L-01

Global regulatory environment for traditional biotech (including asynchronous approvals) Ann Tuttle, Bayer Crop Science, North Carolina, USA

Global regulatory agencies assess plant biotechnology products to ensure food, feed and environmental safety. Assessments consider the safety of the gene(s) introduced, protein(s) expressed, crop characteristics, food and feed compositional equivalence to conventional counterparts, and the environmental safety of the biotech product. Safety studies are conducted, with guidelines from Codex and OECD offering considerations for global agencies for these assessments. Individual global agencies however often have specific data requirements, including locally conducted studies, which need to be met for country approval. The length of time needed for regulatory agency review and approval in each country also differ. These country-specific requirements and approval timelines also change frequently.