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Regulatory update: Significant changes in biotechnology patenting

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INPI Resolution No. 197/2026 – Repeal of INPI Res. 283/2015

On June 19, 2026, INPI Resolution No. 197/2026 was published in the Official Gazette, under which INPI Resolution No. 283/2015 is repealed. The latter had introduced restrictions on patenting in the field of biotechnology, particularly with respect to plants, animals, and naturally occurring substances. This measure is part of a coordinated regulatory policy, as it was issued in connection with the repeal of Joint Resolution No. 99/2001 and 810/2001 by means of Joint Resolution No. 1/2026 of the Secretariat of Agriculture, Livestock, and Fisheries and the Secretariat of Industry, Commerce, and Small and Medium Enterprises.

This measure restores the original wording of the Patenting Guidelines (INPI Res. No. 243/2003), eliminating the restrictions that had created an unfavorable environment for innovation and investment in biotechnology.

The Resolution also establishes a limited exception in its Article 5, grounded by analogy in Article 41 of Patents Law No. 24,481 and following the approach adopted by Joint Resolution No. 1/2026 of the Ministry of Health, the Ministry of Economy, and INPI: holders of patent applications currently pending that are granted as a consequence of this repeal shall not be entitled to demand compensation from bona fide third parties, nor to prevent the continued commercialization of products covered by the subject matter of such patent that are already on the local market as of the date of entry into force of this regulation.



Key Changes to the Patenting Guidelines

The Resolution replaces paragraphs 2.1.7.2 and 2.1.7.9 of Chapter IV, Part C of the Annex to INPI Res. No. 243/2003, as well as Annex VIII of Definitions. Specifically, the patentability exclusions applicable to living matter are redefined:

The following shall not be considered inventions: (a) plants and parts and components thereof that may lead to a whole organism, whether or not modified (including plant species and varieties); (b) animals and parts thereof that may lead to a whole organism, whether or not modified (including animal species and breeds); and (c) essentially biological processes for the reproduction or production of plants or animals.

Furthermore, product claims for plants or animals shall not be allowed, even when produced by means of a microbiological process, since the exclusions under Article 6 of the Patent Law Regulations apply irrespective of the manner in which they are produced.

With respect to the replacement of Annex VIII – Definitions Relating to Chapter IV of the Annex to INPI Res. No. 243/2003, the technical definitions used to interpret Chapter IV on living matter are updated or restored. Specifically, the following definitions are adjusted: (i) animals; (ii) plants; (iii) cells; (iv) organism; (v) microorganism; (vi) fungi; (vii) substances; (viii) viruses; and (ix) genetic material.

The Resolution provides that the requirement for parts and components to specify their “isolated state” only acquires meaning and functionality when they are embedded in a living organism, and that their isolation deprives them of industrial applicability—an essential requirement for an invention to be patentable. It further acknowledges that this requirement imposes a formal condition that discourages the effective protection of technological developments in the field of biotechnology.

Effective Date

The Resolution entered into force on June 19, 2026, the date of its publication in the Official Gazette.