

# Ensuring the Safety and Sustainability of Bio-Innovation: A Guide to Building Fit-for-Purpose Governance Frameworks – The case of simplified approval procedures

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## Abstract

In order to ensure the safety and sustainability of bio-innovations, it is essential to have functional and fit-for-purpose governance frameworks in place. Ideally, they would be developed from a comprehensive plan; anyhow, there is no single best approach nor standard that reflects countries' heterogeneity even though worldwide exists much experience in this matter. Some systems have worked with efficiency since their establishment, and others have undertaken an evolution of their regulatory system that allowed them to make better use of their human, financial, and institutional resources. The latter is the case of the recent experience undertaken in Paraguay. As a result of a collaborative program, the regulatory authorities in Paraguay incorporated the problem formulation approach to risk assessment into their regulatory processes, leading to improved efficiency with more timely decisions. Nevertheless, shifting to a problem formulation-based decision-making system was not straightforward since practice and experience are always required to make professional risk assessors. Considering that decision documents from third countries have always been an important basis in risk analysis in Paraguay, since 2019, a simplified approval procedure for events assessed by sound and experienced regulatory systems was introduced. Several lessons have been learned from this path. Procedures are to be appropriate to the regulatory system's context, which means they will cause the least amount of disruption to the existing regulatory framework, taking into account the country's protection goals. Concepts such as familiarity, history of safe use, substantial equivalence, transportability, problem formulation, and the use of consensus documents favor the establishment of the acceptance system. However, countries must mostly have a clear understanding of the scientific grounds underlying decisions; it is always of the most crucial importance to develop proper risk hypotheses and rely on regulators with solid backgrounds on risk assessment.

**Key words:** genetically engineered crops, regulatory system, acceptance of third-country assessments, problem formulation, capacity building.