

Law Draft

Disposes on the registration, evaluation and control of industrial chemicals.

The PRESIDENT OF THE REPUBLIC, decree and sanction the following law:

Article 1. This law establishes the registration, evaluation and control of industrial chemicals, in order to minimize adverse impacts on health and the environment from its production, import and use in the country.

Article 2. For the purposes of this law are considered.

I - Additive: a chemical substance intentionally added to stabilize the chemical that is desired to end the process;

II - Impurity: constituent not intentionally present in a chemical substance after its manufacture, and that may have been originated in the raw materials used or result from a secondary or incomplete reactions during the production process. Despite being present in the final substance, is not intentionally added;

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

IV - Finished (Final) product: product intended for the use of final consumer and that does not require modification or preparations to be placed in the market;

V- Industrial Chemical: a chemical element and its compounds in the natural state or obtained by a manufacturing process, including any additive necessary to preserve its 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 changing its composition;

VI - Chemical in development or intended for research: chemical extracted, developed, produced or imported, directly used in study or research in the country, including the phases of testing. Such chemical substances may not be available for sale or trade in any form.

Article 3. Excluded from the application of this law:

I- radioactive chemicals;

II- chemicals under development or intended exclusively for research, observing the quantity set out in the secondary law;

III not isolated intermediaries of reactions, impurities, contaminants and chemicals substances produced by unintended reactions, including those produced on storage or due to environmental factors;

IV - ores and its concentrates, as well as other rocks and minerals, including coal and coke, crude oil, natural gas, liquefied petroleum gas, natural condensate gas, gases and mineral components from minerals production processes, except for those which are chemically modified or which are formed or contain chemicals substances classified as hazardous, according to the criteria and requirements of GHS (Globally Harmonized System of Classification and Labelling of Chemicals);

V- metals and its alloys in the form of plates, sheets, strips, billets, ingots, beams and others similar forms used in structural purposes;

VI- active ingredients of agrochemicals, if used exclusively for this purpose;

VII - active ingredients of drugs, if used exclusively for this purpose;

VIII - active ingredients of veterinary products, if used exclusively for this purpose;

Article 4. It is established the National System for Register of Industrial Chemicals, to be implemented and maintained by the federal agency responsible for the environmental sector.

Article 5. The producers and importers of industrial chemicals as such or present in intentional mixtures, in an amount equal to or greater than 1 (one) ton per year are required to provide the following information in the National System for Register of Industrial Chemicals:

I- identification of the producer or importer company;

II- identity of the industrial chemical, according to the name and registration number in the Chemical Abstracts Service (CAS) and, where applicable, its structural formula;

III- quantity range of production or import per year;

IV- uses of the industrial chemical;

V- hazard classification regarding health and the environment, according to GHS.

§ 1. The Deliberative Committee for Industrial Chemicals can, based on the risk that some industrial chemicals could cause to health or environment, establish lower quantities than 1 ton per year for the registry in the National System for Register of Industrial Chemicals.

§ 2. When it comes to intentional mixtures, just the industrial chemicals that compose it should be registered in the National System for Register of Industrial Chemicals.

Article 6. The period for registry in the National System for Register of Industrial Chemicals will be 3 (three) years, from the day of its creation, without any prejudice of current production or import activities.

§ 1. The production and import of industrial chemicals as such or present in intentional mixtures shall be subject to prior registration in the National System for Register of Industrial Chemicals after the period of 3 years mentioned.

§ 2. The information in the National System for Register of Industrial Chemicals must be updated every time occurs changes on the use of the industrial chemical, on the annually quantity range of production or import and on the hazard classification.

§ 3. It is ensured publicity to the contents of the National System for Register of Industrial Chemicals, safeguarded the secrets and confidentiality of personal information, industrial and trade, according to current law regarding this issue.

Article 7. Industrial Chemicals subjected to this law shall be classified and labeled by the producers and importers according to GHS, detailed in the secondary law.

Article 8. The federal agencies in charge of environment, health, labor and industry sectors will form the Technical Committee for Industrial Chemicals, in order to select and evaluate, regarding the risk to the environment and human health, the industrial chemicals present in the National System for Register of Industrial Chemicals.

Article 9. The criteria for selecting the industrial chemicals to be evaluated by the Technical Committee for Industrial Chemicals are:

- I- persistence, bioaccumulation or toxicity to the environment;
- II- carcinogenicity, mutagenicity or reproductive toxicity;
- III- endocrine disruptors characteristics, based on scientific evidences;
- IV- significant potential for human exposure or the environment;
- V- to be controlled under some warning, international agreement or convention that Brazil is signatory.

§ 1. The industrial chemicals which do not fulfil the criteria above, but for which there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to those of other industrial chemical listed in the above points and which are identified on a case-by-case basis, could be object of selection and evaluation by the Technical Committee for Industrial Chemicals, in accordance with the secondary law.

§ 2 The producers and importers of industrial chemicals subject to evaluation will be demanded to provide additional information, studies and safety data sheets to support the risk assessment.

Article 10. The federal agencies in charge of environment, health, labor and industry sectors will form the Deliberative Committee for Industrial Chemicals, in order to establish the risk management measures to be adopted for evaluated industrial chemicals, in view of eliminate or reduce the risks to health and the environment. It may be adopted one or more of the following measures:

I- voluntary agreements between government and industry to achieve the objectives of protection of health and the environment;

II- setting lower quantities than 1 ton of production or import per year to provide information on the National System for Register of Industrial Chemicals;

III- ban on production, import, export, trade and use of the industrial chemical;

IV- restriction on production, import, export, trade and use of the industrial chemical;

V- limit the concentration of the industrial chemical in final products or intentional mixtures;

VI- requirement of prior authorization for the production and import of a industrial chemical.

§ 1 Federal institutions responsible for sectors that may be impacted by the risk management measures shall be consulted prior the decision of the Deliberative Committee for Industrial Chemicals.

§ 2. Producers and importers of chemical substances subject to risk management measures must provide periodic information on the National System for Register of Industrial Chemicals, with frequency and information to be requested defined by the Deliberative Committee for Industrial Chemicals.

Article 11. The risk management measures defined by the Deliberative Committee for Industrial Chemicals shall be met by:

I- Producers and importers of industrial chemicals subjected to risk management measures;

II- Importers of intentional mixtures and final products which have in its composition industrial chemicals subjected to risk management measures;

III- producers of intentional mixtures and final products which have in its composition industrial chemicals subjected to risk management measures;

Article 12. Failure to comply with obligations under this law shall subject the violator to the sanctions:

I- warning;

II- fine;

III- partial or total suspension of activities;

IV- recoil of the industrial chemical, intentional mixture or final product;

V- destruction of the chemical substance, intentional mixture or final product;

VI- promotion of programs projects and studies in order to improve industrial chemicals management.

VII - evaluation and damage repair to human health and the environment.

Article 13. It is subject to the application of sanctions those who:

I- do not register in the National System for Register of Industrial Chemicals information regarding the industrial chemicals as such or present in intentional mixtures that produce or import;

II- to provide false, misleading or omit information in National System for Register of Industrial Chemicals;

III- to fail in updating the information in National System for Register of Industrial Chemicals when new data become available;

IV- to present false, misleading or omitted studies to support the evaluation of the industrial chemical;

V- do not comply with the risk management measures defined.

VI- to produce, import, put into market, donate or use industrial chemicals in noncompliance with the provisions of this law and its secondary law.

Article 14. The inspections regarding the compliance with this law will be carried out by the federal agencies in charge of environment, health, labor and industry sectors, according to the secondary law.

Article 15. The Executive Power shall regulate this law within 180 days from the date of its publication.

Article 16 The secondary law will establish procedures for the registration, evaluation and definition of risk management measures for industrial chemicals.

Article 17. This Law shall enter into force on the date of its publication.