* (UDBHR) [8] has the following principles relating to the human person: human dignity and human rights, beneficence and non-maleficence, autonomy and individual responsibility, consent, respect for human vulnerability and personal integrity, privacy and confidentiality. The social principles are equality, justice and equity, non-discrimination and non-stigmatization, respect for cultural diversity and pluralism, solidarity and cooperation, social responsibility and health, sharing of benefits. The environmental principles are protection of future generations, protection of the environment, the biosphere and biodiversity.

The complex effects of pesticides on human health and the environment permeate all the ethical principles contained in the UDBHR. Socially, they impact the most vulnerable populations and generate all types of exclusion. Environmentally, they cause a reduction in biodiversity, mainly of pollinating insects, and contaminate the three main environmental compartments: soil, water, and air.

The extensive and abusive use of pesticides in Brazil violates the provision set forth in Article 16 of the UDBHR, as many of these compounds cause DNA mutations; that is, they are genotoxic carcinogens, in addition to inducing congenital malformations (teratogenesis), with transgenerational effects, given that they also cause mutations in germ cells [9]. There is a clear contradiction between such use and most of the UDBHR principles, as it directly affects rural workers who handle and apply these poisons—the most vulnerable population—and indirectly affects many other populations through contaminated air, water, and food.

The media, subservient to capitalist elites, propagates a false perception of Brazilian agribusiness, disseminating massive amounts of one-sided information without critical counterpoint. This perception suggests that food security is intrinsically linked to agricultural productivity, normalizing the abusive use of pesticides. Thus, it is implied that the use of pesticides is a necessary evil.

The revocation of Law 7,802/1989, the Pesticides Law, represented a setback in the protection of human health regarding the carcinogenic effects of pesticides, as the new Law 14,785/2023 [10] removes the Brazilian Health Regulatory Agency's (ANVISA) power to veto the prohibition of pesticides with carcinogenic characteristics, reducing the agency to a mere advisory body to the Brazilian Ministry of Agriculture, which is the body responsible for registration.

In a world connected by the internet, it is very easy to access the databases of the International Agency for Research on Cancer (IARC), the Brazilian National Cancer Institute (INCA), the National School of Public Health of the Oswaldo Cruz Foundation (FIOCRUZ), and other cancer databases. State regulatory agencies have the prerogative to use an advisory board of scientists specializing in environmental carcinogenesis. Thus, the regulatory authority cannot claim a lack of information or knowledge when making its decisions.

Rocha and Grisolia [7] demonstrated that decision-making based on data from the scientific literature is a complex process, since laboratories at public/state universities are contracted by chemical companies to perform bioassays with their pesticide formulations. Moreover, this process revealed an ethical bias, given that the vast majority of negative results for cancer came from contracted (paid) studies produced in private institutions.

The agribusiness caucus's lobbying in the Brazilian Congress culminated in the revocation of the Pesticides Law and the approval of Law 14,785/2023 [10], weakening the regulatory action of ANVISA and IBAMA in the pesticide registration processes in Brazil. In addition, the Brazilian government grants tax reductions and fiscal subsidies on the production and trade of pesticides: a 60% reduction in ICMS [11]; total exemption from PIS/Pasep and from the Contribution for the Financing of Social Security (COFINS) [12]; and exemption from the Tax on Industrialized Products (IPI) [13]. Sadly, the Brazilian government and Congress place agribusiness above environmental protection and human health. The economic power of agricultural oligarchies dominates the political scenario, skewing government decisions that should be directed toward the protection of citizens' rights.

This contradiction is evident and can be demonstrated with examples. The IARC [14] published a monograph classifying the herbicide

glyphosate as a probable human carcinogen, associated with the incidence of non-Hodgkin lymphoma. The herbicide was classified in Group 2A, demonstrating the existence of sufficient evidence in laboratory animal studies and limited evidence in humans [14]. On the other hand, in Brazil, ANVISA, upon re-evaluating glyphosate, concluded in Technical Note 23/2018 that it does not present mutagenic, teratogenic, or carcinogenic characteristics, is not an endocrine disruptor, and is not toxic to reproduction [15].

The IARC [16] also classified triazine herbicides in Group 2A, which were then withdrawn from the market in Europe due to cancer risk and hormonal dysregulation. In Brazil, triazine herbicides are authorized for use. Thus, the ethics of State regulatory agencies must be questioned, as they, even in the face of well-established evidence, expose farmers to this type of risk. This lack of accountability by the State produces inequities in rural areas, harm to personal integrity, maleficence, and other types of economic and social vulnerability, contrary to the principles of the UDBHR.

In both reported cases, the precautionary principle should be applied. This ethical-legal principle, established by the United Nations and present in the *Rio Declaration on Environment and Development* [17], is applicable when there is scientific uncertainty, but the activity or technology presents high risks of irreversible damage to human health, especially to vulnerable populations. This principle is particularly applicable to the IARC's Group 2A classifications of glyphosate and triazine herbicides and has legal force as a binding norm under Article 225 of the Brazilian Federal Constitution [5].

According to Bombardi [18], savage capitalism in the countryside produces three types of cleansing: 1) physical, with deforestation followed by defaunation, fires, evictions, expulsions, and murders; 2) biological, with the decimation of biodiversity and of Indigenous, *Quilombola*, and *Ribeirinho* communities; and 3) chemical, through widespread pesticide poisoning, which overlaps with social, physical, and environmental violence, in clear violation of the human rights provided for in Articles 6, 216, and 225 of the Brazilian Federal Constitution [5]. The predominance of the economic and political interests of the elite over the needs of an entire society, mainly with regard to health and the environment, demonstrates a crisis of moral and ethical values and a State and its agents captured by the interests of this elite.

## Final considerations

The negative externalities generated by the intensive use of pesticides are evidenced by the contamination of surface and groundwater, air, and soil, as well as pesticide residues in food, which cause intoxication in rural workers and contamination of the general population, leading to chronic degenerative diseases. The Federal Constitution of 1988 [5], in paragraphs 2 and 3 of Article 225, obliges the polluter (exploiter) to restore and repair any environmental damage. The polluter-pays principle, instituted in the Brazilian National Environmental Policy according to item VII of Article 4 of Law 6,938/1981 [19], is completely neglected by the responsible State agents and agencies, which characterizes legal and ethical omission.

The pesticide regulatory system in Brazil is flawed, with very serious ethical implications, as 100% of the studies carried out by chemical companies that produce pesticides for registration purposes and submitted to regulatory agencies are negative for cancer. There are currently various instruments for obtaining reliable information that could be used by the regulatory authority, which must be aware that it cannot rely on a single source of information to guide its decision-making. However, by doing so and approving the registration of pesticides posing a cancer risk, it would incur civil liability for negligence and omission as provided by law, in addition to transgressing ethical values.

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**Contribution of the authors**

Glenda Morais Rocha: conceptualization; methodology; data curation; writing – original draft. Cesar Grisolia: formal analysis; writing – review & editing.

**Data availability:** All data used or generated in this study are described and presented in full in the body of the article.

**Editor in charge:** Dilza Teresinha Ambrós Ribeiro

**Received:** 1.6.2026
**Revised:** 2.27.2026
**Approved:** 3.26.2026

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