

DRAFT BILL OF LAW

Ordains on the registration, risk assessment and control of chemical substances.

THE PRESIDENT OF REPUBLIC, I hereby make known that the National Congress decrees and I enact the following law:

Article 1. This law establishes the inventory, the risk assessment and the control of chemical substances, in order to minimize adverse impacts on health and the environment, arising from their production, import and use in the national territory.

Article 2. For the purposes of this Law, the following shall be considered:

I- Acquirer of imported good: a legal entity that acquires good of foreign origin as chemical substances, mixtures or articles, through a commercial importing legal entity under import regime of import by Order on Behalf of Third Parties;

II- Article: an object which, during production, is given a specific shape, surface or design that is more decisive for its end use than its chemical composition. An article does not undergo any change of chemical composition or shape during its use, in addition to that resulting from its use;

III- Ordering party of an imported good: legal entity that acquires goods of foreign origin as chemical substances, mixtures or articles, through a commercial importing company under a system of import by order;

IV- Unpublished studies in Brazil: studies of hazard and risk assessment of chemical substances carried out by manufacturers or importers that are not available to the public or that are protected by property rights clauses in any country;

V- Manufacturer: individual or legal entity engaged in the production of chemical substances or mixtures or articles;

VI- Importer: includes the Direct importer, the Ordering party and the Acquirer of imported goods;

VII- Direct Importer: an individual or legal entity who promotes the entry of foreign goods, such as chemicals, mixtures or articles, into the customs territory, in its own order and account;

VIII- Impurity: a constituent not intentionally present in a chemical substance after its manufacture and may originate from the raw materials used or be the result of secondary or incomplete reactions during the production process. Although present in the final substance, it was not added intentionally;

IX- Intermediate non-isolated reaction: intermediate substances which, during processing into a new substance, are not intentionally withdrawn from the equipment in which the transformation takes place, except for sampling;

X- Mixture: intentional combination of two or more chemical substances, without chemical reaction between them;

XI- New chemical substance: chemical substance not present in the National Inventory of Chemical Substances;

XII- Polymer: a substance composed of molecules characterized by the sequence of one or more types of monomer units containing and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units;

XIII- Only representative of the foreign manufacturer: an individual or legal entity, established in Brazil, with financial, administrative and technical capacity, who, in agreement with the foreign manufacturer of chemical substances or mixtures, acts as its only representative, assuming all the responsibilities and obligations imposed on the importer by this law;

XIV- Natural substance: substance which occurs in nature and which is not processed or processed only by manual, gravitational or mechanical means, as well as by dissolution in water, by flotation, or by heating, solely to remove water or that extracted from the air by any means;

XV- Chemical substance: means a chemical element and its compounds, whether in the natural state or obtained by a manufacturing process, including any additives necessary to preserve their stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or modify its composition;

XVI- Chemical substance of unknown or variable composition (UVCB): chemical substance of unknown or variable composition, complex reaction

product or biological material, derived from natural sources or complex reactions and which cannot be characterized in terms of constituent chemical components or represented by single structure or molecular formula;

XVII- Chemical substance in development or intended for research: chemical substance extracted, synthesized, produced or imported, used directly in a study, experiment or scientific research in Brazil, including the phases of tests, and as long as they are not available for sale or trade, in any form;

XVIII- Recommended uses of the chemical: use of the chemical substance under conditions, or for purposes, according to the specifications and instructions recommended by the manufacturer;

XIX- Downstream user: a natural or legal person who is neither the manufacturer nor the importer and who carries out the activity of compounding, fractionating, storing, packing, dispatching, marketing, distribution or using a chemical substance, mixture or article, in the scope of their industrial or professional activities.

Article 3. Excluded from the application of this law:

I- radioactive substances;

II- chemical substances under development or intended exclusively for research, observing the quantitative established in the secondary law;

III- non-isolated reaction intermediates, impurities, contaminants and chemicals produced by unintentional reactions, including those produced in storage or due to environmental factors;

IV- chemical substances, mixtures and articles subject to customs control, which are in temporary storage, in free zones or free warehouses with a view to their re-exportation, or those in transit;

V- narcotic, psychotropic and immunosuppressive substances regulated under specific legislation;

VI- substances used exclusively as ingredients of tobacco and derivatives;

VII- metallic alloys and metals in the form of plates, sheets, strip, billets, ingots, beams and the like for structural purposes;

VIII- explosives and their accessories;

IX- residues;

X – The following products, subject to control under specific legislation:

- a) agrochemicals, pre-mixtures for agrochemicals and technical products;
- b) medicines and medical gases;
- c) cosmetics, toiletries and perfumes;
- d) sanitizers;
- e) veterinary products;
- f) foods, food additives and manufacturing technology co-formulants;
- g) products intended for animal feed;
- h) fertilizers, inoculants and soil correctives;
- i) wooden preservatives;
- h) environmental remediation products.

XI- the following substances, other than those chemically modified or consisting of, are constituted by or contain substances classified as dangerous according to the criteria and requirements of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS):

- a) ores and concentrates thereof, as well as other rocks and minerals, including coal and coke, crude oil, natural gas, liquefied petroleum gas, natural gas condensate, gases and components of mineral production processes;
- b) natural substances;
- c) fats, essential oils and fixed oils extracted by the milling, pressing or bleeding method, even when purified, provided that they result in products having the same characteristics as the originals;
- d) glasses, frits and ceramics.

Article 4. These are constituted:

I- The Technical Committee for the Assessment of Chemical Substances, which is a collegiate body with a consultative nature, composed by the federal agencies responsible for the environment, health, labor and industry, with the purpose of evaluating the risk of the prioritized chemical substances and suggest risk management measures.

II- The Deliberative Committee of Chemical Substances, which is a collegiate body with a deliberative, normative, consultative and appellate nature, formed by the federal agencies responsible for the environment, health, work and industry, with the purpose of determining the risk management measures.

Sole paragraph: The federal agency responsible for the environment sector shall preside over and coordinate the work of the Deliberative Committee, as well as be in charge of providing administrative and legal support to its operation.

Article 5. Manufacturers, importers and downstream users are responsible for the chemical substances, mixtures and articles that they place in the national territory.

Paragraph 1. The manufacturers and importers of chemical substances as such or used as ingredients of mixtures shall be responsible for:

I- providing information on the National Registry of Chemical Substances System;

II- provide information, studies and complementary safety data sheets to support the chemical's risk assessment, when required;

III- present the information required for the new chemical substances;

IV- update the information registered when there is change in the data;

V- provide adequate and accurate information, keeping them always available;

VI- comply with the risk management measures determined by the Deliberative Committee of Chemical Substances.

Paragraph 2. The downstream user and the importing legal entity acting on behalf of third parties or by contract with the ordering party of an imported good, does not have obligations regarding the provision of information provided for in items I to IV of paragraph 1, but must comply with the risk management measures determined by the Deliberative Committee of Chemical Substances and to keep available accurate and adequate information about its operations with chemicals, mixtures and articles.

Paragraph 3. The foreign manufacturer of chemical substances and mixtures exported to Brazil can designate an only representative in Brazil to

assume the tasks and responsibilities imposed on importers in items I to V of paragraph 1.

THE NATIONAL INVENTORY OF CHEMICAL SUBSTANCES

Article 6. The National Registry of Chemical Substances System is hereby instituted, implemented and maintained by the federal agency responsible for the environment, with the objective of forming the National Inventory of Chemical Substances after the period of time mentioned in article 7.

Article 7. The chemical substances as such or when used as ingredients of mixtures, individually affecting a quantity equal to or greater than one (1) ton of production or import per year, considering the average of the last 3 years, shall be registered in the National Registry of Chemical Substances System, with the following information:

I- identification of the manufacturer or importer;

II- identity of the chemical substance, according to the name in the *Chemical Abstracts Service (CAS)* or *International Union of Pure and Applied Chemistry (IUPAC)* and CAS registry number;

III- range of quantity produced or imported per year;

IV- recommended uses of the chemical substance;

V- hazard classification according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), in accordance with the current Brazilian standard.

Paragraph 1. The Deliberative Committee of Chemical Substances may, for certain chemical substances, according to the criteria defined in article 14, define quantities lower than that specified in the head provision for manufacturers and importers to provide information in the National Registry of Chemical Substances System.

Paragraph 2. Chemical substances of unknown or variable composition (UVCB) shall be registered as a single substance.

Article 8. The following are covered by this law, but should not be registered in the National Registry of Chemical Substances System:

I- mixtures

II- articles

III- monomeric units as part of polymers and the additives added to preserve the stability of the polymers;

IV-polymers of low concern, according to criteria to be defined in the secondary law.

Paragraph 1. In the case of mixtures, only the chemical substances that compose them shall be registered in the National Registry of Chemical Substances System.

Paragraph 2. The polymers must be registered in the National Registry of Chemical Substances System, except those of low concern.

Paragraph 3. The Deliberative Committee of Chemical Substances may establish in specific regulations exclusions not listed in this article, by means of technical justification.

Article 9. The manufacturers of chemical substances as such or when used as an ingredient of mixtures are obliged to provide information in the National Registry of Chemical Substances System under Article 7; and the importers of chemical substances and mixtures.

Sole paragraph: The importer may give access to specific fields of the Registry System to the foreign manufacturer so that the latter provides the information directly, according to the secondary law.

Article 10. The term for inclusion of information in the Registry System to form the National Inventory of Chemical Substances shall be three (3) years, counted from its availability, without prejudice to the activities of production, import and use.

Sole paragraph: After the period mentioned in the head provision, those that initiate activities of production or import of chemical substances listed in the National Inventory of Chemical Substances in quantities of one (1) ton of production or import per year, or quantity stipulated based on paragraph 1 of article 7, are obliged to provide information in the Registry System, according to Article 7, until March 31 of the following year.

Article 11. The information registered must be updated when there are data changes, until March 31 of the following year.

NEW CHEMICAL SUBSTANCES

Article 12. Production and import of new chemical substances as such or when used as ingredients of mixtures, in quantities equal to or greater than 1 tonne per year, which have some characteristic of items I to VII of article 14, shall be subject to prior presentation of information to be provided by manufacturers and importers, in a specific module of the Registry System.

Paragraph 1. The information referred to in the head provision is those provided for in items I to V of article 7, besides additional information to be defined in the secondary law, varying in complexity according to the expected range of quantity produced or imported per year.

Paragraph 2. Manufacturers and importers may submit a risk assessment for the new chemical substance as a supplement to the provisions of paragraph 1.

Paragraph 3. When there is a change in the range of quantity produced or imported per year, manufacturers and importers shall supplement the information presented, in accordance with the secondary law, by March 31 of the following year.

Paragraph 4. When the new chemical does not meet the criteria of items I to VII of article 14, it shall be registered in the Registry System, according to article 7 and its manufacturers and importers shall prepare and maintain available technical documentation attesting that the substance does not fulfill those criteria, according to the secondary law.

Article 13. The new chemical substances will be included in the National Inventory of Chemical Substances immediately upon submission of the required information.

Paragraph 1. In cases in which unpublished studies in Brazil have been prepared to enable the submission of information, the new chemical shall be included in the National Inventory of Chemical Substances only after a period of 10 years, or at any time, at the request of the manufacturer or importer who holds the rights to the studies.

Paragraph 2. The holder of the right on the unpublished study in Brazil can authorize its use by third parties, who must present a letter of access to the data, as a requirement for the production or import of the new chemical.

Paragraph 3. The list of new chemical substances shall be publicized to the same degree as that available for chemical substances already listed in the Inventory for those who have submitted the required information and are awaiting the deadline established in paragraph 1.

THE RISK ASSESSMENT OF CHEMICAL SUBSTANCES

Article 14. The chemical substances listed in the National Inventory of Chemical Substances and the new chemicals shall be selected and prioritized for risk assessment to human health and the environment.

Paragraph 1. The criteria for the selection of chemical substances to be prioritized for risk assessment are:

I- persistence and toxicity to the environment;

II- bioaccumulation and toxicity to the environment;

III- persistence, bioaccumulation and toxicity to the environment;

IV- carcinogenicity, mutagenicity or reproductive toxicity;

V- characteristics of endocrine disruptors, based on scientific evidence;

VI- relevant potential exposure to humans or the environment; or

VII- to be included in an alert, agreement or international convention, of which Brazil is a signatory.

Paragraph 2. Chemical substances which do not meet one or more of the criteria of items I to VI but which, based on scientific evidence, are likely to cause serious health or environmental effects giving rise to a level of concern equivalent to those, identified on a case-by-case basis, may be selected and evaluated by the Technical Committee.

Paragraph 3. The application of the criteria referred to in paragraph 1 shall be detailed in the secondary law.

Article 15. The Technical Committee shall recommend, based on the criteria of article 14 and on the opportunity and analytical capacity, the chemical substances to be prioritized for risk assessment, with a well-founded technical justification.

Paragraph 1. The Deliberative Committee of Chemical Substances shall periodically publish work plans for the risk assessment of chemical substances.

Paragraph 2. At any time, in the light of new evidence, the chemicals already evaluated may be related again in the work plan referred to in paragraph 1 for reassessment.

Article 16. When the chemical prioritized for risk assessment is used, among other uses, as an ingredient of mixtures listed in item X of Article 3, and if its use in this mixture is considered relevant for health or environment risk assessments, these aspects may be evaluated by the Technical Committee, only in cases when the specific legislation is silent on these aspects.

Paragraph 1. The Deliberative Committee shall inform the result of the risk assessment to the competent authorities responsible for the mixtures listed in item X of Article 3 to enable them to decide on the risk management measures they deem appropriate.

Paragraph 2. The risk management measures determined by the Deliberative Committee do not apply to the mixtures listed in item X of Article 3.

Article 17. In order to subsidize the risk assessment, the Technical Committee shall use information and studies available from recognized national and international institutions and may require from manufacturers and importers complementary information, studies and safety data sheets.

Paragraph 1. Manufacturers and importers may submit additional information as well as risk assessment studies already performed and presented in other countries related to the chemical substance under evaluation in Brazil.

Paragraph 2. The deadline for manufacturers and importers to submit the information and additional studies required shall be 120 days, counted from the request of the Technical Committee, extendable by technical justification of the interested party, and the risk assessment can be concluded only on the basis of the available information.

Paragraph 3. Downstream users and any other interested parties may submit information on chemical substances to support the risk assessment.

Paragraph 4. The minimum technical criteria for the assessment of information presented to subsidize the risk assessment of chemical substances shall be defined in the secondary law.

Article 18. Further studies on the use of animals shall be the last resort after all alternative methods have been exhausted.

Paragraph 1. The alternative methods to animal experimentation referred to in the head provision shall be scientifically recognized and present a degree of reliability considered adequate for a decision by the Technical Committee.

Paragraph 2. The federal authority responsible for the environment, in consultation with affected institutions, shall establish a strategic plan to promote the use of alternative methods to animal testing.

Article 19. The Technical Committee may form an advisory group or invite experts and researchers from academia, industry and civil society to subsidize the risk assessment of the chemical substances.

Sole paragraph: The advisory group shall have a temporary mandate to be defined by the Technical Committee.

Article 20. The results of the risk assessments conducted by the Technical Committee shall be submitted for public consultation before their final publication.

THE RISK MANAGEMENT OF CHEMICAL SUBSTANCES

Article 21. The chemical substances assessed may be subject to risk management measures.

Article 22. The decision of the Deliberative Committee shall consider the outcome of the health and environmental risk assessment and social, economic and technological aspects for the adoption of the risk management measures, according to the secondary law.

Article 23. Depending on the outcome of the risk assessment and on the basis of a reasoned report, the Deliberative Committee may determine one or more of the following risk management measures:

I- improvement of communication strategy and dissemination of information on the chemical;

II- elaboration and implementation by manufacturers and importers of plans and programs aiming at risk reduction and adoption of codes of good practice for the use of the chemical;

III- adequacy of the chemical safety information label (SDS) and label of the chemical, mixture or article, when applicable;

IV- definition of concentration limits of the chemical in mixtures or articles;

V- restriction of production, import, export, trade and use of the chemical;

VI- requirement of prior authorization for the production and import of the chemical;

VII- prohibition of production, import, export, trade and use of the chemical;

Paragraph 1. Provided that duly justified, other risk management measures may be established by the Deliberative Committee of Chemical Substances.

Paragraph 2. Other federal bodies responsible for the sectors that may be impacted by the risk management measures shall be consulted prior to the decision of the Deliberative Committee.

Paragraph 3. The Deliberative Committee may invite specialists and researchers from academia, industry and civil society to subsidize decision-making on risk management measures.

Article 24. Manufacturers and importers of chemical substances subject to risk management measures may be required to provide periodic information in the Registry System, and the periodicity and information to be requested shall be defined by the Deliberative Committee.

Article 25. The Deliberative Committee shall inform the federal bodies responsible for chemicals, mixtures or articles that are already regulated by specific legislation, when the chemical as such or when used as an ingredient of mixtures or articles is subject to risk management measures in use different from that already disciplined, so that they take the appropriate measures.

Article 26. Risk management measures that are determined by the Deliberative Committee should be met by all manufacturers, importers and downstream users of chemicals, mixtures and articles.

Article 27. The risk management measures determined by the Deliberative Committee may be appealed against legality and merit reasons.

Paragraph 1. The appeals shall be submitted to the Deliberative Committee and its procedure shall follow the procedures and deadlines established in Law No. 9.784/1999, which regulates the administrative proceeding in the scope of the Federal Public Administration.

Paragraph 2. The administrative appeals brought on merit grounds shall be received when there are new elements to be considered or when the applicant demonstrates that the determination of the Deliberative Committee:

I- do not contribute to the achievement of the objectives of this law;

II- violates consolidated and pacified technical understanding of recognized national and international institutions, when applicable;

III- do not provide the statement of reasons for its decision in a sufficiently clear manner.

PUBLICITY AND SECRECY

Article 28. Publicity on information obtained through the application of this law is guaranteed, protecting personal information and those that constitute industry or trade secrets, which shall be classified as confidential.

Paragraph 1. It is a trade or industry secret, without prejudice to other intellectual property protection norms, technical or scientific information, possibly presented by the authorities, which seek to clarify processes or methods used in the manufacture of chemical substances and mixtures and that their non-protection secrecy could lead to unfair competition between companies.

Paragraph 2. Except as necessary to protect the public or the environment, the protection of information which is the secret of industry or commerce shall be guaranteed for an indefinite period or until the manufacturer or importer declares otherwise or the first information in any country.

Paragraph 3. The following are not considered as an industry or trade secret:

I- identity of the chemical substance, according to the name in the *Chemical Abstracts Service (CAS)* or *International Union of Pure and Applied Chemistry (IUPAC)* and CAS registry number;

II- recommended uses of the chemical substance;

III- results of studies related to health and the environment;

IV- hazard classification of the chemical substance;

V- conclusions of the chemical's risk assessment.

Paragraph 4. In exceptional cases, the manufacturer or importer may request, for a maximum period of 5 years, protection regarding the disclosure of the identity of the chemical and its CAS registration number, according to the secondary law.

Article 29. In case of submission of unpublished studies in Brazil to subsidize the risk assessment of chemical substances or to provide information on the new chemical substances, the manufacturer or importer may, whenever appropriate, indicate to the Technical Committee the confidential information that is a secret of industry or trade, so that they are protected and not disclosed.

Sole paragraph: The analysis of which shall take into account the accessibility to information by competitors, industrial and intellectual property rights, the possible damage that the disclosure of the information may cause to its holder, to whom it employs or provides, as well as the public interest in its disclosure.

Article 30. In order to respect the legitimate proprietary rights of manufacturers and importers conducting unpublished studies in Brazil to subsidize the risk assessment of chemical substances or to provide information on new chemical substances, these should be for a period of five and ten years, respectively, counting from the presentation of the studies, the right to claim compensation from other manufacturers and importers who benefit from this data, by means of a letter of access.

Paragraph 1. The period established in the head provision shall cease when any other country makes public the information of risk assessment for similar conditions of use of the same chemical in Brazil, with a minimum of one year of protection being guaranteed;

Paragraph 2. After the protection period, the competent authorities shall guarantee free access to the general public to the information presented, without prejudice to other norms for the protection of intellectual property, the environment, public health, consumers and antitrust.

Paragraph 3. Data sharing by manufacturers and importers is legitimate and joint submission of studies concerning the chemicals under evaluation or new chemical substances.

ENFORCEMENT

Article 31. The enforcement of the obligations related to the provision of information provided by this law is the responsibility of the organs and entities of the National Environmental System (SISNAMA).

Article 32. The enforcement of the risk management measures imposed by this law is the responsibility of the federal agencies responsible for the environment, health, labor and industry.

Sole Paragraph: The Deliberative Committee, in establishing the risk management measure, should base and justify the primary concern that led to its decision and, when there is more than one aspect of concern, propose coordination mechanisms between the competent authorities, whose performance will be oriented according to the specific laws that govern its activities.

Article 33. In the exercise of the duties of verification, supervision and inspection, the public inspection agent is assured free access to the establishments in accordance with the law.

Article 34. The manufacturer and importer of mixtures and articles, when required by the competent authority, shall submit the test results indicating the concentration of the chemical subject to risk management measures in the same, within a stipulated period, defined if the according to the measure.

§ 1 The tests prescribed in the head provision shall be carried out in a laboratory accredited by Inmetro or by an accrediting body signatory to a mutual recognition agreement within the framework of international accreditation forums of which Inmetro is a Party for the specific scope.

Article 35. The enforcement actions shall not affect the final consumer.

VIOLATIONS AND PENALTIES

Article 36. The following is a violation of this Law and shall be subject to administrative penalties:

I- fail to register the information relating to the chemical as such or when used as an ingredient of mixtures produced or imported in the Registry System;

II- provide false, omissive or misleading information in the Registry System or to subsidize the risk assessment of substances or to provide information about of new substance;

III- fail to update the information in the Registry System when there is a change in the data, pursuant to article 11;

IV- qualify as confidential information that does not have legal protection forecast;

V- do not inform the CAS registration number when it exists;

VI- produce, import, market, donate or use chemical substances, mixtures and articles in violation of the provisions of this law and its regulations.

Article 37. It shall be incumbent upon the competent authority, pursuant to Articles 31 and 32, to process and adjudicate administrative violations proceedings and apply the relevant penalties, in accordance with the specific laws governing its activities, without prejudice to applicable civil and criminal liability.

COST RECOVERY

Article 38. The Inspection and Assessment Fee for Chemical Substances is established.

Paragraph 1. It constitutes a triggering factor for the Tax of Assessment and Inspection of Chemical Substances the regular exercise of police power conferred by this law in relation to the following activities:

I- registration of chemical substances;

II- registration of new chemical substances;

III- risk assessment of chemical substances;

IV- analysis of request for protection regarding the disclosure of the identity of the chemical and its CAS registration number, according to § 4 of article 28.

Paragraph 2. The manufacturers and importers of chemical substances, as well as manufacturers and importers of mixtures and articles that use chemical substances subject to risk management measures, are taxpayers subject to the Fee.

Paragraph 3. The amounts and terms of the Fee shall be established in accordance with the respective tax event, according to the secondary law, in a bank account linked to the federal agency responsible for the environment sector.

Paragraph 4. The Assessment and Inspection Fee for Chemical Substances shall be due from the entry into force of this law.

GENERAL PROVISIONS

Article 39. The Deliberative Committee of Chemical Substances may define differentiated procedures for registration, risk assessment and risk management measures when Brazil establishes cooperation agreements with other countries that have mechanisms for controlling chemical substances as or more restrictive than this law.

Article 40. Situations that constitute a conflict of interests involving occupants of positions or employment within the scope of the Federal Executive Branch, the requirements and restrictions to occupants of position or employment who have access to privileged information, impediments subsequent to the exercise of the position or employment and the competencies for inspection, evaluation and prevention of conflicts of interest are regulated by the provisions of Law No. 12.813 of May 6, 2013.

Article 41. Members of the advisory group and academics, industry and civil society experts and researchers invited to subsidize the risk assessment and the establishment of risk management measures must comply with the principles of legality, morality and isonomy, as well as ensuring the safeguard of the information obtained through the work carried out, which will be considered a relevant public service, without remuneration.

Article 42. The Executive Branch shall regulate this law within 180 days from the date of its publication.

Article 43. This law shall take effect on the date of its publication.