Regulation of Genetically Engineered Crops in Paraguay: A Science-Based Approach for Adequate Access and Safe Use

Danilo Fernández Ríos[1]*, Nidia Benítez Candia[1] & Carmen Vicién[2]
[1]*Universidad Nacional de Asunción, Facultad de Ciencias Exactas y Naturales, San Lorenzo, Paraguay*
[2]*University of Buenos Aires, School of Agriculture, Buenos Aires, Argentina*
*e-mail: dfernandez@facen.una.py

Abstract

Paraguay's transition to a simplified, science-based approach in the regulation of genetically engineered crops was motivated by the need to make better use of their human, financial, and institutional resources while achieving adequate access and safe use of biotechnology-derived products. Agricultural biotechnology was first regulated in Paraguay in 1997. In 2012, the system was adjusted through the creation of the National Agricultural and Forestry Biosafety Commission (CONBIO), with the purpose to manage evaluations and recommendations for GE crops. Initially, the risk assessment process followed a checklist criterion with extensive forms, but the lack of a methodological framework resulted in lengthy, costly evaluations. In 2015, the regulatory authorities adopted a problem formulation approach to environmental and food and feed risk assessments, leading to the development of science-based guidelines and application forms. However, the transition towards the integration of the methodology of problem formulation in daily decisions was not easy, as members of the Commission were not fully dedicated and frequently replaced. This situation led to unnecessary delays in the assessment process. In 2019, members of CONBIO proposed a simplified procedure for genetically engineered crops based on decision documents of material that have already been approved by sound and experienced regulatory systems while maintaining the procedure for crops not previously assessed. The simplified procedure applies to commercial releases, considering scientific assessments from third countries' regulatory authorities, provided that certain criteria have been met. On one side, Paraguay's regulatory authorities have a history of using information and data from existing risk analyses, making it appropriate to develop a simplified procedure that allows them to focus resources on novel genetically engineered crops. But mostly, the simplified process helped maintain confidence in Paraguay's decisions on the safety of GE crops, making it a fit-for-purpose, modernized approach.

Key words: genetically engineered crops, regulatory system, acceptance of third-country assessments, simplified procedure, problem formulation.