All Roads Lead to Rome: Understanding the Variety of National Regulatory Mechanisms for Genetically Modified Organisms

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Abstract

The earliest regulatory frameworks for the regulation of recombinant DNA organisms began to take shape in the mid-1980s. As the use of these technologies, particularly in agriculture, expanded globally more and more countries developed national regulatory frameworks using a combination of legislative and regulatory tools at their disposal. These frameworks share a common purpose: to provide a pathway to approval for the use of beneficial technologies while ensuring an appropriate level of safety for people and the environment through the use of risk assessment. However, each country has used the tools and normatives available in their national context to construct their regulatory framework and the procedural and process differences amongst regulatory frameworks can be significant. This has been a source of confusion and anxiety for both applicants as well as regulators and has led to challenges of public perception that have impeded harmonization efforts between countries. This presentation will provide examples of the regulatory and procedural mechanisms that have been employed around the world and talk about their commonalities and differences, addressing what it means for risk and safety assessment and how improved understanding can remove much of the perceived impediment to harmonization.

Key Words: regulation, ERA, harmonization, food safety assessment