Regulatory approaches that compromise innovation: the case of agricultural biotechnology in the EU.

Nancy Podevin[1], Maica Martinez Parrilla[2], Esteban Alcalde[3], Rocio Fernandez Canton[4], Petra Kostolaniova[5*], Monica Garcia-Alonso[6*], Pascale Delzenn e[7]

[1]*Corteva Agriscience, Belgium*
[2]*BASF, Italy*
[3]*Syngenta, Belgium*
[4]*BASF, Belgium*
[5]*CropLife Europe, Belgium*
[6]*Estel Consult Ltd, UK*
[7]*Bayer, Belgium, UK*
* petra.kostolaniova@croplifeeurope.eu

Despite 26 years of worldwide experience and evidence on the contribution of agricultural biotechnology to food security and sustainable agriculture, the EU continues lagging behind the rest of the world in the uptake of genetically modified (GM) crops. As in other geographies, these products require pre-market approvals that include food and feed safety assessments and environmental risk assessments. EU data requirements for GM food and feed safety assessments follow Codex Alimentarius guidelines and appear in line with the requirements in rest of the world. However, in practice, these assessments are currently the most cumbersome in the world. The main issues stem from the introduction of Implementing Regulation (EU) 503/2013 (IR), a legislation that not only incorporates the European Food Safety Authority (EFSA) guidance GM food and feed safety assessments, but also includes politically driven data requirements advocated by some EU Member States.

The IR provides a legally binding list of data requirements for all applications, regardless of the crop/trait combination and the potential hazard posed by the product. The studies have to be conducted and presented in compliance to specific EFSA methodology, described in an ever-increasing number of guidance documents that continues to evolve. In addition, extensive exposure assessments have to be conducted, even when no hazards are identified. The result is an inflexible and complex system, difficult to navigate, with a disproportionate approach to risk that compromises the case-by-case approach and does not consider the extensive experience gained on GM crops around the world with regards to food and feed safety.

In this paper we explore the main issues that applicants encounter when preparing GM crop food and feed safety assessments for the EU and provide recommendations for improvement, with the objective to increase the predictability and efficiency of the EU regulatory process.

Keywords: agricultural biotechnology, GM crops, EU, food and feed safety